Creating a New Object of Government: Making Genetically Modified Organisms Traceable

Javier Lezaun

Social Studies of Science 2006; 36; 499
DOI: 10.1177/0306312706059461

S|S|S

ABSTRACT Since the late 1990s, the European Union (EU) has embarked on an effort to make fully traceable and identifiable every genetically modified organism (GMO) that travels through its territory. New regulations force market operators to record the presence of genetically modified material in foods and feed, and to pass this information along in every transaction, thus creating a continuous paper trail for every bioengineered organism as it moves through the EU market. This new regulatory regime represents a momentous change in the nature of biotechnology governance in Europe, for it enunciates as its fundamental unit a novel bio-legal entity – the 'transformation event' meant to identify the particular instance of genetic modification from which each GMO has been developed. This paper describes the processes through which this new regulatory entity acquires a concrete and material meaning and thereby becomes a viable object of governance. Two parallel developments are described in detail: the creation of international rules for attributing to 'transformation events' unambiguous names – an instance of 'bureaucratic nominalism' – and the creation of detection methods and biometrological chains of custody capable of identifying the fragments of DNA that mark the specificity of each 'event'. These two interventions involve the creation of infrastructures of referentiality capable of giving the 'event' a singular and unambiguous referent. By analysing how a new regulatory category like the 'transformation event' becomes an identifiable bio-legal object, I suggest that the governance of biotechnology should be understood as a series of acts of 'demarcation', through which the categories and entities enunciated in regulatory texts acquire a material foundation in bureaucratic practices and in the organisms these bureaucracies are expected to oversee.

Keywords biotechnology in Europe, genetically modified organisms, regulation, spatial demarcation, traceability, transformation event

Creating a New Object of Government:

Making Genetically Modified Organisms Traceable

Javier Lezaun

New techniques of genetic manipulation have given rise to novel kinds of organisms incorporating 'foreign' or transgenic DNA, and the governance of these 'genetically modified organisms' (GMOs) has since become the object of a 'global controversy' (Bauer & Gaskell, 2002). GMOs were once confined to bounded spaces – laboratories, greenhouses, field trial sites – and their control was often a matter of keeping these locations properly

Social Studies of Science **36/4(August 2006) 499–531**

ISSN 0306-3127 DOI: 10.1177/0306312706059461
www.sagepublications.com

sealed.[1] Since the mid-1990s, however, GMOs are routinely released into the environment at large. The introduction of transgenic seeds in agriculture, and the subsequent commercialization of genetically modified (GM) foods throughout the world, has intensified the debate over the forms of governmental oversight and mechanisms of control that should accompany GMOs at large and keep them under regulatory supervision.

Europe has been a most fertile ground for this debate (Jasanoff, 1995; Gottweis, 1998; Marris et al., 2002). Since the late 1980s, the European Union (EU) has introduced different pieces of legislation aimed at treating GMOs as an object of specific regulation (Cantley, 1995). By treating transgenic organisms as a regulatory category, the EU has effectively abandoned the principle of 'substantial equivalence' between molecularly engineered organisms and their conventional counterparts. That principle had been espoused in the initial international agreements on the governance of biotechnology products (Organisation for Economic Co-operation and Development, 1993) and still characterizes North American regulatory regimes. Rather than dealing with transgenic organisms as, in principle and in the absence of proof to the contrary, equivalent to 'conventional' or 'natural' ones, the EU has chosen to consider 'GMOs' as a prima facie object of governance: a distinct class of biological entities requiring specific regulatory attention. The successive pieces of legislation introduced by the EU in the past 15 years can be seen to be part of a continuous and strenuous effort to sustain this fundamental distinction between GMOs and conventional organisms. This is an effort to make the category of 'GM' real in the world by imposing increasingly stringent testing, identification and labelling obligations on genetically engineered products. The fundamental question is whether European authorities will be able to maintain this regulatory separation of 'natural' and 'artificial' biological entities, and apply to the latter a different set of rules and principles in the face of an environment and a food production system in which both kinds of organism are increasingly mixed and difficult to differentiate. In other words, the question is whether or not the EU will be able to impose its political will on the complex realities of biological organisms, and through the intricate and opaque structures of agricultural and food trade, to create an integrated European 'technological zone' (Barry, 2001): a zone in which a set of clearly formulated and uniformly applied rules serve to differentiate between organisms on the basis of their genetic origin and history.

A New Tool for Europe

The question of how to govern bioengineered organisms is not simply a matter of bringing a clearly defined set of entities under control. Far from being a definitive and immutable regulatory category, 'GM' is slightly altered with each new piece of legislation.[2] The regulation of biotechnology has a performative character; it is an ontological project (Mol & Law, 1994), in the sense that every new legal instrument and administrative rule

inscribes into the world a particular distinction between 'natural' and 'artificial' organisms, institutes new categories, such as 'GMO', and gives those categories a precise technical and legal meaning. Biotechnology regulations, like most governmental interventions, therefore have a creative dimension; they call new bio-legal entities into existence. This crucial generative character of regulation is even more apparent with the latest addition to the European regulatory apparatus: the establishment of an infrastructure capable of ensuring the 'full traceability' of GMOs; the creation of a set of administrative practices and detection instruments able to track GMOs throughout the food production system, 'from the farm to the table'.

GMO traceability has become European law with the passing of Regulation 1830/2003, 'concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms' (European Union, 2003a), a regulation that attempts to make GMOs traceable by forcing all operators in the food chain to record the presence of modified genetic material in their products and to pass on this information through every market transaction – all the way to the supermarket or the animal feeding lot.[3] Such a traceability system can have a number of different uses, and European institutions have been studiously ambivalent on the ultimate rationale behind their efforts. Ensuring that market operators produce an exhaustive record of the GM material present in the food chain will serve to facilitate the labelling of 'GM foods', and to strengthen the monitoring of GMOs more broadly – allowing, for instance, the withdrawal of hazardous products in the event of adverse environmental or health effects.[4] But traceability has other political uses beyond the strictly regulatory ones. It fulfils the promise of European institutions to foster 'consumer choice' vis-a-vis GM foods. The Regulation was presented by the European Commission as 'a direct response to the voices of consumers who have made it clear that they want – and have a right – to make informed choices' (European Commission, 2003). In the imaginary of regulatory authorities, the Regulation is also expected to generate what they have come to consider a direct corollary of consumer choice: 'consumer confidence' in biotechnology and in the institutions responsible for its regulation.[5]

The Regulation has generated an intense political debate over its economic and legal implications, and the meaning of traceability and its compatibility with the rules governing international trade remain under discussions at the World Trade Organization (WTO) and the Codex Alimentarius Commission, where critics of the EU regime have argued that traceability is not an acceptable risk management tool. It is, they argue, a generic feature of production systems, not a specific measure justified as a response to a clearly differentiated risk. It contradicts international WTO rules – particularly the agreement on Sanitary and Phytosanitary (SPS) measures and Technical Barriers to Trade (TBT) Agreement – which restrict the ability of governments to impose mechanisms for tracing products to situations in which a concrete and scientifically defined

risk is at hand. The stakes in this debate are obviously very high, because a legal obligation to identify individual GMOs poses a fundamental challenge to an international trade infrastructure that depends on the aggregation and rapid movement of large volumes of undifferentiated organisms. That is, it relies on the creation of 'commodity streams' where the segregation of different kinds of organisms on the basis of their genetic origin is unfeasible or impossibly expensive. International handlers of agricultural commodities and grain-exporting countries have led the opposition to the EU traceability regime for biotechnology. These critics argue that such a high level of scrutiny is simply unworkable in a world of massive trade flows, where agricultural and food products are routinely mixed together and shipped in bulk across borders, and where essential economies of scale are generated precisely by ignoring genetic distinctions between organisms and commingling transgenic and conventional products.[6]

In this paper I address the political and economic implications of the EU GMO Regulations by making a broader argument about the significance of traceability as a novel principle of governance and by asking the question of its feasibility in a slightly different fashion. First, I will argue that the new Regulation is not just a further refinement in the expanding and convoluted EU legislative apparatus of EU biotechnology regulation, but represents a momentous change in the nature of biotechnology regulation in Europe. It brings about a critical shift in this regulatory regime because it proclaims as the object of government and its fundamental unit a new bio-legal entity: not the genetically modified *organism* that previous legislation had tried to make governable, but a unit of greater specificity, the 'transformation event', or the particular instance of genetic modification from which a GMO is derived. Despite this new centrality, the meaning of the category of 'transformation event' is not resolved in the text of the Regulation itself. In fact, the Regulation barely mentions it.

My guiding question is then, how does the 'transformation event' become a viable category of government? How is it practically constituted as a distinct and governable kind of object? I will argue that the work of making the 'transformation event' real is not purely legal or regulatory, if these terms are understood, narrowly, to describe solely processes of legal formulation and enforcement. This work of materializing the 'transformation event' takes place elsewhere: through the creation of administrative systems capable of generating unambiguous names for individual 'events', and in the development of laboratory tools that can detect and visualize the fragments of DNA that give each 'event' its unique specificity. These are sites and domains of action where fundamental political questions are addressed, and particular solutions are given to administrative and technical problems of GMO traceability that reshape the nature and degree of governmental intervention in the management of biotechnological organisms. By taking a detailed look at these simultaneous processes of bureaucratic and analytical demarcation, I aim to shed light on the processes

through which new bio-legal entities are constituted as feasible objects of government.

Delimitation and Demarcation

In June 1999, after several years of intense public controversy over the introduction of GM foods, in which citizens were actively mobilized in anti-GMO campaigns throughout Europe, five EU Member States decided to block any future authorization of GMOs until stricter controls and identification mechanisms could be introduced.[7] In their declaration, the five countries emphasized 'the importance of the Commission submitting without delay full draft rules ensuring labelling and traceability of GMOs and GMO-derived products', and announced that 'pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorisations for growing and placing on the market suspended'. It took the EU 4 years to respond to this regulatory challenge with the adoption of Regulation 1830/2003, 'concerning the traceability and labelling of genetically modified organisms' and 'food and feed products produced from genetically modified organisms' (European Union, 2003a).

