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Explaining local variation in agri-food biotechnology policies: 'green' genomics regulation in comparative perspective

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This paper develops a comparative framework for biotechnology policy analysis based on work by Paarlberg, Haga and Willard, and Isaac and applies this framework to help understand the evolution and differences in the regulatory regimes related to agri-food genomic innovations found in six countries: Italy, Spain, Australia, New Zealand, Canada and the US. Applying this framework to the six cases shows that these governments have fostered different types of regulatory regimes over the last quarter century that are closely connected with the manner in which governments have pursued either promotional or precautionary orientations towards new technologies; and second whether regulatory policy-making has been driven by state or public actors and interests. The implications of these findings for the study of biotechnology, and especially genomics-related matters, regulation and policy-making are then discussed.

OVER THE PAST 25 YEARS, biotechnology innovation has been a very important focus of economic development efforts in both advanced economies and emerging markets. This innovation has guided regulatory responses in a number of areas (e.g. health and safety, research ethics, and commercialization), but has also been guided by state actions linked to science and technology, economic and industrial policy goals and efforts. As a result, technological innovations in this area have engendered a range of regulatory responses on the part of different governments. Understanding the nature of these variations is an important task of comparative biotechnology policy inquiry and policy design.

Investigating these different policy responses to, and attitudes towards, specific biotechnologies such as genomics-related innovations begins with the observation that this field, like many other policy areas, is a complex, nested, area of scientific, commercial and governmental activity. As Kleinman *et al*. (2009) noted, an analysis of the regulation of biotechnological activities in different jurisdictions cannot be undertaken in isolation from their corresponding technologies and contexts. Functionally, for example, there is a range of different uses for genomics biotechnologies stretching from 'green' activities such as agri-food production, 'white' uses related to various industrial applications such as pulp and paper digestion, 'red' uses related to health, 'black' areas such as energy (for example producing fuels from mine waste) and various 'rainbow' mixes such as the 'red–green' or 'black–green' use of agricultural crops to produce pharmaceuticals or biofuels. Different genomics applications also span a spectrum of 'invasiveness' ranging from modification of genomes through enhanced natural selection to more extensive artificial manipulations through various kinds of 'omics technologies (genomics, metabolomics, transcriptomics and proteomics).[1]

Each of these different socio-technological contexts affects the nature of the activities which are regulated as well as the content of the regulations that are enacted. Some 'black' and 'white' activities which do not directly affect humans, for example,

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tend to undergo less scrutiny than 'green' or 'red' ones which do, while less intrusive techniques like enhanced natural selection also tend to involve less regulation than artificial genetic manipulations linked with genetic engineering.[2] The uses of biomarkers (the measurable indicator of a biological or pathogenic processes or of the pharmacological responses to therapeutic activity), marker-assisted selection (using a marker to indirectly select a genetic determinant for specific traits), and genetic diagnoses, for example, tend to evoke little regulatory oversight.

But regulatory regimes for specific biotechnologies are constructed around these different technological and functional contexts as well as around their policy and political ones and, as a result, exhibit important spatial and temporal differences. The regulatory regimes which emerge in specific areas of innovation are influenced not only by technical considerations relating to the specific nature of the technology at work, but also due to additional factors such as those relating to economic viability, public opinion and consumer responses to these new technologies and processes (Montpetit, 2005; Falkner, 2007; Gaskell, 2005). Each different use tends to encounter and involve a different set of actors and interests in different countries. And typically, this occurs within an existing context of rules and regulations which had been established to address earlier issues with similarly then-innovative technologies (Arzenton, 2006; Cantley, 2007; Petrini, 2009; Kleinman *et al*., 2009). Thus, within common technological, international or transnational policy spaces, different countries regulate, foster, and support specific biotechnologies, including genomic ones, in different ways (Lindner, 2008).

Temporally, for example, in the agri-food area products that trigger existing oversight rules based on the presence of 'novel' traits or products tend to date back to earlier concerns with food additives and the use of chemical preservatives and tend to undergo much more extensive review than those which do not. This is well illustrated by the well-known case of Bt Corn, a genetically modified (GM) plant that carries the genetic code of the Bacillus thuringiensis (Bt) permitting it to act as an 'internal' pesticide. It has had to undergo extensive regulatory reviews in most jurisdictions based on such 'novel traits' doctrines or standards developed in earlier eras of food safety regulation but has evaded review in jurisdictions lacking these earlier sets of rules.

Spatially, while they tend to emerge at the national level, biotechnology regulatory regimes are closely connected with international developments in terms of their links with global or transnational frameworks such as the Cartagena Protocol on Biosafety (Newell, 2008), the Codex Alimentarius in the area of food safety (Lindner, 2008), or multi-level regulatory frameworks such as those developed in the EU relating to genetically modified organisms (GMOs) (Falkner, 2007). Transnational learning and communication thus constitutes an important driver of policy and regulatory responses to novel biotechnologies and innovations such as those linked to various 'omics applications.

The challenge of identifying which aspects of the technological and societal context are significant in regulatory regime construction lies before students of regulatory development in the face of innovative technology. Especially important is attempting to understand any 'general model' of regulation that might exist as well as any 'local variations' in such regulations. Understanding the nature and origins of these 'local variations' in biotechnology policy and regulation in particular is of interest to both proponents and opponents of new biotechnology policies and regulations as well as to students of other sectors faced with similar regulatory challenges from scientific and technologically innovative activity; such as nanotechnology or synthetic biology (Bowman and Hodge, 2007; Hodge *et al*., 2007; Furger *et al*., 2007; Kuzma and Tanji, 2010).

Here we develop a comparative framework for biotechnology policy analysis based on the works of Paarlberg (2000), Haga and Willard (2006) and Isaac (2002) in order to describe the 'general model' of genomics regulation. We then apply this framework to help understand the local variations in the regulatory structures existing in several agri-food producing countries (Italy, Spain, Australia, New Zealand, Canada and the US) selected in order to provide two cases in each of three major territorial locations of biotechnology and regulatory innovation. For these six cases we show that over the past 25 years, different governments have fostered one of several distinct possible types of 'green' genomics regulatory regimes connected with:

- The manner in which governments have supported either a promotional or a precautionary orientation towards new biotechnologies.
- Whether or not regulatory policy-making has been driven by state or public actors and interests.

