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## **Recasting “Substantial Equivalence”: Transatlantic Governance of GM Food**

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### **Abstract**

When an intense public controversy erupted around agricultural biotechnology in the late 1990s, critics found more opportunities to challenge risk-assessment criteria and test methods for GM products. In relation to GM food, they criticised the concept of “substantial equivalence”, which EU and US regulators had adopted as the basis for a harmonised “science-based” approach to risk assessment. Scientific uncertainty was framed in different ways by competing policy agendas. “Substantial equivalence” was contested and was eventually recast to accommodate some criticisms. To explain how the concept changed, this paper links two analytical perspectives. “Regulatory science” perspectives illuminate how the “scientification of politics” and “politicisation of science” led to shifts in the boundary between science and policy. “Governance” perspectives illuminate how the “collective problem” for policy was redefined to provide a new common ground for some stakeholders. Overall “substantial equivalence” was recast to govern the social conflict and address legitimacy problems of regulatory procedures.

Key words: substantial equivalence, regulatory science, scientisation, scientification, politicisation, science/policy boundary, governance, Codex Alimentarius Commission, Transatlantic Consumer Dialogue (TACD)

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## 1. Introduction

In the late 1990s agricultural biotechnology became a legitimacy crisis for government decision making. In the European Union (EU) public protest led to delays in approving GM products, blockages of US maize exports, and a commercial boycott of GM grain. These developments in turn created more opportunities for critics to challenge safety claims. In particular they criticised the concept of “substantial equivalence”, which governments were using to assess the safety of GM food. Various called a concept, a principle, a risk-assessment tool or all three at once, substantial equivalence has played an ambiguous and controversial role. This paper examines how “substantial equivalence” was contested and recast.

Material cited in this paper comes from three research projects (see Acknowledgements). In both projects, analysis of policy and regulatory documents informed research questions for semi-structured interviews. Interviews were conducted with policy actors at the interface between constituencies in conflict over the issues. This allowed research to focus on changing relationships and strategies. The paper includes some interview quotes taken from transcripts or from notes checked by the interviewee. More generally the interviews informed our analysis and our selection of documentary evidence.

The empirical sections of this paper are structured in a largely chronological way. They outline how “substantial equivalence” was agreed, implemented, challenged, recast and then re-interpreted, especially in EU practice (see Table I). This happened through overlapping discussions in diverse institutional settings over time. To analyse how they recast the concept, the story draws on two analytical perspectives discussed at the outset – “regulatory science” and “governance”. Through the story we answer three questions about substantial equivalence: What agendas initially shaped the concept? How has its meaning changed over time? How can these changes be explained? More broadly we ask how different policy agendas framed scientific uncertainty about GM food safety.

[Insert Table I here.]

## 2. Analytical Perspectives: Regulatory Science and Global Governance

This section outlines the analytical perspectives that we use later. Drawing on social studies of science literature, we discuss “regulatory science”, which helps us to analyse conflicts around risk assessment criteria. From political science we discuss “governance”, which helps us to analyse stakeholder interactions and competing policy agendas. By linking these perspectives we analyse how “substantial equivalence” was recast as a means to govern social conflicts around GM food.

### *2.1 Regulatory Science*

In the 1970s, when governments depended increasingly on technical expertise to guide or justify regulatory decisions, this dependence was seen as potentially exercising a technocratic control over policy. However, various technological and risk controversies complicated that scenario. In these controversies, protest was aimed “less against specific technological decisions than against the declining capacity of citizens to shape policies that affect their interests; less against science than against the use of scientific rationality to mask political choices” (Nelkin: 1979: 11). Opposition groups developed and used their own experts with various aims, such as “to prove that technical data are at best uncertain and subject to different interpretations”.

Conflicting technical interpretations generated political activity and demands for a greater role for the public in decision making (ibid: 15-17).

Technological and risk controversies feature various languages of risk, which can be analysed as contending issue-frames. When different groups describe risks, “Some talk of cost-effective solutions, of efficiency; others use the language of ‘rights’, emphasising moral issues and questions of social responsibility, justice and obligation.” If risks are defined in terms of insufficient technical evidence, for example, then this implies that risk assessment is the appropriate approach to regulation. “In some cases, increased knowledge may eventually depoliticise an issue ...” (Nelkin, 1982: 18-21).