The text of the Regulation defines traceability as 'the ability to trace GMOs and products produced from GMOs at all stages of the placing on the market throughout the production and distribution chains, facilitating quality control and also the possibility to withdraw products' (article 3.3), and it attempts to create this ability by imposing an obligation on all market actors 'to transmit specific information that a product is produced from GMOs to the next operators in the production and distribution chain'. Traceability begins with the first 'placement on the market' of a GMO in the EU – that is when the initial record of the presence of GM material is produced and a paper trail initiated. From then on, every product that 'consists of or contains' GMOs (or 'products produced from GMOs') will be accompanied by a written certificate stating the presence of GM material and the identity of every individual transgenic organism. The latter will be recorded through an individual code or 'unique identifier', which, according to the Regulation, will serve 'to identify a GMO *on the basis of the transformation event from which it was developed*' (article 3.4, my emphasis). That is, the codes used to identify individual GMOs will not describe a particular *kind* of transgenic organism, but the specific 'transformation event' from which the GMO 'was developed'.[8] By forcing market actors to record the presence and identity of 'transformation event' contained in their products and to pass this information along the food chain, the regulators hope to create a continuous paper trail that spans the trajectory of every GMO, and its derivatives, from the moment it enters the EU to its final appearance in a consumer product.

The Regulation does not specify mechanisms for the detection of GMOs or how the certificates of the presence or absence of GM material ought to be verified. More importantly, the Regulation does not even offer

a definition of 'transformation event', the entity market actors are asked to identify through the 'unique identifiers'. In contrast to other key terms (for example, 'traceability', 'genetically modified organism' or 'product produced from genetically modified organisms'), for which the Regulation offers a legal definition in its articulation, the 'transformation event' is left undefined. As a matter of fact, it is barely mentioned in the text of the Regulation.

To find a formal definition of 'transformation event' we must turn to a semi-legal and transitory document, a memorandum attached to a draft of the Regulation that the Commission made public in 2001. 'A transformation event', we can read in the memorandum, 'is where a conventional organism is "transformed", through the introduction of modified DNA sequences' (European Commission, 2001: 4).[9] This is an intriguing definition. It is, in a literal sense, a *metaphysical* understanding of the 'transformation event', for it refuses to give the category a precise technical or legal content, and can ambiguously refer to either the place or the moment in time (the 'where' of an 'event') in which an organism is transformed by the introduction of transgenic DNA sequences.

There is a good reason for this ambiguity at the core of the Regulation: at the time it was articulated there was simply no concrete meaning of 'transformation event' available, let alone a set of instruments capable of detecting and recording its substantive referent. The Regulation enunciated and presumed – yet studiously failed to call attention to – an entity that did not yet exist in the world at large. This apparent paradox, of a Regulation that pronounces in its articles a system of obligations for the traceability of 'transformation events', yet avoids specifying the meaning of such an entity, leads us to the key dynamic explored in this paper: the dialectic between the enunciation of a new object of government in a legal text, and the administrative and technoscientific instruments that give it material meaning.

To emphasize and draw attention to this distinction between these two forms of governmental action – the enunciation of new entities and obligations, and their materialization in organisms and bureaucratic systems – I propose to differentiate between two kinds of regulatory activities: *delimitation* and *demarcation*. Delimitation refers to the capacity of the letter of the law to pronounce and articulate a regulatory object, while demarcation describes the administrative practices and technical instruments through which such an object is made bureaucratically unambiguous and analytically distinct. Both delimitation and demarcation are boundary-making exercises, but they are worth distinguishing, as each is characterized by different sets of tools and practices.

The distinction is borrowed from Henry McMahon, the British military officer who in the late 19th century explored and mapped much of the frontier region between India and China (and who gave his name to the 'McMahon line' separating both countries). In a lecture at the Royal Society of Arts in 1935, he described the two elements that go into drawing an effective boundary:

> 'Delimitation' I have taken to comprise the determination of a boundary line by treaty or otherwise, and its definition in written, verbal terms; 'Demarcation', to comprise the actual laying down of a boundary line on the ground, and its definition by boundary pillars or other physical means. (McMahon, 1935: 2)

McMahon points here to the problematic relationship between map-making and state-making – between drawing lines on maps and asserting sovereignty over a territory. His argument reminds one of the relationship between a map and the world described by Bruno Latour: 'The outside world is fit for an application of the map only when all its relevant features have themselves been written and marked by beacons, landmarks, boards, arrows, street names and so on' (Latour, 1987: 254). In McMahon's phrasing, demarcation describes a manipulation of the material world that is part and parcel of every act of successful map-making.[10]

Delimitation and demarcation are thus distinct but inseparable activities in the stabilization of control over space. In my extrapolation of this distinction for analysing boundary-drawing in the governance of biotechnology, delimitation refers to the enunciation of novel bio-legal entities, such as 'transformation events', in texts or documents with explicit legal force; demarcation identifies the processes through which such entities become physically embedded into the world, the administrative and technical procedures through which regulators produce a external referent to the text of the Regulation. I use the distinction to emphasize the fact that the implications of the regulatory disputes over the governance of biotechnology cannot be exclusively understood through an analysis, however exhaustive, of the legal rules and definitions enunciated in regulatory texts and negotiated in the policy process. A proper investigation must go beyond the arguments and counter-arguments articulated in documents and take into consideration the concrete *acts of demarcation* – in laboratories and elsewhere – that create new bio-legal entities on which control can be enforced. Regulatory disputes are struggles to impose new categories, to make them real in the world – or, alternatively, to make them increasingly unfeasible – and this struggle takes shape in technical and bureaucratic work, as much as in the explicit policy arena.

The following sections focus our attention on two kinds of demarcation activities: first, on some of the administrative decisions that were necessary to give each 'transformation event' a uniquely identifying name – what I will describe as an example of *bureaucratic nominalism*; and second, on the development of DNA-mapping technologies and laboratory practices necessary to turn different 'transformation events' into *analytically identifiable* objects. In both cases we are dealing with the creation of *infrastructures of referentiality* (Latour, 1999), capable of referring singular objects (names, DNA fragments) to a certified origin. It is at the intersection of these infrastructures, through mechanisms of bureaucratic and laboratory referencing, that the 'transformation event' emerges as a viable object of government, and that the EU Regulation on traceability creates a traceable referent outside its own text.

Bureaucratic Nominalism: Naming 'Transformation Events'

The term 'transformation event' is not new. It has long been used in biotechnology laboratories to identify individual instances of genetic modification. The successful genetic transformation of an organism is, to a large extent, a trial-and-error process, and in the course of modification work biotechnology laboratories generate a multitude of 'transformation events', most of which end up being discarded for a variety of reasons (for example, when the inserted transgenic DNA is not properly expressed, or when the act of modification somehow affects the development of characteristics of the resulting organism). In the case of GM plants, only a small minority of the transformations generated in a laboratory will be developed into mature organisms and turned into commercial varieties by plant breeders. The rest will remain experimental 'events', confined to a laboratory existence.

When biotechnology firms submit an 'application for consent' to European authorities for a particular instance of transformation, they do so for a specific 'event', rather than for a kind of 'organism', and the regulatory assessment applies to the specific 'event'. Yet while companies and regulators routinely use the 'transformation event' designation, their denomination practices have not been standardized. Inconsistencies abound in how 'events' are named and indexed across countries and organizations. The same 'event' can, for instance, be designated with different codes by different regulators, or a name already in use can sometimes be used again to name a newly generated 'event'. These largely unsupervised practices of denomination become especially problematic when the 'transformation event' shifts from being just a technical term (with multiple vernacular uses in different organizations) to becoming a formal EU regulatory category, henceforth expected to have a 'harmonized' meaning across nations and organizations. This suddenly transforms the frequent registration inconsistencies into codification errors.

The Regulation leaves the concrete details of the future system of 'unique identifiers' to 'developments in international fora' (European Union, 2003a: Article 8).[11] This task was tackled in a series of meetings convened by the Organisation for Economic Co-operation and Development (OECD), as part of the effort of this institution to 'harmonize' international biotechnology governance.[12] The OECD's 'working group on unique identification systems for transgenic plants' agreed, first of all, that a need existed to smooth out the 'information flow through the regulatory community', and that 'unique codes (identifiers) [should] be assigned at the level of the transformation event' – rather than, say, on the basis of new plant varieties or crops (Organisation for Economic Co-operation and Development, 2001: 11). The 'unique identifier', it was emphasized, 'should facilitate the ability to cross reference information in different databases, and improve access to and management of information by regulators and other interested stakeholders' (Organisation for Economic Co-operation and Development, 2001: 13). The fundamental problem was

thus how to produce a set of *unambiguous references* for individual 'transformation events' (Organisation for Economic Co-operation and Development, 2001: 13). In the words of one of the OECD officials who supervised these meetings:

> The need for a unique identifier arose as a technical solution to ensure that people are always referring unambiguously to the same commercialised product. This has become increasingly important with an increasing number of products and an increasing number of links (and interoperability) between various national and international databases. In other words, it is a means of ensuring that everyone is referring to the same product.[13]

What appears at first glance as a mere classification problem – the technical minutiae of denomination, resolvable through some sort of bureaucratic fiat by which governments and companies agree on a series of names, and attribute them unambiguously to a series of 'transformation events' – is, however, a substantial political task, because the particular form of 'bureaucratic nominalism' developed at the OECD meetings not only settled the issue of how to name things, but also provided answers to two previous questions: who should be entitled to generate those names, and what does a name stand for.[14] Built into these answers were judgements over the legitimate purview of government supervision and the degree of public access to biotechnological information.

A few of the issues raised at the OECD meetings will help clarify the importance of the nominalistic decisions taken at this forum. First, it was generally emphasized at the workshops, and is implicit in the statements quoted above, that the unique identification system is not merely a collection of names, but is inseparably linked to other pieces of technology – it is part of an 'information system' that consists of databases, identifying codes and rules of access – and the particular relationship between names and the rest of the information infrastructure was a highly controversial matter. To some participants in the working group, a code was 'a key attributed unambiguously to a biotech product, which could unlock information from a range of databases, as well as an harmonised unique entry point enabling information management related to that product' (Organisation for Economic Co-operation and Development, 2001: 9). In this view, the 'unique identifier' is primarily a *reference* instrument. The name of the 'transformation event' is simply a means of accessing information stored elsewhere. Others, however, thought that the unique identifier should be more than a simple reference, that it should have some *descriptive* value as well. They argued for a unique identifier that 'consists of administrative reference *and* descriptive components' (Organisation for Economic Co-operation and Development, 2001: 11). While everybody agreed that a 'short, simple, and user friendly' numeric or alphanumeric code should be generated, which idiosyncratic characteristics of the 'event', if any, should be *contained* in the code and which ones would be merely *accessible* through it were matters of dispute. Significantly, the biotechnology industry was keen to leave as much information as possible *out* of the

inscription – that is, to eliminate all its descriptive elements in favour of purely administrative-referential ones. The rationale for this was that a descriptive name 'is not necessary to establish uniqueness'. In the words of the Business and Industry Advisory Committee (the body representing the industry's viewpoints to the OECD):

> If the objective of developing the unique identifier for each transformation event is to *reference* further information that will be complete in the OECD database, any information apart from the transformation event would be superfluous. The name of the applicant is not a necessary component of the identification system if the purpose is as stated.[15]

In addition to arguing that applicant names were unnecessary, the industry also objected to including in the 'unique identifier' a description of the particular trait introduced in the organism, or of the variety and crop to which the organism belonged. Data on these features would be available in the databases (presumably under specific confidentiality guarantees), but the industry representatives argued that such data ought not to be deducible from the alphanumeric code of a particular biotechnology product. In practice, this meant that a description of the GMO would not be directly accessible to, say, the final consumer of a GM product, which was precisely what consumer groups in Europe were demanding at the time: that the description of the genetic modification present in a given consumer product should accompany (that is, be inscribed onto) the products placed on the market.