This analysis suggests a more complex set of alternative policy and regulatory regimes exists in this

area than is commonly proposed in the literature on the subject and also suggests several new directions that comparative biotechnology policy analysis should follow in assessing their impact and effectiveness.

Describing the agri-food genomics general model: a comparative framework of analysis

The area of biotechnology regulation and policy-making has been the subject of a considerable amount of research and work in the agri-food area. This work provides a useful starting point to assess the nature of 'green' genomics regulatory regimes. We argue that a synthetic systematization of two already existing frameworks developed to deal with agri-food biotechnology regulation in general helps to set out the key factors that differentiate national regulatory approaches to agri-food genomics innovations. These frameworks – developed by Haga and Willard (2006) and Paarlberg (2000) on the one hand; and Haga and Willard (2006) and Isaac (2002) on the other – can be used to identify and model both the general approach taken by states towards new green genomics applications as well as to highlight the significant local variations found in these regulatory approaches.

Identifying a substantive national agri-food biotechnology regulatory orientation

In their work, Haga and Willard (2006) discuss biotechnology policy as the policy and regulatory approaches towards biotechnologies that are framed within a country's science and technology policy. These include the amount of funding dedicated to biotechnology, the relative openness to the introduction of novel biotechnologies in the market, the relevance that biotechnology has in a country's advanced technology policy, and the regulatory framework that translates government policies into existing investment, research and marketing of biotechnology products.

They argue that agri-food and most other biotechnology actors engage in seven distinct areas of social activity relating to:

- intellectual property rights;
- public information and inclusiveness of deliberation;
- retail and trade issues;
- safety and human health;
- consumer choice;
- public research investment; and
- commercialization of biotechnology-related products.

These seven areas of activity cross-over into five areas of regulatory concern related to:

- monitoring and control of research activities;
- development and implementation of legal governance frameworks;
- a variety of economic aspects associated with biotechnological innovation;
- a range of education issues (Haga and Willard, 2006: 967); and
- a range of implemention issues.

A wide range of specific regulatory problems or issues exists at the intersection of these seven areas of actor activity and five areas of regulatory concern. For example, at the intersection between activities related to public information/deliberation and regulatory economic concerns we find issues such as those related to who bears the costs of consultation. Similarly, at the intersection of safety issues and regulatory implementation concerns we find a set of problems revolving around the trust of the public in the safety of, for example, regulated biotechnology-related food products (see Table 1).

The specific handling of these kinds of legal issues, of public research investment, policy deliberations and of risk management and regulatory oversight are key differentiating features of the regimes that developed in many countries over the past two to three decades and have received some detailed treatments in the literature (Talukder and Kuzma, 2008: 131). For example, participation of the public and stakeholder groups in the policy process when new technologies are involved, is a subject that has received a great deal of attention and very different treatment in different countries in recent years (Sharp *et al*., 2004; Haga and Willard, 2006; Haddow *et al*., 2007; Metha, 2004; Tutton, 2007; Fischhoff and Fischhoff, 2001).

Using this lens, agri-food genomics-based biotechnology regulation, can be defined as any biotechnology application based on genetic manipulations including both GM and non-GM applications and innovations in the agricultural or food sector. It can be seen to involve the design and adoption of a set of policies to deal with the presence or absence of the above-noted regulatory issues in the context of specific technologies and local circumstances.

While Haga and Willard's model suggests that each technology and jurisdiction thus forms a distinct regulatory 'space', looking specifically at agri-food genomics innovations from a comparative cross-national perspective, Paarlberg (2000) highlighted the commonalities he found in the approaches taken by different countries. He did so by compressing Haga and Willard's seven categories of biotechnology into five (combining public information and consumer activities and those related to commercialization and research) and scoring national regulatory responses in terms of their general orientation towards the promotion or discouragement of the biotechnology in question. This reclassification resulted in a country-specific measure of the overall national regulatory approach in terms of its orientation towards the biotechnology in

Table 1. Regulatory issue field in biotechnology

Biotechnology areas of activity	Regulatory concerns				
	Research-related	**Legal**	**Economic**	**Education-related**	**Acceptance and implementation-related**
Intellectual property rights (IPRs)	Patent policy	Intellectual property and licensing practices	Cost-effectiveness		Acceptance of biotech private ownership
Public information and deliberative activities	Ethics review	Privacy and confidentiality	Cost of broad consultations Intellectual property	Development of clinical guidelines Classroom education Public education Risk communication	Behaviour modification in response to biotechnology results
Retail and trade activities	Patent law	Trade agreements	Market value and pricing Supply and demand Commercialization of public-sector initiatives Creation of new market segments	Labelling	Public adoption of biotechnology
Health and safety	Creation of a regulatory framework	Regulatory oversight (product and manufacturing review, labeling, laboratory quality and environmental impact)	Costs related to testing	Education of health professionals	Acceptance of safety of food products by public
Consumer activities	Media advertising	Genetic discrimination	Different responses in consumer behavior	Information directed towards consumers	Cultural respect
Research investment activities	Prioritization of research areas (basic, applied and technology development) Allocation of funds Provision of facilities Access to tools and research samples	Protection of human subjects Ownership of research results	R&D funding Economic incentives for biotechnology research	Information directed towards citizens	Acceptance of value of biotechnology investment
Commercialization activities	Reliance on private or public generated research Patent policy	IPRs	Accessing venture capital Creation of technology licensing organizations	Labelling Pedagogical research	Acceptance of value and safety of biotechnology products Public opinion research

Source: Haga and Willard (2006: 967)

question, ranging from 'promotional', 'permissive', or 'precautionary' to 'preventive' responses. For example, Paarlberg termed regulations that accelerated the spread of GM crops and food technologies within the borders of a nation as 'promotional'. Those that are more neutral towards the new technology, e.g. neither speeding up nor slowing down its spread, were termed 'permissive'. Regulations intended to slow the spread of GM crops and foods for various reasons were termed 'precautionary', while those that tended to block or ban entirely the spread of this new technology were defined as 'preventive' (Paarlberg, 2000: 4) (see Table 2).