Efforts to depoliticise risk through technical evidence can be understood as scientising politics. Scientisation “implies that political and social issues are better resolved through technical expertise than democratic deliberation” (Bäckstrand, 2004: 24). However, each group interprets scientific uncertainty and appeals to criteria for evidence in ways favourable to their respective policy stances, so it is difficult to reconcile such conflicts through science alone (e.g. Bedsworth et al., 2004). Moreover, various scientific disciplines and cognitive approaches generate conflicting evidence (Beck, 1992: 167). Thus efforts to scientise politics can be undermined by expert disputes.

Beyond the scientisation of politics, Peter Weingart (1999: 154). has theorised the “scientification of politics”. In this process, expertise plays two related roles: (1) it acts instrumentally by clarifying scientific problems through more reliable knowledge; (2) it legitimises decisions by absorbing scientific uncertainty into expert advice and thus supporting policy decisions. As distinct from scientisation, however, scientification means that regulatory authorities become more dependent upon scientific progress e.g. new methods and knowledge. This dependence can lead to an abundance of knowledge, open to diverse interpretations. Science can raise new issues for which further expertise is needed.

Ultimately the scientification of politics can result in the politicisation of science, with a competition for the latest scientific evidence which supports or undermines a specific policy. This competition “drives the recruitment of expertise far beyond the realm of consensual knowledge, right up to the research frontier where knowledge claims are uncertain, contested and open to challenge” (ibid: 158). The inflationary use of expertise can intensify controversies, open up policy to non-expert views, and de-legitimise science as a basis for decisions, particularly when experts disagree in public (Weingart, 1999).

We can explore these issues further by examining the flexible, contested boundary between science and policy. In practice regulatory experts are not engaged in ‘science’ in the ordinary sense, but rather “a hybrid activity that combines elements of scientific evidence and reasoning with large doses of social and political judgement” (Jasanoff, 1990: 229). When scientists give advice on regulatory decisions, the cognitive authority of science may be jeopardised. This difficulty arises partly because the available scientific knowledge may not provide authoritative answers to policy questions. In such situations it becomes more difficult to justify any particular version of ‘science’ as policy-free (Jasanoff, 1987).

The science/policy boundary also matters for institutional power in regulatory decision-making. Broader accounts of “science” increase the scope for expert advice to influence or constrain regulatory decisions. When the US Environmental Protection Agency was regulating toxic chemicals in the 1980s, for example, expert advice was generally more favourable than regulators to safety claims, so industry defined the scope of ‘science’ more broadly to enhance

the authority of expert advisory bodies (Jasanoff, 1987). Defining narrowly or broadly the scope of ‘scientific’ questions is therefore central to setting or contesting a boundary between science and policy.

## 2.2 *Global Governance*

Global rules are often designed to promote regulatory harmonisation and trade liberalisation. The Organisation for Economic Cooperation and Development (OECD), for example, tries to harmonise data requirements for the risk regulation of products to enhance regulatory efficiency and avoid trade barriers. However, such rules “effectively narrow the menu of regulatory choices open to governments” (Newell, 2003: 61, 64). More generally, and less tangibly, constraints are imposed on governments through “a discourse of technical-rational knowledge” which represents all problems as amenable to technocratic solutions and control (Ford, 2003: 124-25). These tendencies are illustrated by the World Trade Organisation’s Agreement on Sanitary and Phytosanitary Measures.

Over the past decade or so, such developments created the context from which the term “governance” emerged as a policy concept. As some political scientists have argued, “economic globalisation and political change have created a crisis of the old hegemonic structures and forms of political consent, which are now coming apart...” (Lipschutz, 1996: 55; citing Gill, 1993: 32-33). This provided an opportunity for new transnational networks to form and protest. Protest in turn has led governments and international bodies to develop more consultative or participatory forms of decision-making. The outcome can be “alliances between coalitions in global civil society and the international governance arrangements associated with the UN system” (Lipschutz, 1997: 96). Global governance, therefore, “can be seen as a product of two phenomena: the pursuit of neoliberal forms of globalisation, and the resistance to such centralisation of power” (Paterson et al., 2003: 2).

How are such deep conflicts governed? In the political science literature, governance is often understood as co-operation to deal with collective problems and related conflicts. For example:

... governance involves the establishment and operation of social institutions in the sense of rules of the game... capable of resolving conflicts, facilitating cooperation, or, more generally, alleviating collective-action problems in a world of interdependent actors. (Young, 1994: 15)

Along similar lines, governance has been described as “a continuing process through which conflicting or diverse interests may be accommodated and co-operative action may be taken” (CGG, 1995: 2).