The conclusion reached by the OECD working group on the issue of descriptive versus referential names was ambivalent. It decided that the 'unique identifier' would include three different elements (separated by dashes in the final code): an identifier for the notifier (the biotechnology company submitting the application), a code designating the 'transformation event' and one digit for verification purposes.[16] For example, the identifier CGN-89564-2 could in the future be used to designate the ripening-resistant Flavr Savr tomato, developed by the firm Calgene (Organisation for Economic Co-operation and Development, 2004). While the first component identifies the applicant (CGN), the five digits of the second component identify the specific transformation event. Neither the engineered trait, nor the type of organism in question, is directly deducible from the code. Of the information eventually stored in the database, only the name of the applicant (Calgene) could be directly retrievable from the identifier, although companies would be under no obligation to use letters that corresponded to their names.

A second point of discussion throughout the OECD meetings concerned who would be entitled to give 'transformation events' their definitive names. Should the 'unique identifier' be generated by the biotechnology companies (and assigned at a time of their choosing), as had traditionally been the case, or should they be generated by regulatory authorities when approving an application for release? Initially, many participants seemed to favour a system in which government agencies,

perhaps even a central international authority, would generate the identifiers. The biotechnology industry, in contrast, argued that in order to generate standardized, unambiguous and non-repetitive codes, it was best to continue relying on the industry's record-keeping procedures. The OECD group ended up agreeing with this argument, and concluded that:

> Each applicant has their own internal mechanisms to avoid applying the same designation of the 'transformation event' to a different product .... This provides applicants with the flexibility to generate the unique identifier at the time they believe appropriate or necessary. (Organisation for Economic Co-operation and Development, 2004: 8)

Two justifications are put forward in this statement to support the right of companies to continue generating the official names of their biotechnological inventions. One is that repetitions can best be avoided by letting biotechnology firms design and manage their own identification systems and provide the names for the different 'events' generated in their laboratories. Second, that biotechnology firms are also the best placed to choose the right time to name a new 'event'.[17] The OECD-sponsored expert group thus decided that relying on the 'internal mechanisms' of biotechnology firms is the best way of ensuring coherence and consistency in the new international denomination regime.[18]

In order to address the referential nature of 'unique identifiers' and assign the authority to generate these codes, the OECD designed a 'regulatory communication debate', akin to the 'science communication regimes' described by Hilgartner (1995). As in the case of scientific databases, the matter of striking a boundary between public access and private ownership of data was paramount in the OECD-led regime. The form of bureaucratic nominalism developed by the OECD expert group tackled two questions that, as we will see below, loom large throughout the disputes over the emerging GMO traceability infrastructure: the autonomy of biotechnology firms in managing and recording their research practices, and the public transparency of their product to regulators and consumers. These two issues emerge even more clearly in the other process of demarcation: the development of laboratory instruments capable of identifying individual 'transformation events' by mapping concrete fragments of DNA in transgenic organisms.

Specifying the Physical Limits of the 'Transformation Event'

Since the introduction in 1997 of Novel Foods Regulation, which established the first obligation to label certain foods as 'GM', European authorities have tried to develop tools for the detection of GMOs in foodstuffs. This testing infra-structure is based on the meticulous validation of a series of official methodologies for identification of the pieces of foreign DNA that are present in transgenic organisms and foods. The history of GMO detection in the EU is not simply one of increasing capacity and sensitivity, but also one of subtle but significant changes in the understanding of what constitutes a 'GMO' and of how a transgenic organism should be detected.

These evolving understandings are built into a variety of identification methods, most of which are variations of the polymerase chain reaction (PCR) technique.[19] The turn to the 'transformation event' as the new unit of regulation represents a displacement in this trajectory, for it shifts the *locus* of specificity: the fragment of DNA that is targeted by the detection instruments.

Like all PCR techniques, GMO testing tools are designed to target and visualize specific fragments of transgenic DNA in plants and foods. These methods can identify an organism as 'GM' by visualizing recognizable sequences of transgenic DNA. Most of the methodologies developed over the last 10 years have been designed to target the so-called 'regulatory sequences' in transgenic organisms. These are segments of DNA – the 'promoter' and the 'terminator' – that bracket the transgene (the gene conferring, for instance, herbicide resistance to a plant), and activate and deactivate its reading. Testing for these fragments of 'regulatory' DNA is the most economical detection strategy, because a handful of promoters and terminators – most notably the cauliflower mosaic virus promoter (CaMV 35S) and the *nos* terminator – are common to most of the GMOs authorized by the EU.[20] By looking for these ubiquitous 'signatures' of genetic manipulation, a technique can 'cast the net widely', catching multiple GMOs in one single test.

For a while, this detection strategy met the fundamental objective of EU regulations, which was to maintain the fundamental distinction between 'GM' and 'non-GM' organisms – to stabilize the binary classification scheme necessary for food labelling. In this sense, the detection of a promoter or a terminator provides enough evidence that a food or organism has been modified through the insertion of transgenic material, even if the precise nature of that modification (the identity of transgene and other elements inserted into the organism) cannot be determined by the test. However, the results generated by targeting these DNA fragments are not specific enough to differentiate between different types of GMO, because the same 'promoter' or 'terminator' can be present in multiple GMOs. Nor are they specific enough to differentiate between authorized and unauthorized GMOs, since many transgenic organisms banned in the EU but authorized elsewhere contain the same 'regulatory' sequences as those that are permitted in Europe.[21] This difficulty with detecting GMOs is compounded by the introduction of traceability provisions, because the Regulation obligates market operators to differentiate GMOs 'at the level of the transformation event', and the 'event' is meant to be an entity of *higher* specificity than the organism. This means that two apparently identical GMOs, identical organisms sharing the same set of transgenic elements, could still be differentiated at the level of the 'transformation event'. The reason is the particular intersection of the temporal and spatial dimensions of genetic modification.

A 'transformation event' is constituted by the *temporal* dimension of genetic modification in the sense that a different 'transformation event' results every *time* an organism is successfully transformed by inserting

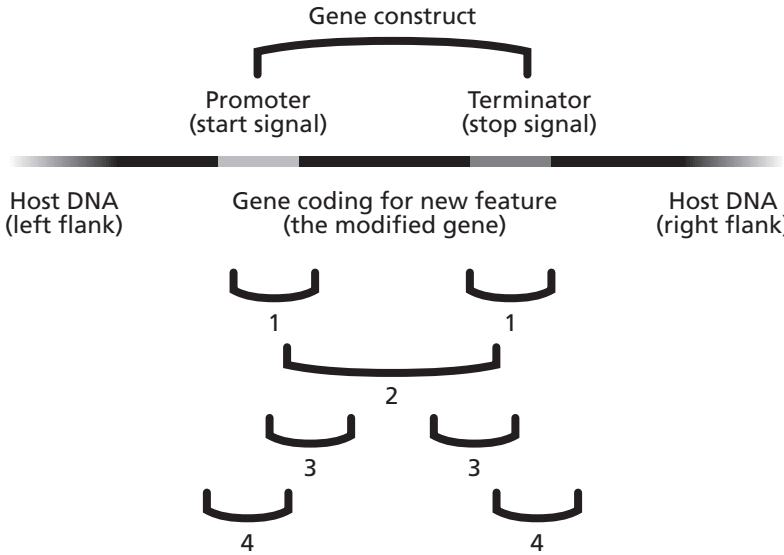
foreign DNA into it. Even when exactly the same transgenic construct – the same collection of foreign DNA elements – is incorporated into the same host organism twice, each instance of modification will generate a different 'transformation event'. This principle rests on the fundamental *spatial* dimension of genetic modification: given the degree of (im)precision of current genetic engineering techniques (such as bombardment with a 'gene gun', or insertion through the *Agrobacterium* vector, procedures that do not control where the inserted DNA will land in the host organism), it is safe to assume that each *time* an organism is transformed, the DNA will be inserted into a different *place* in the host genome. In other words, there is an extremely high likelihood that the transgenic DNA will land on a different site of the host organism's genome, because the techniques of modification are random, as far as the *locus* of insertion is concerned. This is why the ambiguous definition of the memorandum quoted in a previous section – that 'a transformation event is *where* an organism is transformed through the introduction of modified DNA sequences' – has in fact both a spatial *and* a temporal meaning, both of which are inextricably linked by the degree of precision (or, rather, lack thereof) of current molecular biological techniques. The level of specificity of the 'transformation event' must be understood as the intersection of multiple legal and technical trajectories, rather than as a quality intrinsic to the unit of regulation, or to the analytical tools capable of detecting it.[22]

Given the spatio–temporal constitution of transformation events, identification is achieved by *displacing* the target of detection, and by mapping and marking a new segment of DNA in the GMO: not the regulatory sequences, or even the whole transgenic construct, but the *junction areas*, the two regions where the transgenic DNA is 'welded' to the genome of the host organism. These sites at which the foreign DNA meets the genomic DNA are unique to each instance of genetic modification. The mixture of technical and regulatory considerations that go into drawing this conclusion is articulated by the developers of a new detection method as follows:

> [S]ometimes the same genetic elements are used in several different GMOs, of which some may be approved while others are not ... This necessitates the development of event-specific assays. Current methods of constructing GMOs lead to random integration of insert DNA into the plant genome. The junction regions will thus, *with high probability*, be unique for each particular transformation event and will occur only once per haploid genome. The junction regions therefore constitute suitable targets for event-specific methods. (Holck et al., 2002: 449, emphasis added)[23]

This is, clearly, a probabilistic judgment, based on the relative bluntness of genetic engineering techniques and the limits of detection of current testing methods. The two DNA fragments encompassing the points of intersection between transgenic and genomic DNA are 'transformation-event-specific' because of the high probability that they will be unique to each instance of genetic modification. It is in these border regions, or 'edge

FIGURE 1
Degree of specificity and locus of detection. Targets for PCR-based detection of genetic modifications, ordered after degree of specificity: 1, low specificity ... 4, transformation-event specific. Source: European Commission Research Project QLK1-1999-0131: Reliable, Standardized, Specific, Quantitative Detection of Genetically Modified Foods. Reproduced with kind permission from Arne Holst-Jensen.



fragments', where the *locus* of 'transformation event' specificity can be found. As the director of one of the European GMO testing network puts it: 'the only unique signature of a transformation event (within the limitations of present day technology) is the junction at the integration locus between the recipient genome and the inserted DNA' (Holst-Jensen et al., 2003: 987).