The Paarlberg framework generates a useful spectrum of possible substantive regulatory responses which is applicable to the case of agri-food related genomics technologies. This spectrum can then be applied to the substance of regulation found in different countries in order to classify their general policy orientation towards these new and emerging biotechnologies. However, it should be noted that Paarlberg was only discussing genetic modifications, a single application of genomics technology. Using this framework to assess the complex set of policies existing towards multiple biotechnologies in the genomics areas raises the possibility of governments pursuing some promotional activity in some areas, such as promoting areas of scientific research/industry, while at the same time discouraging others, such as GM applications in the field. A government

Table 2. Paarlberg model of policy options and regimes towards GM crops

	Promotional	Permissive	Precautionary	Preventive
IPRs	Full patent protection, plus plant breeders' rights (PBR) under International Convention for the Protection of New Varieties of Plants (UPOV) 1991	PBRs under UPOV 1991	PBRs under UPOV 1978, which preserves farmers' privilege	No IPRs for plants or animals or IPRs on paper that are not enforced
Biosafety	No careful screening, only token screening, or approval based on approvals in other countries	Case-by-case screening primarily for demonstrated risk, depending on intended use of product	Case-by-case screening also for scientific uncertain ties owing to novelty of GM process	No careful case-by-case screening; risk assumed because of GM process
Trade	GM crops promoted to lower commodity production costs and boost exports; no restrictions on imports of GM seeds or plant materials	GM crops neither promoted nor prevented; imports of GM commodities limited in same way as non-GM in accordance with science-based World Trade Organization (WTO) standards	Imports of GM seeds and materials screened or restrained separately and more tightly than non-GM; labeling requirements imposed on import of GM foods or commodities	GM seed and plant imports blocked; GM-free status maintained in hopes of capturing export market premiums
Public information and consumer choice	No regulatory distinction drawn between GM and non-GM foods when either testing or labeling for food safety	Distinction made between GM and non-GM foods on some existing food labels but not so as to require segregation of market channels	Comprehensive positive labeling of all GM foods required and enforced with segregated market channels	GM food sales banned or warning labels that stigmatize GM foods as unsafe to consumers required

Source: Paarlberg, 2000

could, for example, promote the sequencing of a genome that they felt might pay off for an industry over time (promotion role), while at the same time having an extremely strict regulatory policy related to genetic modification of the same crop (regulate public risks in a precautionary way). Such variations lead to finer gradations in the framework utilized here: between 'purely' promotional or preventative regimes, for example, or 'quasi' or partially precautionary or permissive ones.

Also, as Haga and Willard argued, in order to provide a comprehensive comparative framework for assessing the nature of different national biotechnology regulatory regimes, a second procedural dimension, that related to the kind of regulatory processes used in each jurisdiction to achieve these ends, also needs to be assessed. Regulatory activities, as they point out, are developed in several ways including 'bottom-up' vs. 'top-down' or state vs. publically driven processes which vary from country to country and effect a state's ability to deliver on its preferred substantive regulatory direction.

Identifying a national biotechnology regulatory procedural orientation

Haga and Willard's (2006) work addresses this second aspect of biotechnology regulation as they noted how biotechnology regulatory issues have been tackled with one, or with a mix, of several basic regulatory approaches, a subject also highlighted by Isaac (2002). These range from public consultations to a more legislative approach, passing through voluntary approaches, guidelines, and regulation, in a pattern of progressively stricter state, and weaker public, control. Top-down or state-based approaches include legislative, regulatory, and guideline approaches while bottom-up or public approaches are based on techniques such as voluntarism or public consultation (Isaac, 2002). When linked to Paarlberg's categories of regulatory orientations, these two elements provide a comparative national biotechnology regulatory matrix (see Table 3).

Using this matrix, we can locate different countries and sectors of activity within each of these four policy quadrants, reflecting the preferences shown in that country by way of its dominant procedural and substantive orientations towards a specific biotechnology development, such as genomics.

Local variations in genomic regulation: comparing national biotechnology regimes

In this section, we use this synthetic model to outline the policy orientations and the regulatory directions that are deployed to address agri-food genomics-related biotechnology in six countries: Italy, Spain, Australia, New Zealand, the US and Canada.

These six countries all have important agricultural sectors and are drawn from three different geographical areas linked together in patterns of transnational actor interactions and learning (Europe, Australasia and North America). They all belong to an economically developed group that has moved towards modern high-technology and capital-intensive agriculture

Table 3. Mapping comparative biotechnology regulatory regimes

Procedural orientation		**Substantive regulatory orientation**
State-driven ◄——► **Public-driven**		
Type I: State promotional/permissive	Type II: Public promotional/permissive	Promotion ↕ Permissive
Type III: State precautionary/preventative	Type IV: Public precautionary/preventative	Precautionary ↕ Preventive

and have focused their agricultural efforts towards substantial exports. Considering the size of their populations, countries like Australia, Canada and New Zealand are important exporters of agricultu ral products. The sample is rather diverse, however, on a variety of other variables including the area planted to commercial GM crops and the percentage that this area represents in terms of all of the arable land available in the country (OECD, 2009: 58). Table 4 highlights some select indicators for each of the countries in our sample in terms of the nature and size of their agricultural systems and present use of GM crops.

By mapping their relative position on the matrix found in Table 3 we provide evidence of the utility of this model for underscoring both the similarities and differences found in the green genomics biotechnology regulatory framework of each country.

In the following subsections we discuss each country's general biotechnology approach, and how genomics and GM applications fit in this model, and how the latter two are regulated. The comparison is focused on three main areas. First, we look at the size of the biotechnology industry in the country, paying particular attention to green biotechnology firms. Second, we provide an overview of the institutional structure that surrounds the sector, and finally we summarize the regulatory and policy approaches that these countries have taken towards both GM and non-GM genomics-related biotechnology applications in the agricultural sector.