Some governance theorists and policy makers take for granted the “collective problem”. By contrast, critical perspectives analyse how problems are (re)defined as collective ones in order to manage conflict. According to Dominique Pestre, global governance has “aimed at establishing common values for the management of a collective, and ultimately reconciled, future”.

Consequently, “The only remaining questions are procedural and managerial in nature”.

As Moreau Défarges [2001] and others have suggested, the vocabulary of governance conveys the idea that the world of politics, as it was invented and has been practiced for more than two centuries, is de facto obsolete. Not only because it is based on an overly conflictual understanding of the social, but also because it relies too much on the State and the formal procedures of representative democracy.... (Pestre, 2007).

In this strategic sense of governance, fundamental conflict can be displaced into supposedly collective problems and their managerial-procedural solutions. Drawing on such critical perspectives, this paper analyses how expert procedures defined new policy problems as collective ones, as a basis for governing the legitimacy crisis over agricultural biotechnology.

### 3. Implementing “Substantial Equivalence”

In the 1990s questions were raised about genetic modification potentially generating unknown risks and about how these could be identified for each product. This section shows how a network of policy actors devised and implemented the concept of “substantial equivalence” as a means to address those uncertainties (see Table I.1). The concept linked science with policy in a way which initially scientised politics. This approach complemented the regulatory harmonisation agendas of the US and the EU.

#### 3.1 OECD Guidelines: “Substantial Equivalence”

Intergovernmental organisations began to discuss GM products in the 1980s. From the mid-1980s the Organisation for Economic Cooperation and Development (OECD) sought risk-assessment methods that would help to liberalise trade in biotechnology products. An early report linked regulatory harmonisation with the aim “to facilitate data exchange and minimise trade barriers between countries” (OECD, 1986: 42).

Specifically for GM food products, an expert contribution came from a meeting organised by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), which jointly host the Codex Alimentarius Commission. According to their expert consultation report, “safety assessment should be based on sound scientific principles and data” (FAO/WHO, 1991: 23). The report agreed that GM foods could be compared with conventional counterparts as part of a safety assessment, but it also drew attention to the lack of baseline information:

Comparative data on the closest conventional counterpart are critically important in the evaluation of a new food, including data on chemical composition and nutritional value. The Consultation believed that such data are not widely available at the present time. (ibid: 24).

The Organisation for Economic Cooperation and Development (OECD) also hosted discussions on the safety of GM food. Nominated by 19 member governments, the participants were regulatory scientists from government agencies and ministries responsible for food safety. The main outcome was a document proposing methods and principles for *Safety Evaluation of Foods Derived by Modern Biotechnology*. According to this document, GM food “does not necessitate a fundamental change in established principles, nor does it require a different standard of safety”; moreover, the precise techniques involved in genetic modification “should enable direct and focused assessment of safety where such assessment is desired” (OECD, 1993: 10). It also promoted the concept of substantial equivalence:

The main conclusion of this report is as follows: if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. No additional safety concerns would be expected. Where substantial equivalence is more difficult to establish because the food or food component is either less well-known or totally new, then the identified differences, or the new characteristics, should be the focus of further safety considerations. (OECD, 1993: 13)

Thus the 1993 OECD report ignored the 1991 FAO/WHO caveat regarding the lack of comparative data. On this basis, the OECD report also implied that substantial equivalence might be used to demonstrate similarity and therefore safety, mainly through tests of physico-chemical composition. Such tests could be implemented and accepted across countries, thus facilitating the transatlantic policy agenda of regulatory harmonisation and trade liberalisation. The concept of substantial equivalence gained support by linking science and policy in this particular way, through an intergovernmental process which did not involve NGOs.

### *3.2 US Practice: “Substantially Similar” Products*

In the 1980s the US government identified biotechnology as essential for the future of US agriculture and its international competitiveness. A key policy document argued that the products of recombinant DNA technology would not differ fundamentally from unmodified organisms or from conventional products (OSTP, 1986). On this basis it was decided that no new legislation was necessary for regulating GM products. Building on this policy, the US Food and Drug Administration published a guidance document on risk assessment of foods derived from new plant varieties, including GM crops (US FDA, 1992).