The 'transformation event' is not, in this sense, a 'transgenic' entity, because the segment of DNA that serves to characterize it straddles the juncture between 'GM' and 'non-GM' DNA, and includes both 'transgenic' and 'genomic' sequences. The following graphic representation in Figure 1, borrowed from one of the European GMO testing initiatives, expresses schematically the changes in the target of detection and the corresponding shift in the *locus* of specificity.

The change in detection targets is reflected in a change of terminology. Methods targeting 'regulatory' sequences, which until recently were deemed highly specific, are now renamed 'screening methods', and proper 'identification methods' are now those with 'event-specific' precision. As the coordinator of one of the EU projects on GMO detection points out, 'although screening may be very useful for industrial bodies to determine whether products are likely to be GM-free or not, as well as to estimate the degree of GM contamination, results of screening are less valid from a legal point of view than results of event-specific analysis'.[24]

This new understanding – that every time a genetic transformation occurs a different 'event' arises, due to the unique location of transgenic DNA in the resulting organisms, and that the areas straddling the boundary between transgenic construct and genome are thus the locus of specificity – is fundamental, but does not offer precise guidance as to how to make an 'event' analytically observable or how to anchor the definition of 'transformation event' in the material elements of the GMO. It is one thing to assume that the 'event' generated in each instance of genetic modification will be a *different* entity, and another that it will be a *distinct* object: the assumed difference can be made analytically visible through a detection technique. This is the challenge for the scientists and technicians working on the development of detection methods, and the solution they have adopted points once again to the centrality of spatial demarcation schemes for materializing this new object of governance.

New Testing Techniques and the Spatialization of Detection Work

With the orientation to the borders of the transgenic insert as the place where the specificity of the individual 'event' can be found, research teams across Europe have embarked on the development of techniques capable of visualizing the junction regions. The new detection instruments continue to be based on the PCR, but researchers have introduced important innovations and face new challenges, the most serious of which is the lack of foreknowledge about these new areas of interest.

The use of PCR techniques requires some previous knowledge of the target sequences. This is because PCR serves to visualize known fragments of DNA. Researchers must cut the DNA of the organism being analysed at specific sites with the use of restriction enzymes, and they have to design primers spanning the area they aim to find. Designing primers requires knowledge of at least part of the DNA sequence with which they are expected to hybridize, and a particular difficulty with mapping the junction areas is that the sequences of DNA that flank the transgenic insert are rarely known. Unlike promoters and terminators, which are well known and already characterized, these regions in the organism's genome are usually terra incognita, because biotechnology firms consider this information proprietary and confidential and have traditionally resisted calls to provide regulators and detection laboratories with detailed descriptions of their GMOs.

Such limitations on access to molecular information have handicapped the *validation* of 'event-specific' methodologies, as we shall see below, but variations of PCR-based methodologies can allow researchers to produce a provisional characterization of these junction areas, even in the absence of precise knowledge of the target sequence. One of these variations of PCR is known as 'anchored PCR'. With this technique, researchers are able to use the edge of the transgenic DNA (usually a promoter or a terminator) to 'anchor' the reaction, and then 'walk' from this known area of the junction

towards the genome of the host organism.[25] The utility of this form of 'genome walking' lies, as a researcher points out, in the way it can be carried out 'independently of information supplied by companies' (De Loose et al., 2000: 46).

It is necessary to emphasize the extent to which these new techniques for 'event-specific' detection, like other PCR applications, are premised on an extensive regimentation of the laboratory space. A glance through the manual of PCR techniques used by the members of the European Network of GMO Laboratories (ENGL) will serve to illustrate the relevance of strategies of compartmentalization and spatial localization in the routine deployment of these detection tools (Querci et al., 2004).[26] The manual recommends that laboratories should carry out different stages of the detection process in physically separated working areas: a 'sample preparation area' in which all the steps prior to actual amplification are performed, a 'PCR set-up room' for the preparation of the reaction and a 'post-PCR area' where the targeted DNA fragment is amplified. The facilities should be arranged in a 'one-way flow system', to make sure that no material, samples or equipment ever moves from the post-PCR area into the PCR locations, thereby contaminating the reaction. Not only must different types of activities be strictly separated and contained in different rooms, but every piece of equipment – from coats and gloves to reagents or machinery – must be immobilized within each separate, enclosed unit of the laboratory.

A second example of the fundamental role that strategies of separation and purification play in the routine work of GMO detection concerns the creation of biometrological chains – the provision, multiplication and circulation of certified reference materials for DNA detection. Any test result is only provisional until it can be referred to certified reference materials with which it can be compared. This referentiality of the materials used in individual tests is itself a matter of traceability – but a traceability that is internal to a laboratory's practices and materials.[27] In the traceability system envisioned in the Regulation, every 'transformation event' named in a commercial transaction or detected in a laboratory would ultimately have a verifiable connection to a biological reference sample of that particular 'event'. The reference sample is provided by its developer and stored in the European Commission's Institute for Reference Materials and Measurements (IRMM, located in Geel, Belgium).

Two elements are necessary to create a verifiable biometrological chain: a certified raw material provided by the developer of the transgenic organism, and a proper 'chain of custody' that safeguards the integrity of those raw materials as they are reproduced and distributed from one laboratory to another. The limited availability of original samples poses problems, discussed below, concerning the confidentiality of molecular information and the reluctance of biotechnology firms to share data and materials.

This task involves, once again, a careful compartmentalization of the spaces in which GMO testing is carried out. The laboratory protocols that

the IRMM produces cover an array of manufacturing activities – grinding, sieving, mixing, storage precautions and so on – necessary for preserving the referentiality of materials. The following quote illustrates the laboriousness of the task of deriving certified reference materials from the biological samples originally provided by biotechnology firms. It is drawn from the IRMM 'Manual of Custody' for samples of the transgenic soyabean 40-3-2, a variety developed by Monsanto that, as we will see below, has played a prominent role in the history of EU traceability. The first part of the quote explains the production of the GM and non-GM soyabean powder (generated separately and later mixed in different proportions of GM content to permit the quantification of transgenic material in a food product). The second part describes an even more mundane practice: the bottling of the resulting mixes in glass vials (which are then sent to national reference laboratories or sold to private laboratories).

> During the production of the GMO and non-GMO powdery base materials each material was treated separately. Cross contamination and contamination with foreign DNA were avoided with the help of glove box systems, clean cells, disposable lab clothing and treatment of all contact surfaces prior to exposure to the base materials with a DNA destroying solution. The kernels used for production were rinsed in demineralised water and after draining dried under vacuum at 30°C for 25 hours. The dried starting materials were then ground using a fine impact mill (track mill). The ground materials were collected in plastic bags and placed in polyethylene containers.
>
> . . .
>
> The dry-mixed products were bottled in well-cleaned 10-ml brown glass vials using an automatic sampling device. The first 30 filled bottles of each batch were discarded as an additional measure against carry over contamination. Bottles were manually closed with rubber stoppers. Before final closure of the vials they were placed in the freeze-dryer, filled with argon and closed using the hydraulically moveable device of the freeze-dryer. All vials were sealed with aluminum caps to prevent opening of rubber stoppers during storage and transport. (Trapmann et al., 2002)

We saw how the routine application of PCR techniques involves a series of spatial isolations and separations, which affect the layout of detection facilities and the movement of tools and personnel within the boundaries of the laboratory. The production of the biological materials used in those tests also depends on strategies of separation, purification and spatial regimentation, inside the reference laboratories and along the networks connecting them with other analytical facilities. While, as we will soon see, it is always critical to obtain the necessary raw materials from the developers of new 'events', the problem of referencing laboratory materials to a standard biological source does not end with the provision of samples by the developers. These samples must still be grown, reproduced, combined in the adequate proportion, verified through other detection techniques, distributed in proper containers and stored under suitable conditions to constitute the kind of 'circulating reference' described by science studies

(Latour, 1999).[28] An analysis of the traceability regime enunciated in the Regulation must thus extend beyond the new regulatory object – the 'transformation event' – and include the multiple 'chains of custody' that connect the private laboratories in which 'transformation events' are generated, the control laboratories where reference materials are produced and the analytical laboratories where those materials are used in the detection of individual 'events'. There is a core of routine manual activities and physical arrangements that underpins the traceability of GMOs.

We will not dwell on this point here, since the centrality of separation and purification practices in laboratory work has been analysed in detail elsewhere.[29] But it is important to keep in mind the extent to which what I have describe here as a 'PCR technique' or a 'GMO detection methodology' is not a packaged, self-enclosed tool, but is constituted by a multitude of spatial demarcations and isolations along the networks of materials, instruments and personnel involved in the detection infrastructure. The ability to trace the highly mobile GMOs as they are transformed throughout the food chain depends on fixing a number of key elements in particular places, and on drawing clear boundaries – inside the genome of the GMO, where a specific fragment of DNA conferring specificity must be demarcated and mapped, but also inside the laboratories where routine GMO detection work is conducted.