Italy, Spain, Australia, New Zealand and North America all have important agricultural sectors and are very important to 'green' genomics-based biotechnologies

Italy

Italy is a less important player in the 'green' biotechnology sector (van Beuzekom and Arundel, 2009: 17; Ernst & Young, 2010)[3] but it has a traditionally important agricultural sector and is strongly linked to the rather precautionary EU policy towards GM products. Italian legal provisions on public consultation and access to information are significant in this sector as is the legislation of the Italian regional authorities. The general policy direction for biotechnology in Italy has been cautiously open to developments in the 'white' industrial and 'red' medical fields while it has emerged as very adverse to the use of 'green' agrifood biotechnology (Cantley, 2007; Barmore, 2010). While in the early 1990s the country had been very active in the trial testing of agricultural GMOs, the general climate in the political system deteriorated rapidly afterwards (Ernst & Young, 2010). As a result, in 2009 over half of Italian biotechnology companies were involved in red biotechnologies and only 13% in green biotechnologies. Only 58 companies overall (about 18%) deal with genomics, proteomics, and enabling technologies (Ernst & Young, 2010: 12). The field of green biotechnology research reflects this situation so that much of the research is focused on the fields of nutraceuticals, diagnostics and the like. Various public institutions and consortia composed of public and private actors, however, have been involved in green genomics sequencing, for example, grapes and apples and GMOs in particular have been an active subject of research and regulation.

In general terms, the Presidency of the Council of Ministries (the Italian Cabinet) through the National Committee for Biosafety, Biotechnology and Life Sciences controls much of the policy process in the biotechnology sector. From a more substantive policy standpoint, various Italian governments have weakly supported biotechnology and have been especially concerned about not being seen to support green biotechnology, if not altogether opposed to it. For example, in responding to the approval by the

Table 4. Selected agricultural indicators

Country	Value of agricultural imports and exports (US$ million) in 2007		Per capita agricultural production index in 2007 (1999–2001 = 100)	Area commercially planted to GM crops (million ha) in 2008	Percentage of all arable land planted to GM crops in 2008
	Imports	Exports			
Australia	7,758	23,643	67	0.2	0.4
Canada	22,442	29,540	99	7.6	17
Italy	39,634	31,585	92	None	None
New Zealand	2,598	13,482	110	None	None
Spain	26,752	31,059	90	0.1	0.7
USA	74,651	92,679	101	62.5	36

Source: FAO (2010: Tables A4; C1; B13); van Beuzekom and Arundel (2009: 77; 83)

EU of GM potatoes in early 2010, the Italian Minister of Agriculture expressed his opposition noting that Italy may resort to a referendum to ascertain the will of the people in terms of GM crops (Cantley, 2007).

This does not mean that there is no one in Italy who is favourable to the introduction of GMOs into the country. At the March 2009 national forum of Confagricoltura (the umbrella organization that brings together large agricultural and agri-business actors), the debate was centred on going beyond the 'superstition' that surrounds GMOs and pushing for the approval of their use. However, while the Italian public is not necessarily opposed to many biotechnologies, and in fact is relatively open to 'red' genomics-related biotechnologies, it finds itself quite concerned about GMOs in the food chain (Bucchi and Neresini, 2006).[4] Thus the substantive Italian approach towards the field of agri-food genomics can be located between the preventive and the precautionary steps in the Paarlberg (2000) continuum.

At the organizational or procedural level, the policy process is very much 'bottom-up' in nature. Although the Ministry of the Environment is a key player, designated as the competent authority to regulate GMOs (Legislative Decree N.224, July 08, 2003, enforcing Directive 2001/18/CE) and the Ministry of Health, and the Ministry of Agriculture and Forestry are also part of the decision-making process in their areas of competence, much authority is left with regional governments which are quite sensitive to public and agricultural opinions on the subject (ONBSV, 2007). Starting in 2004, Italy implemented traceability and labelling regulations (Cantley, 2007: 79) but chose the lowest possible levels of tolerance for GM contaminants in seeds (0.049%). While Italy approved a coexistence law in 2005, that was supposed to bring its internal legislation in line with European legislation and therefore allow for the planting of GM crops, the former was repeatedly shelved and was indefinately postponed in January 2010, due in great part to the poor reception that citizens and a large number of interest groups had given to this type of technology.

Further undermining the use of GM applications in agriculture and underscoring the bottom-up nature of Italian regulatory processes in this regard is the fact that under Italian legislation, the 20 regions that compose the country are allowed to regulate agricultural matters and 15 of them have pronounced themselves GMO-free zones. As of early 2010, Italy had not approved any commercial release of GMOs and only five requests had been presented for experimental crop trials.

Spain

Spain is an important biotechnology player in Europe and in 2006 it had 211 dedicated biotechnology companies (van Beuzekom and Arundel, 2009; Garcés Toledano *et al*., 2009: 13). Overall, the number of biotechnology firms more than doubled in the period 2004–2006 with a very high percentage of R&D firms among them (van Beuzekom and Arundel, 2009: 19–20). The fields of application of Spanish biotechnology are varied. Dedicated biotechnology firms are involved in the agricultural (16%) and food fields (8%), in the diagnostics (18%) and biopharmaceutical fields (19%), in bio-industrial and biochemical processes (10%) and in technical services (29%) (Garcés Toledano *et al*., 2009: 46).

While nominally falling within the precautionary model advocated by EU regulations, Spain is one of the most pro-biotechnology countries in the EU. With 34% popular support for GM foods, Spain ranked relatively high among the EU member states in public acceptance of the technology (Gaskell,

Spain is one of the most pro-biotechnology countries in the EU, with 34% popular support for GM foods

2005: 19). Mainly due to the need to combat climate-related pest infestations, especially the corn borer, Spanish farmers began planting GM crops very early. Bt maize was introduced in 1998 and in 2008 80,000 ha of GM maize were cultivated. This represents the highest amount of GM crops in the EU. In Spain only Euskadi, the Asturias, Menorca and the Canary Islands have discussed becoming GMO-free regions.

At the present time, Spain is still developing national legislation to implement more precise rules regarding issues like separation distances between GM and non-GM crops (Cantley, 2007). However, the application of European legislation seems to have served Spain well enough in the interim. Overall, the Spanish approach to genomics-based biotechnology has been relatively promotional, especially when compared to many other European countries (Migone and Howlett, 2010). Biotechnology is one of the five key areas that the Spanish government identified in its 2008–2011 plan for scientific development and technological innovation (Garcés Toledano *et al*., 2009: 13). This, however, does not mean that there is no internal opposition or concern regarding the regulatory policy process towards specific uses of agri-food genomics technologies.