According to the 1992 guidance, the FDA expected genetic modification of plants to produce components “substantially similar” to those commonly found in food, e.g. those Generally Recognised as Safe (GRAS). Similarity could be demonstrated by testing chemical composition. In cases where such methods could not resolve safety concerns, “feeding studies or other toxicological tests may be warranted”. However, “feeding studies on whole foods have limited sensitivity because of the inability to administer exaggerated doses”. According to the FDA, its guidelines were “consistent with the concept of substantial equivalence” being discussed by OECD experts at that time (US FDA, 1992: 24, 17; see above).

In this way, chemical composition became a central criterion for GM food safety assessment in the US. This emphasis can be explained partly by the methodological problems of testing the toxicity of whole foods or complex mixtures. In retrospect an FDA official stated:

Such animal feeding studies are difficult to design and interpret. For example, the experimental conditions can perturb the nutritional quality of the diet, relative to the control. And it can be difficult to feed large quantities of a specific protein or of a complex substance such as a whole food... (interview, FDA, 04.08.03)

In addition, however, US government policy was promoting agricultural biotechnology as an economic necessity and as a source of predictably safe products. According to the President's Council on Competitiveness, the government must maintain “risk-based regulation” and thus “avoid excessive restrictions that curtail the benefits of biotechnology to society” (BWG/CoC, 1991: viii, 11). In this context the FDA guidelines facilitated safety claims by emphasising compositional tests.

On that basis the US government has not required companies to obtain pre-market approval of GM foods. In practice, companies have sought FDA review; they have submitted data on physical composition of GM foods, as grounds for why no risk assessment is required. Some submissions have also cited data on toxicological tests on the novel protein. In response the FDA has sent each company a lettering noting the safety claim and stating: “it is our understanding that [the developer] has concluded that [the food product] does not raise issues that would require pre-market review or approval of FDA”. In this way the FDA has taken no responsibility for any judgements on data or safety. In the mid-1990s NGOs unsuccessfully proposed that the FDA should classify GM foods as food additives, as a basis to require that risk assessments be done (Krimsky and Wrubel, 1996: 106-07).

### *3.3 EU Practice: simplified procedure*

In contrast to the US, EU policymakers took the view that GM products do raise new uncertainties about risk and so warranted special legislation. Directive 90/220, on the deliberate release of GMOs into the environment, aimed to prevent “adverse effects on human health or the environment”. It established a legal duty on producers to seek prior approval before release of any GMO in the European Union. Producers had to submit a dossier giving information that

could be used to evaluate any risks (EEC, 1990). The Deliberate Release Directive served briefly as the EU's regulatory framework for assessing GM food safety.

In 1997 the EU revised its legislation, giving “substantial equivalence” a statutory role. Regulation 258/97 on Novel Food established a legal duty to seek approval before commercialisation of any novel food, e.g. GM food. Unlike Directive 90/220, however, this new law had a simplified procedure for novel foods “substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein”; the regulation gave no more detail. If a GM product was substantially equivalent to a conventional counterpart, then no risk assessment was required (EC, 1997a: 3). In the late 1990s several GM foods were approved in this way.

This procedure helped to harmonise product approval across the Atlantic, in line with the OECD's intentions for the concept of substantial equivalence. The EU procedure was also consistent with the 1995 New Transatlantic Agenda (NTA), an EU-US inter-governmental initiative focused on liberalising trade in various sectors. Trade liberalisation could be achieved through mutual acceptance of safety judgements; this would be easier if EU and US legislation was underpinned by similar concepts. In 1998 EU and US officials working through the Transatlantic Economic Partnership, an NTA implementation mechanism, were proposing a project on simultaneous assessment of a GM product in both jurisdictions, as a further step towards regulatory harmonisation (Murphy and Levidow, 2006).

#### **4. Challenging “Substantial Equivalence”**

When GM food became more controversial in the late 1990s, so did the meaning of substantial equivalence. Particularly in the EU, regulatory policy became increasingly dependent upon knowledge that was near the research frontier, thus leaving risk assessment vulnerable to criticism. This section describes the scientification of policy, which ultimately went hand-in-hand with the politicisation of science. Policy actors selectively cited empirical results and expert claims favourable to their policy agenda (see Table I.2). This section also illustrates how scientific uncertainties were framed differently by competing policy agendas.

##### *4.1 Early Challenge and Protest*

An early challenge to substantial equivalence came from Consumers International (CI). They emphasised uncertainties associated with genetic novelty and the limitations of laboratory tests:

... consumer experts are concerned that this concept has only limited value. First of all, it is very difficult to assess substantial equivalence... Too much importance is attached to digestibility tests for assessing safety. Finally, there is a lack of available scientific data on safety of traditional foodstuffs used for comparison with GEFs [genetically engineered foods (CI, 1996: 1)... In a field of science in which many of the mechanisms are still a mystery, great caution is needed (ibid: 3).