The Moral Economy of Biological Materials

As indicated earlier, the 'chain of custody' of GMO detection must start with certified original samples of the 'transformation event' in question, which can only be provided by the developer (often a biotechnology company) that generated the original 'event' in question. Also noted was that biotechnology firms generally have been reticent about sharing proprietary molecular information or biological materials, and this 'moral economy' of biological data has handicapped the development of official 'event-specific' testing methods. I speak of a 'moral economy' because the exchange of biological materials between firms and regulators has long been governed, not by a set of formal rules backed with legal force, but by a series of 'best practice' considerations and sufficiently ambiguous 'recommendations'.[30] From the first phase of GMO commercialization, through the passing of the traceability Regulation, this moral economy gave biotechnology firms a great deal of leeway for deciding which information to share with regulatory authorities, and which to define and protect as private and confidential.[31] The ambiguity and lack of legal precision generated ample variations in the nature, extent and specificity of the data accessible to regulators, even when all the literal demands of the law were met.[32]

Even in the absence of accurate genetic maps of the new organisms, unknown DNA can be tentatively mapped with PCR techniques, but the analytical challenge for detection laboratories is to *validate* a particular

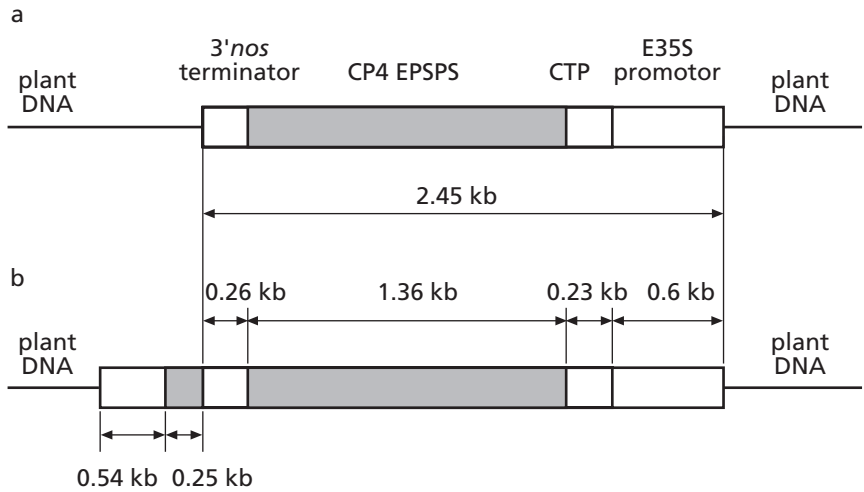
detection methodology. Validation – the ability to turn a laboratory technique into an officially certified method – relies on the availability of original reference materials or on access to accurate sequence data.[33] European regulators have often emphasized the important of official validation: 'We are extremely critical when results are communicated that were not produced with a validated method', the Head of GMO detection at the European Commission argues. 'Even if it is done in a good laboratory', the same European official points out, 'the issue is the method', and for the method to become *official*, its results need to be verified with the help of certified reference materials and accurate sequence data.[34] The validity of detection methodologies – like the specificity of the entities they aim to detect – is thus a techno-legal matter, shaped by the moral economy of biological materials and affecting the robustness of detection tools. The regulatory goal of making GMOs traceable at the level of the 'transformation event' clashes with the implicit rules of exchange between corporate and regulatory laboratories (or, rather, the implicit acceptance of a lack of exchange between them). As a document from the IRMM argues:

> The production of any GMO certified reference material in the future will depend on the provision of suitable raw materials and on the clarification of the legal implications related to its distribution. So far, the production of new materials and the replacement of exhausted batches were delayed or made impossible by the non-availability of raw materials.[35]

This precarious balance between the ability of biotechnology firms to protect the confidential nature of their inventions and the regulatory need for valid detection methods was altered in 2001, while the traceability Regulation was being drafted, with a small, and seemingly accidental discovery in a Belgian laboratory. A group of Belgian researchers trying to develop a 'transformation-event-specific' method for the detection of Monsanto's transgenic soyabean 40-3-2 came across a region of previously unknown DNA – about 500 base pairs next to the terminator limit of the transgenic insert (Windels et al., 2001). Following the injunction to look for the specificity of the 'event' in the junction area straddling the edge of transgenic insert and the flanking plant DNA, the Belgian team had discovered there a fragment of 'mystery DNA' (as a *New York Times* reporter called it), which did not correspond to the map of the GMO that Monsanto had provided in their regulatory submission, or to any known fragment of soyabean DNA available in bioinformatics databases.[36] Figure 2 shows a comparison of the characterization of the GMO that Monsanto had provided to regulators (described by Padgette et al., 1995) with the new map produced in the Belgian laboratory.

This discovery generated a great deal of controversy and public outcry, and prompted calls for an urgent reassessment (and possibly a ban) of the 40-3-2 soyabean 'event'. The argument of the critics was that the 'transformation event' currently on the market was not the one that had received regulatory approval, since the former contained a fragment of DNA, the 500 base pairs of 'mystery DNA', not included in the technical dossier

FIGURE 2
A comparison between the insert structure as reported by (a) Padgette et al. (1995) in Monsanto's technical dossier and (b) the structure of the insert deduced by Windels et al. (2001). Reproduced with kind permission of Marc De Loose (Centre for Agricultural Research, Merelbeke, Belgium), and Springer Science and Business Media.



provided by Monsanto.[37] Beyond the implications for the future regulatory status of this transgenic soyabean, the discovery of the DNA seemed to prove that biotechnology companies could not be trusted as far as the description of their own biotechnological products was concerned, and that regulators should be in a position to verify the claims of biotechnology firms with their own, officially validated detection methods, methods capable of accurately mapping the 'junction areas'. This was the key regulatory conclusion drawn by the Belgian researchers themselves:

> In our opinion, these results indicate that characterisation of junction fragments can offer important information for the accurate description of the insert structure of a transgenic line. Characterisation of junction fragments can be used to check the accuracy of technical dossiers on the one hand and on the other hand this method can be used to complete already existing information. . . . In the future, problems concerning the inaccurate description of transgene events can be avoided through a detailed characterisation of the transgene plant DNA junctions. Therefore, we welcome the idea that a detailed characterisation of the transgene plant DNA junction and of the plant target locus should be included in the technical dossier that is submitted to the competent authorities. (Windels et al., 2001)

To be capable of verifying the accuracy of the information provided by biotechnology companies in their 'notifications for consent', regulators must have the tools necessary to map the junction fragments, and this requires greater access to sequence information and biological materials from the biotechnology firms.

The highly publicized and controversial discovery of Monsanto's 'mystery DNA' occurred at the time when some of the technical aspects of the new Regulation were being drafted, and it left a mark on the policy-making process. The conflict between the desire to establish an effective traceability infrastructure and the private appropriation of biological information and materials is still unresolved, but a number of significant changes in the regulatory regime suggest that the moral economy of biotechnological information is changing, and giving way to a regime of greater legal clarification and access to the materials necessary for GMO detection. Perhaps the most visible sign of this change is the inclusion, against the will of the European Commission (and of some EU Member States), of an article (30.5) in the Regulation on GM food and feed (1829/2003) stating that 'the use of the detection methods and the reproduction of the reference materials ... for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights' (European Union, 2003b: Article 30.5).

This provision is unusually unambiguous for a Regulation of this kind, and has been interpreted as such by researchers involved in GMO detection.[38] 'To me', argues a leading participant in the European Network of GMO Laboratories, 'the text is quite clear: the method provided to the CRL [control laboratory] for validation cannot be kept confidential and cannot be the subject of property rights, in other words: everybody (control authorities, importers, retailers etc.) should be in a position to test'.[39] Thus, a system of exchange in which access to 'confidential information' was extensively restricted is being replaced, at least in some important aspects, by a set of explicit legal rules enforcing exchange.[40]

Obviously, these changes do not institute a new regime of complete disclosure. Molecular information will still be confidential beyond the network of reference laboratories, and biological materials will only be distributed under restrictive conditions. Moreover, and more importantly, the Regulation does not empower EU authorities to collect information about 'transformation events' that have not been submitted for regulatory approval in the EU, which means that regulators cannot validate detection methods for 'events' that are unauthorized in the EU, but have been released elsewhere and are thus likely to enter the EU surreptitiously. This is a critical limitation, and one highlighted very recently by the discovery, in March 2005, that thousands of tonnes of an unauthorized transgenic corn 'event', Syngenta's Bt10, had been imported into Europe illegally since at least 2001. The Bt10 'event' contains an antibiotic-resistant marker gene and is not authorized for release in Europe; but it is very similar to another 'event', Syngenta's Bt11 transgenic corn, which has received authorization from EU authorities. While an official method of detection is available for Bt11, no reference materials or sequence information have been lodged in the official registrars for Bt10, which makes it untraceable in the food chain. When news of the illegal importation of Bt10 broke out, Syngenta was under no legal obligation to submit specific

details about its product and was able to ignore for a while repeated requests from EU authorities to provide a valid testing method.[41] Faced with this unwillingness to cooperate, EU authorities were forced to approve a series of 'emergency measures' in April 2005, including the blockade of any US shipment of corn products that was not accompanied by an analytical report 'proving that the products are not contaminated with the genetically modified maize Bt10' (European Commission, 2005). The measures were welcomed by non-governmental organizations (NGOs) and defenders of the European regulatory regime as an example of the kinds of steps that authorities should take when their ability to trace every GMO entering the EU is compromised, and also of the price that international handlers of agricultural commodities will have to pay when the traceability system is disrupted. 'Clear identification', an NGO declared, 'including documents that state that a shipment contains GMOs, and full information about its identity, including common, scientific and commercial names, transformation event codes and any unique identifier codes, means that the burden to segregate and test GMOs will fall on the exporter, not importing countries, and that any unapproved GMO would more likely be detected before export.'[42]

The Bt10 affair is a reminder, and probably not the last one, of the limits and difficulties that still face the GMO traceability infrastructure. It highlights the fact that the jurisdiction of the Regulation does not completely overlap with that of massive international flows of agricultural commodities and food products, and the resulting battle to shape the international infrastructure of agri-food trade, and to externalize the duties and costs of traceability to grain exporters, is still unresolved. But, despite this incompleteness of traceability, European regulators can now assert a right to the information they require for the identification of all GMOs approved for release in the EU, and intellectual property rights cannot serve to block access to this information. The new sense of legal clarity, although restricted to the 'events' upon which the EU has jurisdiction, is perhaps the most important change in this area of biotechnology governance. The era when a set of carefully ambivalent rules allowed firms to protect biological information and materials under confidentiality clauses is coming to an end.

Discussion: Referential Entities

In his description of the powers that the state brings to bear against pestilence, Michael Foucault wrote that, 'against the plague, which is a mixture, discipline brings into play its power, which is one of analysis' (Foucault, 1977: 197). The present paper has described the creation of a new 'power of analysis', one capable of drawing distinctions between GMOs on the basis of the 'transformation event' from which they are developed, and of making GMOs traceable in their movement through the marketplace.