Organizationally, the Ministries of Environment (Ministerio de Medio Ambiente) and of Agriculture, Fisheries and Food (Ministerio de Agricultura, Pesca y Alimentación) are at the forefront of the activity for agri-food biotechnology (Garcés Toledano *et al*., 2005). Two important farmers' associations, UPA Andalusia and the Asociación Agraria Jóvenes Agricultores (ASAJA), have been quite active in asking for an open policy that would allow them to choose whether or not to plant GM crops. But in terms of European countries, as mentioned above, Spain is relatively open to the production of biotechnologies and its public is relatively interested in consuming GM products (Cantley, 2007). Genoma España is the key organization for promoting both genomics and biotechnology development (Garcés Toledano *et al*., 2009) and Spain is an instance of a more or less top-down policy development process oriented towards the promotion of the new technologies but one which nonetheless enjoys bottom-up support. Regarding the differences that we find in the regulatory approach in Spain, especially when compared to other European jurisdictions such as Italy, we should note that it is an outlier in the EU (Migone and Howlett, 2010). Its positive attitude towards biotechnology (Cantley, 2007) may be explained in terms of both practical needs and the fact that the cultivation of GM products tends to be geographically concentrated.

Australia

The Australian biotechnology industry has grown at a rapid pace, and Australia has become an important international player and one of the most cost-effective locations for biotechnology research (Commonwealth of Australia, 2008). In 2007, under the patronage of the Australian government, Bioplatforms Australia was created, bringing together four platform units (genomics, proteomics, metabolomics, and bioinformatics) to 'promote and leverage Australia's bioscience capabilities for the benefit of all Australian researchers.' (Bioplatforms Australia, 2009: 4). This appears to be similar to the institutional developments that occured earlier with Biotechnology Australia.

Australia launched its National Biotechnology Strategy (Commonwealth of Australia, 2000) in July 2000 and created Biotechnology Australia (BA) as the leading agency in the field. BA was responsible for coordinating non-regulatory biotechnology areas and managing the country's national biotechnology strategy. The particular place of BA as a conduit both from the regulatory environment to the public and from the public to the regulators was very important in influencing, and coordinating, the general perception of biotechnology and biotechnology regulation found in the country.[5]

The Bioplatforms project is designed to function as a hub for the development of many new genomics-based technologies. In 2006–2007, genomics accounted for 67% of client usage for the platforms (Bioplatforms Australia, 2009: 10). In terms of green genomics, scientists at Southern Cross University are working on the sequencing of wheat, sugar cane and rice in cooperation with various international researchers (Bioplatforms Australia, 2009: 16). The Australian Wine Research Institute (AWRI) is also working on genomics with a project on sequencing wine yeast (Dean, 2009). There is no specific regulatory burden on genomics research or applications besides the ones that generally apply to similar products.

The success of the biotechnology industry in Australia was part of a general effort towards the build-up of innovation capacity in the country, but was nonetheless important in itself (Cantley, 2007). In the agri-food biotechnology sector, the Australian government and large farm groups have been pressing for a more liberal application of biotechnologies involving GMOs, especially through the Commonwealth Scientific and Industrial Research Organization (Cantley, 2007: 62). Farmers have been using GM cotton for some time without major issues, and the country has approved GM canola. However, state governments have been reluctant to allow its cultivation. Because Australia has a federal structure, an important part of the regulatory field is in the hands of the States and Territories. These include the regulation of cultivation and trials of GM plants on their territory, and enforcing federal legislation among others. Only in 2008, did New South Wales and Victoria lift a moratorium on planting GM crops, followed in 2010 by Western Australia, and these now follow the federal government lead in this area. In 2001, the federal government passed a standard for the labelling of GM in food by adopting

an EU-style approach in which any food, food ingredient or processing aid that is produced using gene technology must be labelled accordingly if they exceed 1% GM content. Food Standards Australia New Zealand (FSANZ) is tasked with regulating the safety and quality of foods in the two countries and has been regulating these foods on the basis of the principle of the conventional counterpart.

Australia has thus followed a quasi-promotional approach to biotechnology development in general and green genomics technologies in particular, tending towards the permissive side. Like Spain, it has managed to develop a very successful biotechnology sector in which there is both top-down and bottom-up agreement on the general direction of policy. Australia managed this by developing a strong communicative capacity and a trusted broker (BA) through which information and dialogue could be channelled between the public and the scientific community. Australia also has in place a well developed system of public participation and consultation in the area of biotechnology through the Office of the Gene Technology Regulator and FSANZ. Both GMOs and genomic applications have found a place in Australia and government agencies have tended to ensure that both areas would be promoted and fostered at the same time.

New Zealand

New Zealand, even with its small population, has a very respectable world-class biotechnology industry with a significant green genomics component. As New Zealand exports a variety of food products (mussels, wine, meat) there was a concern that introducing GMOs might affect these sales. However, the government has been open to the development of biotechnologies, especially genomics-related ones, and at the same time has worked very hard to do so in a fashion where environmental protection and public participation were important elements of its overall strategy (Cantley, 2007).

In New Zealand, the regulatory framework is relatively strict for biotechnology and this has spurred interest in the development of state-led genomic applications. For example, New Zealand Genomics Ltd. was incorporated in 2004; this structure brings together various government research facilities and some of the country's best academic research centres, and is designed to create 'a collaborative national infrastructure designed to accelerate New Zealand's genomic research and technology' (New Zealand Genomics Ltd, not dated). The interest of the New Zealand government in this hub for the creation of genomic research is proven both by the funding that it has provided to the institution over time and by the direct involvement of the government in the administration of the process (New Zealand Genomics Ltd, not dated).

On the other hand, the New Zealand public has shown itself to be concerned about the possible effects of GMOs on the environmental and economic realities of the country (Cantley, 2007) and the agricultural industry has not applied biotechnology in any major manner. In 1999, the newly installed Labour government took the step of initiating a broad debate based on the work of the Royal Commission on Genetic Modification, which reported on the matter in 2001 (New Zealand, 2003; Biotechnology Sector Taskforce, 2003).[6] The commission argued that the main choice should be one of 'preserving opportunities' for New Zealand by neither closing the door to GM technology nor allowing a clearly promotional model. Rather, it suggested that the technology should be approached cautiously by minimizing and managing risks to human health and the environment. The result was the New Organisms and Other Matters Bill of 2003, which terminated an existing moratorium on GMOs and created a regulatory framework that would allow their marketing and release in the environment (New Zealand, 2008).