Their report recommended that GM food safety assessment should involve a wide range of additional tests, as a means to address scientific unknowns and methodological weaknesses (ibid: 4-11; see later citations).

NGOs hostile to agricultural biotechnology attacked substantial equivalence in stronger terms. For example, some criticised Monsanto for evaluating glyphosate-tolerant soybeans without testing how glyphosate sprays might affect their composition (Tappeser and von Weizsacker, 1996). According to such critics, substantial equivalence is “unscientific and arbitrary.... intentionally vague and ill-defined to be as flexible, malleable and open to interpretation as



possible”. Furthermore, “Genetic engineering carries its own inherent hazards which are unique to it”, e.g. a general hazard from lab techniques which incorporate viral DNA into the new organism (Ho and Steinbrecher, 1997: 8, 6). In this way doubt was cast on the capacity of science to reduce and clarify biotechnological risks through more knowledge.

Some environmental NGOs, especially in Europe, opposed agricultural biotechnology altogether. They explicitly linked GM food with past food crises. Drawing an analogy to the scandal over bovine spongiform encephalopathy (BSE), also known as ‘mad cow’ disease, Greenpeace referred to “untestable” risks of GM food (Greenpeace, 1997a: 5, 11). In a direct attack on substantial equivalence, they stated: “Sheep offal contained the scrapie prion but would not have been picked up by the conventional chemical analysis or short-term testing required to determine ‘substantial equivalence’” (Greenpeace, 1997b: 27). By using metaphors like “genetic contamination”, such opponents characterised all GMOs as pollutants. GM crops were cast as further industrialising agriculture, driven by commercial forces; agbiotech symbolised an ominous form of globalisation that was undermining safety regulation and democracy.

In the late 1990s European consumer activism gained political importance for many reasons: the 1996-97 mad cow crisis, other food scandals, challenges to expert safety claims, food boycotts, and anti-biotech movements stimulating opposition among the public. The director of the UK Consumers Association criticised the agro-food industry for its “unshakeable belief in whizz-bang techniques to conjure up the impossible – food that is safe and nutritious but also cheap enough to beat the global competition” (McKechnie, 1999). In these ways arguments that linked agricultural biotechnology with efficiency were turned upside-down to raise doubts about safety. Consumer NGOs demanded more rigorous risk assessment as well as segregation and labelling.

In Europe the 1990 legislation had formalised an understanding that GM products were inherently different from their conventional counterparts. In this context, substantial equivalence was easily ridiculed as careless and deceptive. It appeared to play down the novelty of GM foods, thus serving the interests of biotechnology companies. Critics turned the concept itself into a problem for consumer confidence in regulation. By 1999-2000, in response to the public backlash against GMOs in Europe, most European food retailers were removing GM ingredients from their own-brand products; this exclusion discouraged commercial cultivation there (Levidow and Bijman, 2002).

#### *4.2 Tighter Criteria in the UK and the EU*

In the late 1990s many companies applied to the UK for product approval under the simplified procedure of the Novel Food Regulation. In response, UK experts discussed whether substantial equivalence would provide an adequate assessment of risks. In the context of the public controversy, the expert advisory body concluded that the simplified procedure was suitable only for fully processed foods, no longer containing intact DNA or protein (ACNFP, 1998).

The advisory committee also tightened the meaning of the concept in other ways, e.g. by requiring tests on the stability of the novel genetic insert. According to a UK expert:

If we must use that criterion alone, then we will tighten its definition... a food cannot be regarded as substantially equivalent if it contains any intact GM DNA, so the product must be highly refined to ensure that all the DNA has been denatured. Moreover, we will specify what tests are required; the company must monitor generations of the crop over two years at six sites. (ACNFP member, interview, 11.05.98).

A similar requirement to test genetic stability had been proposed by NGO-associated scientists (e.g. Ho and Steinbrecher, 1997).

In the UK the problem of ‘consumer-public confidence’ helped to justify more rigorous risk assessment criteria, by transcending expert disagreements about their strictly ‘scientific’ rationale. The ACNFP had included a consumer representative since the early 1990s, and this influenced the committee’s judgements. According to one chairman: “Eventually the scientists learned how to ask questions which would concern consumers” (interview, 28.05.98). Such concerns were seen as going beyond science: “We cannot expect the public to take a strictly scientific view of safety issues”, remarked a scientist on the committee (interview, 10.05.98).