This power of analysis is indeed a response to a plague of sorts. Traceability, as a general principle of food law, has become an increasingly typical response to the modern plagues provoked by dangerous 'mixtures', and by the mobility of products that travel freely through intricate and largely unsupervised production networks (Torny, 1998). In Europe, the first time traceability appears as a legally mandated obligation is with the reorganization of the blood donor system in France in the early 1990s, following the scandal of the HIV-contamination blood banks.[43] Similarly, the first example of an EU-wide system of food traceability is not the GMO scheme described in this paper, but the infrastructure created since the late 1990s to track cattle and beef products in the aftermath of the BSE, or 'mad cow disease' crisis. In all of these cases, traceability represents an effort to control the effects of plagues and to make opaque networks of production governable, by tracing the trajectories of the entities that travel along them.

In Foucault's analysis, the disciplinary response to the plague was characterized by a series of compartmentalizations, designed to subject individuals and populations to absolute spatial regimentation (quarantine being the most characteristic measure in this regard).[44] At first sight, it would appear that traceability constitutes a radically different form of control, one in which mobility is not restrained, but rather accompanied by coextensive record-keeping apparatuses. Moving entities are followed, rather than fixed in place, and oversight is achieved by forcing them to leave recordable trails. And yet, as we have seen, spatial regimentation and processes of location and fixation are central to the effort to turn GMOs into traceable entities. We saw their relevance in the demarcation and mapping of particular regions of the genome of the organism deemed to be the *locus* of a specific 'transformation event': where the singular 'transformation event' can be located. I also noted the importance of processes of regimentation throughout the multitude of routine practices of separation and isolation that accompany the production of reference biological materials and the application of PCR techniques in the laboratory. In a number of important ways, the ability to follow GMOs 'throughout the production and distribution chains' is premised on the capacity to fix things in specific places, to draw visible limits in organism and along the networks through which they move.

It should be clear by now that the acts of bureaucratic and technical demarcation described in this paper have a constitutive role in the creation of 'transformation events' as objects of governance. The goal of these processes is not simply to bring previously existing, yet unruly objects under regulatory control, but to constitute a new biolegal entity and make it real in the world of biological organisms and food production. As we saw, the 'transformation event' had a marginal existence in the text of the Regulation itself (appearing explicitly only in an appendix to the Commission's proposal, and in a rather metaphysical way). And yet, it is the fundamental unit of classification on which the system revolves, replacing the 'organism' as the effective currency of the regulatory apparatus. I

argued that the work of materializing this entity took place through administrative denomination practices and with the development and validation of DNA-testing technologies. These two elements – 'bureacratic nominalism' and the biometrology of 'transformation-event-specific' detection methods – carry with them subtle but significant changes in the 'moral economy' of molecular information. The ability of private biotechnology companies to protect the privacy of their products and practices has been restricted.

Bureaucratic nominalism and biometrology can be seen as intertwined infrastructures of refentiality. They are intended to allow actors to refer to the same thing when they name a 'transformation event' and to give this name a material basis in the DNA of an organism. The traceability of GMOs thus depends on these other traceabilities, internal to the infrastructure of record-keeping in administrative bureaucracies, and to the practices and materials of laboratory testing. The 'transformation event' does not precede the establishment of these infrastructures of referentiality, it emerges at their intersection.

There is little point in trying to clinically separate the legal, administrative and technological elements that go into the making and tracing of the 'transformation event'. These different elements appear inextricably linked in and through the components of the infrastructure I have analysed. A particular PCR application for 'event-specific' DNA detection incorporates in its design legal, technical and regulatory constraints. The choice of the target of analysis – the junction areas – is a response to the regulatory demand to identify GMOs 'at the level of the transformation event', but also a function of the fact that the imprecision of modification techniques allows one to confidently assume that these points will be unique to each instance of transformation. Similarly, the legal status of private DNA samples and sequence information is part and parcel of the 'technical' capacity of GMO detection laboratories, as we saw in the discussion of the evolving 'moral economy', and so are the internal administrative practices that ensure the accurate replication of the reference materials used in particular PCR applications. It is only through the combination of all these elements – a legally mandated but legally undefined level of classification, and a constellation of technologies of administrative categorization, molecular transformation, analytical testing and laboratory intendancy – that the traceable GMO becomes a material entity.

However, I have found it useful to maintain a distinction between *delimitation* and *demarcation* for trying to understand the interplay between processes of regulatory enunciation, and the materialization of the entities upon which the legal text is premised. In our case, the text of the traceability Regulation, and the policy-making process of which it is the result, served to delimitate a new regulatory category, and to articulate a series of obligations regarding the identification and registration of 'transformation events'. Yet to understand how this category is then inscribed into the world at large, we need to turn to acts of demarcation that are not

described in the text of the Regulation itself, but were essential to making GMO traceable.

The creation of traceable GMOs is indeed a matter of drawing and marking limits. Delimitation, or 'determination of a boundary line', to use McMahon's phrase, occurs in the legal articulation of a new biolegal entity. But demarcation, the 'actual laying down of a boundary line', takes place in the DNA of biotechnological organisms, where a new *locus* of specificity is located and made visible. As in the processes of boundary-making that create stable political entities, delimitation and demarcation are distinct but inseparable elements in the governance of biotechnology. As we have seen, it is the combination of both forms of intervention that makes GMOs traceable. This mixture of legal, technical and administrative work creates the external referent for the new Regulation, and adds a new object, the 'transformation event', to our catalogue of bio-legal entities.

Notes

The author gratefully acknowledges the support of the Economic and Social Research Council. Trevor Pinch, Stephen Hilgartner, Matthew Evangelista, Michael Lynch, Michael Power, Chi-ming Yang, Joan O'Mahony and three anonymous reviewers provided excellent comments. The author also wishes to thank the participants at the workshop 'Sensing the Unsensed: Environment, Technological Risk and the Limits of the Senses' (Lancaster University, October 2004), where an early version of this paper was presented.

1. The controversies that accompanied the controlled release of GMOs in laboratories are described in detail in Krimsky (1984). For other studies of the regulatory disputes that characterized the period in which GMOs were confined to bounded spaces, see Wright (1994). Limoges et al. (1993) offer an analysis of the evolving complexion of the public debate over biotechnology, as transgenic organisms move from the laboratory to the field trial, and from there to the environment at large.
2. This is not particularly surprising, if we keep in mind that, for instance, the very term 'gene' has undergone an almost continuous process of redefinition (Rheinberger et al., 2004). The list of transformation techniques that 'result in' proper 'genetic modification' (as opposed to those, such as for instance in vitro fertilization or 'natural' conjugation, that do not) is included in the annexes of EU Regulations. See for instance European Union (2001), Annex I A. This framework Regulation also offers an official definition of a 'GMO': 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination' (European Union, 2001: Article 2).
3. Throughout the paper, the term 'Regulation' will refer to this piece of legislation.
4. These more technical uses of traceability are the ones that EU authorities emphasize in response to the challenges brought up against the new labelling and traceability rules at the World Trade Organization (WTO). See for instance the Response from the European Commission to Comments Submitted by WTO Members under G/TBT/N/EEC/7 and/or G/SPS/N/EEC/150, World Trade Organization, Committee on Sanitary and Phytosanitary Measures and Committee on Technical Barriers to Trade (26 July 2002). Available at <http://europa.eu.int/comm/food/fs/gmo/resp_ec_com182_en.pdf> (accessed 27 April 2005).
5. The logic that 'choice', and information about the trajectory of food products throughout the production system, engenders trust in regulatory institutions and confidence in the marketplace has led to the generalization of traceability as a 'general principle' of European Food Law. Traceability is thus expected to become a general property of all production networks, not simply of those involving GMOs. As established by The European Union General Food Law Regulation (178/2002), 'the

traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution' (Article 18).

6. As Samuel Bodman, former US Deputy Commerce Secretary, put it during a visit to Brussels, 'we believe that the current restrictions will call for a significant readjustment of the entire food distribution network of the United States. The idea of traceability, for example, of particular products is simply not something that we in the United States undertake' ('US dismisses potential EU relaxation of GM ban', *Agence France Press* [28 October 2002]). North American trade groups have repeatedly urged the US Administration to file a WTO case against the new traceability provisions. Dwain Ford, president of the American Soybean Association, declared in testimony before the US House Committee on Agriculture that 'the United States and other exporting countries must not accept the imposition of one set of discriminatory and non-science-based measures by the EU as a condition for ending another non-science-based decision making process' (26 March 2003). Available at <www.iasoybeans.com/whatnew/relatednewsarchive/asa051503.html>, accessed 27 April 2005. Leon Corzine, vice president of the National Corn Growers Association similarly argued that:

> these regulations have nothing to do with human health or environmental safety, rather, they are an extension of the trade barriers we have been dealing with for a long time. They simply discriminate against U.S. producers by targeting our products with severe scrutiny, despite the EU's inability to identify any science-based risks with biotechnology or U.S. commodities. ('NCGA Opposes EU Labeling and Traceability Rules', 12 January 2003)

   The possibility of testing grain shipments upon their arrival in the EU introduces important uncertainties into the customary handling operations of large commodity traders, as was emphasized in one of the letters that industry groups sent the successive Secretaries of the US Department of Agriculture to protest against the European rules:

> Destination testing has not been an accepted practice in the bulk commodity trade because of the high costs associated with rejection of a shipment. Even outside the area of biotechnology, re-sampling and testing vessels poses too great a commercial risk for the trade to accept, and testing in the absence of any identified risk merely introduces unnecessary costs. (Letter of Agri-Food Trade Groups to US Department of Agriculture Secretary Ann Veneman, May 2001)

7. The decision was announced at the Council of Environment Ministers of 25 June 1999. Five States (France, Denmark, Greece, Italy and Luxembourg) signed the statement. Declaration at the 2194 Council Meeting (Environment), Luxembourg, 24/25 June 1999.
8. The system encompasses GMOs and 'products produced from GMOs'. The latter will not necessarily be organisms. In fact, they may not contain any detectable traces of their material origin. A bottle of soyabean oil, for instance, ought to be referable to the particular variety of transgenic soyabean from which it was 'derived', despite the fact that highly refined oil will probably contain no detectable traces of modified DNA. Obviously, given the impossibility of verifying the presence of transgenic material through DNA testing in products that contain no detectable trace of their material origin, the identity of the GMO in question will only be certifiable through a paper trail that connects the multitude of objects that were 'produced from' the GMO (for example, soyabeans, soyabean meal, soya derivatives, soyabean oil and so on).
9. The memorandum is only available in English, but the term 'transformation event' has been translated into several European languages: 'l'événement de transformation' in French, 'Transformationsereigniss' in German or 'evento di transformazione' in Italian.
10. In *Seeing Like A State*, James Scott describes a comparable process: examples of 'high-modernist' endeavours to make landscapes legible, and to make realities on the ground amenable to the systematic grid of maps. See Scott (1999).