Institutionally, the Environmental Risk Management Authority (ERMA), which is part of the Ministry for the Environment, administers the applications that are presented under the Hazardous Substances and New Organisms Act. This is an independent Crown Agency in which is concentrated the capacity to regulate all facets of the importation, research and development, field testing and release of GMOs in New Zealand (New Zealand, 2008). This includes specifying separation distances and planting locations for crops and monitoring the crop and produce. The act also establishes a civil liability system for damage sustained from GMOs if an individual or a company fails to abide by the law. For individuals, the maximum penalty is NZ$500,000, while companies face penalties up to NZ$10 million, or three times the value of any commercial gain that results from the breach, or 10% of the turnover of the company involved (including any subsidiaries). Outside of the civil liability system (which is triggered by a breach in the law) there are also cases of compensation that may result not from a breach in the law but simply by nuisance or negligence (Hindmarsh and Du Plessis, 2008).

As of 2010, ERMA had approved only two GM crop testing projects: between December 2003 and May 2008 for GM onions and beginning in 2008 approval was given for testing in the Lincoln area of cabbage, broccoli, cauliflower and kale with genetic modifications that would make them resistant to caterpillar pests. Regarding transgenic animals, AgResearch, a large Crown research institute that has done considerable research in the sector of biotechnologies, applied to ERMA for approval of these projects. In 1999 and 2001 approval was granted for field tests of GM cattle that would produce milk containing therapeutic benefits. Another proposal for a similar project was approved in 2002. As the original approvals would soon expire, AgResearch submitted new proposals in 2008 and 2009 that are currently being reviewed and submitted to public consultation.

Thus, in New Zealand green genomics biotechnology research is significant and ongoing testing is being undertaken, but these projects face both public opinion and regulatory hurdles in their translation into commercial enterprises. In practice, New Zealand can be seen to have a regulatory system operating between the permissive and the precautionary steps in the Paarlberg (2000) continuum, with an especially precautionary side in the application and commercialization areas and a more open research approach. Organizationally and procedurally, it is very much a bottom-up regulatory process.

United States

The US is a key player in the development of biotechnology (van Beuzekom and Arundel, 2009) and of agricultural genomics innovations. Some of the most important companies dealing with biotechnology and some of the most important biotechnology clusters in the world are based in the US, which is also a world leader in scientific and technological innovation.

In the US, the promotional path to agri-food biotechnology development began early on. Of particular importance in the US has been the ability of the federal government to secure control of the biotechnology regulatory system. The Reagan administration began framing risk assessment of biotechnology by delivering regulatory oversight to the federal level while choosing scientists to define the contents of that regulation (Krimsky, 2005). The 1986 Coordinated Framework for Regulation of Biotechnology was a key factor in concentrating the decision-making process at the federal level. This allowed the federal authorities to nip in the bud the possibility of having to deal with very fragmented systems, as is the case in the EU.

As a result, debate about regulating GM products shifted towards a promotional approach where the characteristics of the products and not the process through which they were created determined whether or not they should be screened differently. Furthermore, the scientific and commercial sides of the biotechnology sector were closely linked to the national development of the sector, and went hand-in-hand with a strong international push for the approval of favourable trade and intellectual property rules which would ensure that American biotechnology products could find their way into foreign markets.

Regarding the area of genomics, the US has been at the forefront of its study and applications. Institutions like the National Human Genome Research Institute or the Centre for Research on Genomics and Global Health are key elements in bringing together the massive research and personnel capacity of the country (van Beuzekom and Arundel, 2009) and the application of these innovations to the health system, for example, is quite impressive (Khoury, 2009). This has been matched by a degree of expectations, perhaps not always met, that the completion of programs like the Human Genome Project would lead to important biomedical advances (Gwinn and Khoury, 2006; National Research Council, 2006). In terms of regulation and legislation, the US has not created any specific instrument dealing with genomic applications.

Public opinion in the US is generally relatively unconcerned about GM foods and crops and more positive about their marketing and use compared to European publics (Fernandez-Cornejo and Caswell, 2006). In the US, GM foods are not an issue in the media even if the latter is not as promotional as it used to be (Horning Priest 2006). Organizations like the Food and Drugs Administration (FDA), the Environmental Protection Agency (EPA), and the US Department of Agriculture (USDA) are key players in the global biotechnology system and have been responsible for the development of many critical regulations that have been mimicked in many other countries (Cantley, 2007).

The success of the agri-food biotechnology sector in the US reflects the importance that innovation and science in general have in the country, the important levels of investment that are found there (van Beuzekom and Arundel, 2009), the structure of the regulatory system which stayed clear of any regional or local fragmentation, and the support displayed by the public in purchasing GM products. At the same time, future success of the US as a developer of green genomics biotechnology will likely pass through its ability to become a major exporter of biotechnology applications and of the products derived from these applications. As things stand, especially for agricultural biotechnology, the resistance of African and European countries to GM products remains a major problem. However, domestically, the US remains the archetype of a top-down, promotional, regulatory approach.

Canada

Early on, Canada attempted to cast itself as a major biotechnology player, but achieved only mixed results (Munn-Venn and Mitchell, 2005; Ryan, 2007; Paquet, 2005; Stanley, 2007). In particular, while research and development and investment numbers were important (OECD, 2005; 2007), the creation of economic returns and the levels of adoption lagged behind expectations (Phillips, 2005; 2007). The Auditor General of Canada, for example, has argued that the 1983 Canadian Biotechnology Strategy failed to provide the top-down unifying approach that was needed to achieve its principal goal of making the country one of the top biotechnology producers and users in the world (Canada, 2005: 10).[7]

Both the federal government and some of the most important provincial governments[8] are nevertheless heavily involved in the genomics-related biotechnology sector, especially research on agri-foods. For example, in British Columbia the Wine Research Institute at the University of British

Columbia is involved in the sequencing of yeast and grapes while federal laboratories in various parts of the country have been instrumental in developing GM crops such as canola and soybeans. Federal and provincial authorities aimed at fostering agri-food biotechnologies and applications, and initially created regulations with a relatively permissive flavour in order to allow for research and testing even of GMOs (Moore, 1999; Phillips and Wolfe, 2001; Canada, 1998, 2003). This was in line with federal and provincial science and technology policies which focused on the commercialization of biotechnology (Canada, 2006, 2007). These policies aimed to foster the competitive edge of the Canadian industry through the creation and protection of a market-friendly environment. Specifically, this involved increasing the role of private companies in the research process, aligning Agri-Food Canada's own research with this policy shift, and securing such incentives as Plant Breeders' Rights (PBR) so that developers of new GM species could claim rights to their creations. This approach was institutionalized in the 1983 National Biotechnology Strategy, which focused on fostering research expenditure through the National Research Council with Saskatoon as the centre for this effort.