11. All the Regulation does is to define the 'unique identifier' as 'a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorized transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO' (Article 3.4).
12. The OECD has played an important role, often behind the scenes, in the international standardization of biotechnology regulations. It was through the OECD that the first definition of 'substantial equivalence' was developed – a principle that specified the conditions under which GMOs could be considered identical, for all practical purposes, with their 'conventional' counterparts, and which served to legitimize the treatment of GMOs as similar enough to traditional organisms to warrant no special regulatory attention. This indifference to the distinction between 'GM' and 'conventional' or 'natural' organisms is precisely what the EU traceability Regulation tries to deny. The primary aim of the regulation is to guarantee the ability to *differentiate* between GMOs and non-GM organisms. And yet the OECD and its harmonization programme have also played an important role in materializing traceability, by leading the formulation of principles and standards by which events are named.
13. Personal communication, 3 February 2004.
14. The politics of categorization and classification discussed below are explored at length in Bowker & Star (2000).
15. Business and Industry Advisory Committee, 'In Response' (26 October 2001, emphasis added).
16. This final digit is calculated by transforming the alphabetic characters into numerical equivalents and then adding all the digits into a single number.
17. Provided the identifier is available at the time of the application for first commercial approval. Organisation for Economic Co-operation and Development, 'Guidance', Article 2.
18. The work of the OECD harmonization committee culminated in a series of recommendations, issued in 2002. These were fully and formally adopted by the EU in January 2004. See, respectively, Organisation for Economic Co-operation and Development, 'Guidance for the Designation of a Unique Identifier for Transgenic Plants', Document ENV/JM/MONO(2002)7, 19 February 2002, adopted as European Commission's Regulation (EC) No. 65/2004. Official Journal of the European Union L10, 16 January 2004. Eventually this system of unambiguous identification should become part of the Biosafety Clearing-House envisioned in the Cartagena Protocol on Biodiversity.
19. For a history of this critical technique in molecular biology, see Rabinow (1996). For a detailed analysis of the process (and limits) of standardization in the situated use of PCR, see Jordan & Lynch (1993, 1998).
20. The first validated method for the detection of GMOs, developed in Switzerland in 1997, was based on the identification of both the 35S promoter and the *nos* terminator. See Pietsch et al. (1997). See also European Commission, DG Joint Research Centre Institute for Health and Consumer Protection Food Products and Consumer Goods Unit, *Validation of Analytical Methods for the Identification and Determination of Genetically Modified Organisms (GMOs) in Food and Food Ingredients*, Ispra, 15 June 2000.
21. In fact, the same transgenic construct – an identical combination of foreign DNA elements – can be common to more than one type of GMO. Sometimes identical 'gene cassettes' are used to generate different GMOs, a situation that will likely become more and more frequent in the future, as the number and typologies of transgenic organisms expand. For instance, two different varieties of insect-resistant corn – Monsanto's 809 and 810 varieties – contain the same transgenic construct (consisting of a copy of the *cry1Ab* gene, which produces the insecticidal protein, flanked by a CaMV 35S promoter and a *nos* terminator), but have different regulatory status: Mon810 has received regulatory approval in the EU, while Mon 809 was never submitted for authorization and is therefore illegal in Europe. See Holst-Jensen et al. (2003): 987.
22. Cambrosio & Keating (1995: 112) describe similar networks, from which 'specificity' emerges, in their study of hybridoma technology.

23. This understanding of where to find the specificity of the 'transformation event' is then translated into regulatory protocols and 'best practice' guidelines from regulatory authorities. The British Advisory Committee on Releases into the Environment (ACRE), the body in charge of reviewing the applications for new transgenic organism, recommends that applications for the authorization of new transgenic organism include the molecular characterization of the junction areas. 'The point of insertion of novel DNA generates two junctions with the host DNA. Effectively, these will be unique for each successful transformation event. Increasingly, regulators will need to differentiate between specific transgenic events that result in the harbouring of the same trait will exploit this information' (Advisory Committee on Releases into the Environment, 2001: paragraphs 2.7 and 4.11).
24. Arne Holst-Jensen, personal communication (15 April 2003).
25. The techniques involve a series of steps. First, DNA is cut into 'restriction fragments' that straddle the boundary line between insert and host organism. Then adaptors are ligated to the ends of the fragment. The ends of the fragment, located in the insert area (the transgenic component), serve to 'anchor' the reaction. The other primer hybridizes with the adaptor joined to the unknown DNA. The primers thus bracket a segment of DNA that is part-transgenic and part-genomic – and which can then be amplified and visualized through gel electrophoresis.
26. The European Commission's Institute for Health and Consumer Protection (IHCP) hosts the Central Reference Laboratory for GMO detection, and coordinates the European Network of GMO Laboratories.
27. For metrology in other areas see O'Connell (1993). See also Sims (2005).
28. The continuous documentation and description of this process is itself part of the certification process. Documents describing the production of reference materials, like the certificate quoted above, are part of the paper trail accompanying any reference material. They are carefully placed in a field of documentary activities, and this placement carries with it legal implications that are carefully modulated in the text itself. For instance, the reference material certificate for soyabean 40-3-2 quoted above includes a legal notice stating that:

    > neither the Commission of the European Communities nor any person acting on their behalf make any warranty or representation, expressed or implied, that the use of any information, material, apparatus, method or process disclosed in this document does not infringe privately owned rights; or assumes any liability with respect to the use of, or for damages resulting from the use of any information, material, apparatus, methods or process disclosed in this document. (Trapmann et al., 2002)

29. See, for instance, Mody (2001).
30. I draw here on the work of Robert Kohler (1994: 11–13), who employs the term 'moral economy' to designate the rules governing the exchange of experimental tools and materials between the laboratories working with the *Drosophila* fly.
31. The Directive governing the release of GMOs (Directive 2001/18/EC) establishes in its annexes the data that biotechnology companies need to submit, including 'where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny .... Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified' (Directive 2001/18/EC, Annex IV). Note that the provisions of this annex merely oblige companies to identify that information they are unwilling to make available to regulators 'for confidentiality reasons'.
32. A company could, for instance, provide a plasmid map and a succinct verbal description of the DNA that has been incorporated into a GMO, but very rarely would it submit a full characterization of the DNA that flanks the insert. Moreover, as we noted, no detailed information is submitted on 'transformation events' that are not subjected to regulatory review in the EU, which means that European regulators often

have no data on GMOs that are commercialized outside Europe, even though it is likely that they will enter the EU in transnational grain shipments and through other transnational exchanges, as has been the case several times.

33. A laboratory that develops a new PCR application for the characterization of a 'transformation event' without such help has two alternatives. It can submit the results of its research to the biotechnology firm that generated the 'transformation event', and request confirmation of the newly developed junction maps. This solution depends, as a leading researcher argues, on 'collaboration by companies that hitherto have been restrictive in their distribution of materials and sequence data, and could lead to restrictions or delays in publication'. The other alternative – to validate the results with the available materials or with cloned DNA fragments – sets the official detection methodologies on very shaky ground, for the materials used are not of certified origin to begin with. See Holst-Jensen et al. (2003).
34. Interview, Ispra (Italy), 6 June 2001. In this regard, an important difference exists in the approach to the *officialization* of GMO detection methods in the EU and the USA. US regulators (in our case, the US Department of Agriculture's [USDA] Grain Inspection, Packers and Stockyards Administration, or GIPSA) have been unwilling to prescribe official methodologies and give laboratories more leeway in choosing their detection strategies. What the USDA has done is to certify laboratories and to *verify* (not validate) the claims made in regard to different detection technologies. Donald Kendall, Director for Biotechnology at GIPSA, describes this difference in approaches as follows: 'There is actually a little bit of a philosophical difference .... In the U.S. we don't like to prescribe methods. We let laboratories develop methodologies, and then we evaluate their performance and their ability to do that test' (Comments made at the fourth plenary meeting of the USDA Advisory Committee on Agricultural Biotechnology, 18 April 2001, Washington DC).
35. JRC Project Knowledge System. Institute for Reference Materials and Measurements, FP6-Action number 4211: 'GMO CRMs and Biometrology'.
36. The original Monsanto description of the transgenic soyabean was published in 1995 (Padgette et al., 1995: 1459).
37. For some of the news coverage and public statements on the controversy caused by the discovery of the 'mystery DNA' see: Andrew Pollack, 'Mystery DNA is Discovered in Soybeans by Scientists', *The New York Times*, 16 August 2001; Greenpeace Press Release, Washington, 15 August 2001; Janet Cotter-Howells, 'Roundup Ready Soya: Incomplete Data, Missing Evaluations and Insufficient Controls', Greenpeace Background Information, 15 August 2001 (available at <www.biotech-info.net/RRsoyBackground.PDF>, accessed 21 September 2003); 'CBOT Soy Futures Tumble on Roundup Ready Soya News', *Reuters*, 16 August 2001; Michael Fumento, 'Bogus Biotech Hype', *National Review*, 28 August 2001.
38. This article was absent from the first regulatory proposal presented in July of 2001. Compare the final formulation of the article with the one proposed by the Commission in the negotiations with the Council and the European Parliament. In its proposal, the Commission had stated that: 'all provisions on public access should however be *without prejudice to the protection of intellectual property rights relating to the data concerned*' (European Commission, Amended Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed [COM/2002/0559 final, emphasis added]). The article, in its final form, was adopted by the Council of the European Union in 2002.
39. Personal communication, 9 February 2004.
40. The role of intellectual property rights here is parallel, yet inverse, to that described by Barry (2001). It is the abrogation of intellectual property rights, not their recognition and extension, that gives this particular European 'technological zone' of full GMO traceability a chance at existing.
41. 'Concern Over US Modified Corn Imports', *Financial Times*, 12 April 2005.
42. Statement by the Third World Network Biosafety Information Service, 'Europe Adopts Emergency Measures for Unapproved BT10 from the U.S.' (19 April 2005).

43. The purpose of the reform was to ensure, through the enforcement of a series of administrative measures, that in the case of the eventual identification of an individual as HIV-positive, all the blood and blood products derived from this donor could be located and withdrawn from the system.
44. The fundamental spatial dimension of the disciplinary mechanism is thoroughly emphasized in Foucault's description of the 'state of plague':

> This *enclosed*, *segmented space*, observed at every point, in which the individuals are inserted *in a fixed place*, in which *the slightest movements* are supervised, in which all events are recorded, in which an uninterrupted work of writing links the *centre and periphery*, in which power is exercised without division, according to a continuous hierarchical figure, in which each individual is constantly *located*, examined and distributed among the living beings, the sick and the dead – all this constitutes a compact model of the disciplinary mechanism. (Foucault, 1977: 197, emphasis added).

References

Advisory Committee on Releases into the Environment (2001) Guidance on Best Practice for the Presentation of Molecular Data in Submissions to the Advisory Committee on Releases to the Environment. Available at <www.defra.gov.uk/environment/acre/molecdata/pdf/acre_mdr-guidance.pdf> (accessed 18 August 2005).

Barry, Andrew (2001) *Political Machines: Governing a Technological Society* (London: Athlone Press).

Bauer, Martin & George Gaskell (2002) *Biotechnology: The Making of a Global Controversy* (Cambridge: Cambridge University Press).

Cambrosio, Alberto & Peter Keating (1995) *Exquisite Specificity. The Monoclonal Antibody Revolution* (Oxford: Oxford University Press).

Bowker, Geoffrey C. & Susan Leigh Star (2000) *Sorting Things Out: Classification and its Consequences* (Cambridge, MA: MIT Press).

Revolution (Oxford: Oxford University Press).

Cantley, Mark (1995) 'The Regulation of Modern Biotechnology: A Historical and European Perspective', in H.-J. Rehm & G. Reed (eds), *Biotechnology. Legal, Economic and Ethical Dimensions* (Weinheim: VCH).

De Loose, M., P. Windels, A. Depicker & E. Van Bockstaele (2000) 'Roundup Ready Soya: Detailed Characterization of the Locus of Insertion', presented at the Joint Workshop on Method Development in Relation to Regulatory Requirements for the Detection of GMOs in the Food Chain, European Commission's Joint Research Centre and International Life Sciences Institute, Brussels (11–13 December).

European Commission (2001) 'Explanatory Memorandum for the Proposal for a Regulation of the European Parliament and of the Council Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC'. Presented by the European Commission, 25 July 2001. Available at <http://europa.eu.int/comm/food/fs/gmo/biotech09_en.pdf> (accessed 27 April 2005).

European Commission (2003) 'Consumer Voice' (Health and Consumer Protection Directorate General, 1 April).

European Commission (2005) Decision of 18 April 2005 on Emergency Measures Regarding the Non-Authorised Genetically Modified Organism Bt10 in Maize Products. Official Journal of the European Union, L 101/14 21 April 2005. Available at <www.fsai.ie/legislation/food/eu_docs/GMOs/Dec2005_317.pdf> (accessed 28 April 2005).

European Union (2001) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC. Official Journal of the European Union L 106/1 17/4/2001. Available at <http://

europa.eu.int/eur-ex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf> (accessed 28 April 2005).

European Union (2003a) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC. Official Journal of the European Union L268/24 18/10/2003. Available at <http://europa.eu.int/eur-ex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf> (accessed 28 April 2005).

European Union (2003b) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed. Official Journal of the European Union L268/1 10/10/2003. Available at <http://europa.eu.int/eur-ex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf> (accessed 28 April 2005).

Fox Keller, Evelyn (2002) *The Century of the Gene* (Cambridge, MA: Harvard University Press).

Foucault, Michael (1977) *Discipline and Punish* (New York: Vintage).

Gottweis, Herbert (1998) *Governing Molecules: the Discursive Politics of Genetic Engineering in Europe and the United States* (Cambridge, MA: MIT Press).

Hilgartner, Stephen (1995) 'Biomolecular Databases: New Communication Regimes for Biology?', *Science Communication* 17(2): 240–63.

Holck, Askild Mar Va, Luc Didierjean & Knut Rudi (2002) '5′-Nuclease PCR for Quantitative Event-Specific Detection of the Genetically Modified Mon810 MaisGrad Maize', *European Food Research and Technology* 214: 449–53.

Holst-Jensen, Arne Sissel B. Ronning, Astrid Lovseth & Knut G. Berdal (2003) 'PCR Technology for Screening and Quantification of Genetically Modified Organisms (GMOs)', *Analytical and Bioanalytical Chemistry* 375: 985–93.

Jasanoff, Sheila (1995) 'Product, Process, or Programme: Three Cultures and the Regulation of Biotechnology', in Martin Bauer (ed.), *Resistance to New Technology* (Cambridge: Cambridge University Press): 311–31.

Jasanoff, Sheila (2005) *Designs of Nature: Science and Democracy in Europe and the United States* (Princeton, NJ: Princeton University Press).

Jordan, Kathleen & Michael Lynch (1993) 'The Mainstreaming of a Molecular Biological Tool: A Case Study of a New Technique', in G. Button (ed.), *Technology in Working Order: Studies of Work, Interaction and Technology* (London: Routledge): 160–80.

Jordan, Kathleen & Michael Lynch (1998) 'The Dissemination, Standardization and Routinization of a Molecular Biological Technique', *Social Studies of Science* 28(5/6): 773–800.

Kohler, Robert E. (1994) *Lords of the Fly: Drosophila Genetics and the Experimental Life* (Chicago, IL & London: University of Chicago Press).

Krimsky, Sheldon (1984) *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: MIT Press).

Latour, Bruno (1987) *Science in Action: How to Follow Scientists and Engineers Through Society* (Cambridge, MA: Harvard University Press).

Latour, Bruno (1999) 'Circulating Reference: Sampling the Soil in the Amazon Forest', in *Pandora's Hope: Essays on the Reality of Science Studies*, Chapter 2 (Cambridge, MA: Harvard University Press): 24–79.

Limoges, Camille, Alberto Cambrosio, Frances Anderson, Denyse Pronovost, Dominique Charron, Eric Francoeur & Eric Hoffman (1993) 'Les Risques Associés au Largage dans l'Environnement d'Organismes Génétiquement Modifiés: Analyse d'une Controverse', *Cahiers de Recherche Sociologique* 21: 18–51.

Lynch, Michael & Ruth McNally (2005) 'Chains of Custody: Visualization, Representation, and Accountability in the Processing of Forensic DNA Evidence', *Communication and Cognition* 38(1/2): 297–318.

McMahon, Henry (1935) 'International Boundaries', *Journal of the Royal Society of Arts* 84: 2–16.

Marris, Claire, Brian Wynne, Peter Simmons & Sue Weldon (2002) *Public Perceptions of Agricultural Biotechnology in Europe*. Final Report of the PABE Research Project.
Mody, Cyrus C.M. (2001) 'A Little Dirt Never Hurt Anyone: Knowledge Making and Contamination in Materials Science', *Social Studies of Science* 31(1): 7–36.
Mol, Annemarie & John Law (1994) 'Regions, Networks and Fluids: Anaemia and Social Topology', *Social Studies of Science* 24(4): 641–72.
O'Connell, Joseph (1993) 'Metrology: The Creation of Universality by the Circulation of Particulars,' *Social Studies of Science* 23: 129–73.
Organisation for Economic Co-operation and Development (1993) 'Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles'. Available at <www.oecd.org/dataoecd/57/3/1946129.pdf> (accessed 28 April 2005).
Organisation for Economic Co-operation and Development (2001) 'Report on the OECD Workshop on Unique Identification Systems for Transgenic Plants', Environment Directorate. Series on Harmonization of Regulatory Oversight in Biotechnology No. 17 (28 June).
Organisation for Economic Co-operation and Development (2004) 'Guidance for the Designation of a Unique Identifier for Transgenic Plants', Environment Directorate. Series on Harmonization of Regulatory Oversight in Biotechnology No. 23 (20 October).
Padgette, Stephen R., H. Kolacz, X. Delannay, D.B. Re, B.J. LaVallee, C.N. Tinius et al. (1995) 'Development, Identification, and Characterization of a Glyphosate-Tolerant Soybean Line', *Crop Science* 35: 1451–61.
Pietsch, K., H.U. Waiblinger, P. Brodmann & A. Wurz (1997) 'Screening-Verfahren zur Identifizierung "gentechnisch veraenderter" pflanzlicher Lebensmittel', *Deutsche Lebensmittel Rundschau* 93: 35–38.
Querci, Maddalena, Marco Jermini & Guy Van den Eede (2004) *The Analysis of Food Samples for the Presence of Genetically Modified Organisms: User Manual* (Brussels: Joint Research Centre, Institute of Health and Consumer Protection, European Commission).
Rabinow, Paul (1996) *Making PCR: A Story of Biotechnology* (Chicago, IL: University of Chicago Press).
Rheinberger, Hans-Jörg, Müller-Wille & Staffan Müller-Wille (2004) 'Gene', in E.N. Zalta (ed.), *The Stanford Encyclopedia of Philosophy*. Available at: <http://plato.stanford.edu/entries/gene/> (accessed 18 August 2005).
Scott, James (1999) *Seeing Like a State: How Certain Schemes to Improve the Human Condition Have Failed* (New Haven, CT: Yale University Press).
Sims, Benjamin (2005) 'Safe Science: Material and Social Order in Laboratory World', *Social Studies of Science* 35(3): 336–66.
Torny, Didier (1998) 'La Traçabilité Comme Technique de Gouvernement des Hommes et des Choses', *Politix* 44: 51–75.
Trapmann, S., P. Catalani, P. Conneely, P. Corbisier, D. Grancberg, E. Hannes, et al. (2002) 'The Certification of Reference Materials of Dry-Mixed Soya Powder with Different Mass Fractions of Roundup Ready™ Soya. Certified Reference Materials IRMM-410S' (Geel: Institute for Reference Materials and Measurements).
Windels, Pieter, Isabel Taverniers, Ann Depicker, Erik Van Bockstaele & Marc De Loose (2001) 'Characterisation of the Roundup Ready Soybean Insert', *European Food Research and Technology* 213: 107–12.
Wright, Susan (1994) *Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972–1982* (Chicago, IL: University of Chicago Press).

Javier Lezaun is ESRC Postdoctoral Research Officer at the Centre for Analysis of Risk and Regulation, London School of Economics and Political Science. His work focuses on the changes in political institutions that accompany developments in the life sciences. This paper is based on work conducted for his PhD dissertation, *Policing Purity: Testing, Traceability, and*

the Governance of Genetically Modified Organisms (Department of Science & Technology Studies, Cornell University, 2003).

Address: Centre for Analysis of Risk and Regulation, London School of Economics and Political Science, Houghton Street, London WC2A 2AE, UK; fax: +44 20 7955 6578; email: j.lezaun@lse.ac.uk