While permissive, the Canadian regulation allows for a broader set of regulatory triggers than the US one, relying on novelty to trigger product/technology review. Canada includes all genetically engineered plants but also some plants with novel traits that did not come from biotechnology applications within its regulatory remit (Montpetit 2005:346).[9] The product-based approach was institutionalized in the 1993 'Regulatory Framework for Biotechnology'. But its central assumption is that products derived from genetic manipulation are not inherently riskier than any other (Royal Society of Canada, 2001). In 2003, however, the 'Framework for the Application of Precaution in Science-Based Decision Making and Risk' was approved which looked at the applicability of the precautionary principle for Canadian science and technology policy (Health Canada, 2003). It made it explicit that, when applied, the precautionary principle is subject to three limitations. First, the precautionary principle is of a temporary nature (based on the progression of scientific knowledge). Second, domestic and international obligations may limit its application. Finally, while public participation is welcome, its effective use is dependent on the timeframe of the decision and on the context. In this sense, the precautionary principle is subject to a cost–benefit analysis that involves both social and economic values. This is a fairly promotional top-down regulatory approach compared to that taken in other countries and jurisdictions (Moore, 2007).

Since 1994, Health Canada has approved over 100 novel foods, many of which involved genetic manipulation (Canada, 2008: 5).[10] Its promotional approach to biotechnology is reflected in various areas. For example, it was only in 2004 that the Canadian General Standards Board produced a voluntary labelling standard for GM foods where genetically engineered material is over 5% of the product. [11] In terms of genomics research, Canada has been relying on the central organizational structure of Genome Canada and of its regional centres.[12] Genome Canada has contributed massively to investment in the area and has developed important networks and research in fields ranging from agriculture to biodiversity, biofuels and child health (Genome Canada, 2010).

The Canadian government's substantive attitudes in terms of the substance of biotechnology regulation thus can be located on the Paarlberg's continuum somewhere between the promotional and the permissive areas although with strong precautionary elements. They are closer to the promotional American approach than to the more restrictive one of the EU, but still unique. Procedurally they are very much top-down in nature. That is to say that, genomic applications do not encounter any special regulatory issues. In terms of policy approach, Canada has engaged in a long-term, top-down promotional strategy providing material and financial support and designing a regulatory system that would foster the development of even the most intrusive green genomics applications.

Conclusion

The analysis presented here aimed at assessing country differences in the way in which national biotechnology regulatory systems are constructed, especially as applied in the green genomics and agri-food biotechnology areas. As noted above, the approach that the six sample countries have kept towards biotechnology applications are broadly similar but different in many regards. They are remarkably similar in the sense that their principal substantive and procedural components, as Haga and Willard (2006) and Paarlberg (2000) argued, can be located and mapped within a framework focusing on the promotional vs. preventative character of regulatory substance and the top-down vs. bottom-up nature of regulatory policy-making (McNally and Cambon-Thomsen, 2004; Petrini, 2009; Migone and Howlett, 2009, 2010). The results of the country surveys are summarized in Table 5. The scoring for the substantive regulatory orientation is done by including both the regulations and the policy preferences of the individual country and by weighing the effects of regulatory schemes on the green biotechnology sector. This finer grained analysis allows us to score differently EU member countries like Spain and Italy that, under an 'EU-only' regulatory lens, would appear very similar when they in fact are not.

As this discussion has shown, in Australia a top-down quasi-promotional model has developed that is supported by a public-oriented approach to participation. This openness was an important tool in overcoming a relatively more fragmented regulatory

Table 5. Comparative biotechnology regulatory regimes

Procedural orientation	*Substantive regulatory orientation* — **State**	**Public**	
	US Spain Canada Australia	New Zealand	**Promotion** ↕ **Permissive**
		Italy	**Precautionary** ↕ **Preventive**

and legislative system than those found in many other countries. Spain, on the other hand, featured a more bottom-up procedural direction coupled with a more promotional orientation. A different situation exists in New Zealand where openness in the regulatory system did not lead the public to embrace agricultural GM products, but nor did it lead to a preventative regulatory outcome as was the case in Italy. In Canada the policy regime is operating on a quasi-promotional approach with precautionary elements imposed through a mainly top-down system of scientific risk assessment that includes a series of efforts aimed at educating the public, but otherwise with only limited effective public engagement. The 'executive' dimension of the Canadian biotechnology development strategy is relatively strong and the federal government was especially important in developing the direction in which the system has moved. The same situation, more or less, is true of the US but without the precautionary elements.

The results of this study also show that specific clusters of countries have emerged in the green biotechnology area. Most of the surveyed countries have embraced a promotional or quasi-promotional approach to agri-food biotechnology married with a rather state-centrered approach to regulation, but others have arrived near the same place in a more bottom-up fashion.

This is a more complex picture than has typically been portrayed in other research. For example, Isaac (2002) argued that the North American and EU approaches towards the regulation of 'green' agricultural biotechnologies differed only according to their diverging interpretations of the precautionary principle, with North American jurisdictions highlighting and prioritizing scientific concerns in state-led regulatory processes while European countries emphasized social concerns and responsibilities in more precautionary, bottom-up, processes. Our analysis also reveals significant differences between pairs of countries often thought to be quite similar (e.g. Spain and Italy or Australia and New Zealand) suggesting that regional forces towards policy convergence are weaker than is often assumed.

Although further work needs to be done to test our model against additional cases, it appears from this initial survey that the model developed here is useful in mapping the nature of the regulatory approaches found and followed in different jurisdictions with respect to agri-food genomics and helping to shed light on the local variations found in national patterns of biotechnology regulation. It also suggests several fruitful areas for future comparative research.

From this analysis, for example, we can glimpse some indications of the kinds of factors which have influenced the origins and evolution of specific biotechnology regulatory regimes. Countries that in our sample have a strong biotechnology sector (e.g., the US, Australia, Canada, New Zealand) all have a promotional or quasi-promotional regulatory regimes. And the model also shows the impact on the regulatory system of public opinion in modifying these promotional impulses. But this requires the existence of some institutional venue for allowing public opinion to manifest itself, as with the case of local governments in Italy. In both Australia and New Zealand, it should be noted, the public was quite concerned about the possible side effects of some agri-food biotechnology applications, especially GMOs, but only New Zealand had the kind of public-oriented participatory policy development system which allowed this direction to be reflected in regulatory outcomes.

Notes

1. Metabolomics deals with the study of the chemical footprint left by cellular processes. Proteomics studies the activity of proteins and transcriptomics is interested in the activity of ribonucleic acid molecules.
2. It should be noted that the field of science policy is very complex and this is especially so, for example, in terms of biotechnology applications. One problem that often appears is a terminological confusion among biotechnology, genomics and genetic modification. This can be addressed relatively simply by resorting to commonly accepted definitions. In 2002, the OECD defined biotechnology as:

   > …the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services. (van Beuzekom and Arundel, 2009: 9)

   This is a rather broad definition that the OECD supplemented with baseline definitions, especially for measurement purposes. Both genetic engineering and genomics are included here. Genomics was defined very simply as:

   > …the study of genes and their function. (OECD, 2005: 39)

   Genetic engineering was defined as:

   > …altering the genetic material of cells or organisms in order to make them capable of making new substances or performing new functions. (OECD, 2005: 39)

3. In Italy the area of genomics, proteomics, and of their enabling technologies is undertaken by 18% of the companies present on the territory (Ernst & Young, 2010: 12); this is broadly in line with other European countries (Ernst & Young, 2010: 49). The Italian government especially through the Ente per le Nuove Tecnologie, l'Energia e l'Ambiente (ENEA) has been active in the development of genomics-based research (ONBSV, 2007: 32) and has, over time, provided interesting funding both in general to innovative research and to the field in particular (ONBSV, 2007: 80).
4. Italians appeared to be relatively in favour of GM foods in the 2005 Eurobarometer research with 34% supporting them (Gaskell *et al*., 2005: 19). This seems to have changed slightly since: a recent opinion poll commission by the Italian farmers' association (Coldiretti), 72% of Italians believe that GM foods are more damaging to your health than other products. However, in a different poll, Italians still seem to be less worried about GMOs negatively affecting the quality of food (16.9%) than the use of pesticides (33.5%) (Arzenton and Bucchi, 2009: 45). Concern about the use of GMOs in agriculture also comes behind the use of pesticides and fertilizers when Italians are asked to name an environmental concern. Interestingly, these come much further down the list of environmental concerns (seventh and ninth), much behind climate change (47%) and various types of pollution (Arzenton and Bucchi, 2009: 119).
5. BA was closed in June 2008 as the program it supervised was terminated. A post-program review completed in early 2008 (Commonwealth of Australia, 2008) found that the institution had been very important in the development of biotechnology in the country, serving to link a top-down regulatory process with a permissive orientation towards the technology.
6. The Royal Commission heard over 400 experts and received upwards to 10,000 public submission in the period between 8 May 2000 when it was established and 27 July 2001 when it presented its final report.
7. The 2005 report of the Auditor General of Canada found that:

   > Overall, the Canadian Biotechnology Strategy has not functioned as planned. It was designed for leadership from the top, which was not provided; however, management and working-levels did provide some coordination. (Canada, 2005: 10)

8. In Canada the main actor in the development of a science and technology policy and of its attendant regulative framework has been the federal government, followed by provincial authorities. A more marginal role has been taken by industry and academic researchers. This is not a surprise as governments have traditionally played an important part in the development of biotechnology in all areas, from the funding of what is inherently a risky scientific enterprise, to the provision of regulation (Etzkowitz, 2006; Monpetit, 2005). The federal government in 2003 spent US$549 million in biotechnology R&D, accounting for 12.4% of all federally funded R&D, being outdone only by New Zealand (24.2%) and South Korea (15.3%) (van Beuzekom and Arundel, 2006: 19). It is more complicated to map provincial funding to the sector. However, in the period 2000–2008, Genome Canada raised close to $1 billion dollars to match the $840 million that the federal government provided from a variety of sources. When the funding for operating the Genome centres was excluded, provincial governments had provided 23% of the money (Genome Canada Website <http://www.genomecanada.ca/en/about/>, last accessed 4 November 2010).
9. According to Directive 94-08, the Canadian Food Inspection Agency defines plants with a novel trait (PNT) as:

   > …plants containing traits not present in plant of the same species already existing as stable population (see <http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml>, last accessed 4 November 2010)

   While it formally applies a substantial equivalency risk assessment tool (Canada, 2001: 11), the Canadian regulatory process is still stricter and more broadly interested in checking the nature of new GMO products than the US one. This reflects the hybrid nature of the overall approach to biotechnology with promotional research and commercialization processes and a permissive testing side.
10. The OECD BioTrack database can be very useful for a general comparison of approved biotechnology. See <http://www2.oecd.org/biotech/byCountry.aspx>, last accessed 4 November 2010.
11. Under this standard, processing aids, enzymes below 0.01% by weight in a food as offered for sale (for exceptions, see par. 6.2.7 a.), veterinary biologics, animal feeds, and substrates for micro-organisms (where the substrate itself is not present in the finished food product) do not affect whether or not a food or ingredient is considered to be a product of genetic engineering. We can compare the Canadian approach with the EU regulations that 1830/2003 on the Traceability and Labelling of GMOs and 1829/2003 on Genetically Modified (GM) Food and Feed (implemented in 2004), which required that any more than a 0.9% of unintended presence of an EU-approved genetically engineered substance would trigger a mandatory labelling of the product as GMO. Even if this regulation exempted from labelling products like milk, eggs and meats from animals fed with GMO feeds, it created massive limitations to trade and in 2006 the World Trade Organization ruled that this was a de facto moratorium on US, Canadian and Argentine products. General international standards have also been elusive as the Codex Committee on Food Labelling (CCFL) of the Codex Alimentarius Commission has discussed this topic for over 15 years without making much progress.
12. Genome Canada has regional branches in British Columbia, Alberta, the Prairies region, Ontario, Quebec and the Atlantic region. While the approach can be somewhat justified by the focus on specific resources and areas of research the fragmentation in regional centres may have contributed to some inefficiencies (Phillips, 2005).

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