The more cautious advice from UK experts was soon incorporated into EU guidelines (StCF, 1998). Thus a national move towards more stringent criteria led to new EU-wide standards. As the criteria for substantial equivalence were tightened, the concept was given a more modest role.

#### 4.3 Expert Controversy

As the public backlash against GM food intensified in the late 1990s, the UK government funded a major project to improve and standardise whole-food tests on animals. Based at the Rowett Research Institute (RRI), the project was led by Arpad Pusztai, an internationally renowned expert on lectins – naturally occurring toxins that protect plants from insects. The new project used GM potatoes containing a transgene for a lectin that was presumed to be harmless to mammals. However, when unexpected results were announced on a UK television programme in 1998, they fuelled the GM food controversy. After ingesting the GM potato, rats apparently suffered damage to their immune systems and organ development. Pusztai raised the possibility that the process of genetic modification had led to an unknown change. This hypothesis was explosive because it questioned the safety of products already on the EU market, e.g. GM soya and maize, which likewise could have unknown changes in composition.

The RRI responded by ending its support for the group’s research. It terminated Pusztai’s employment and denied him access to his research data. The RRI was then accused of giving priority to industry research contracts over independent science (sources cited in Levidow, 2002). Asserting its authority on the issue, the Royal Society convened a special committee, which concluded, “We found no convincing evidence of adverse effects from GM potatoes” (Royal Society, 1999: 1). In response, *The Lancet* criticized the Royal Society for a “breathtakingly arrogant” approach to risk research on GM safety (Editorial, 1999). It also published a paper based on the GM lectin study, along with various commentaries. International networks of scientists now took sides for or against the validity of Pusztai’s research. This intensified the debate over substantial equivalence.

Around this time *Nature* published an opinion article reflecting some activist views, thus signalling that these must be addressed. Referring to the Pusztai controversy, the article attacked substantial equivalence as an inadequate basis on which to judge whether a GM food is as safe as its non-GM counterpart. The authors criticized the concept on three specific grounds: it emphasises chemical composition at the expense of biological, toxicological and immunological tests; it does not define the point at which a substance is no longer substantially equivalent; and the concept actually impedes risk research (Millstone et al., 1999). More broadly the critics attacked the concept as an example of business influence on policy:

Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgement masquerading as if it were scientific. It is, moreover, inherently anti-scientific

because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests (ibid: 526).

In response, advocates of substantial equivalence denied that it had ever been meant as a ‘scientific’ concept. Rather, it was simply a conceptual tool, which “neither specifies nor limits the kind or amount of testing needed for new foods” (Miller, 1999). OECD staff defended it as appropriate

Substantial equivalence is not a substitute for a safety assessment. It is a guiding principle which is a useful tool for regulatory scientists engaged in safety assessment... In this approach differences may be identified for further scrutiny, which can involve nutritional, toxicological and immunological testing (Kearns and Mayers, 1999: 640).

Thus they mentioned a range of tests, as if these had always been associated with the concept. This defence emphasised broader uncertainties than in the OECD’s original 1993 interpretation of substantial equivalence.

## **5. Recasting “Substantial Equivalence”**

By the late 1990s EU regulation of GMOs was in crisis. In June 1999 the EU Environment Council imposed an unofficial de facto moratorium on approval of any additional GM products. Council members argued that before the approval procedure could resume, risk assessment must be made more transparent, based on precaution – especially as means “to restore public and market confidence” (cited in FoEE, 1999: 3). This regulatory blockage in turn led to a trade conflict with the US. Agbiotech critics demanded greater public accountability for expert judgements.

In high-level international fora, substantial equivalence was recast, while ‘science’ was opened up as a policy issue. In this process, a trans-Atlantic ‘consumer rights’ agenda converged with European expert moves towards more stringent regulatory criteria (see Table I.3). Divergent views were mediated by a new collective problem: how to maintain or restore consumer-public confidence. This section focuses on three fora involved in this governance process.

### *5.1 Transatlantic Consumer Dialogue (TACD)*

The Transatlantic Consumer Dialogue (TACD) was created in 1998 with co-funding from the EU and USA. Its creation was a response to complaints that the Transatlantic Business Dialogue was driving forward the transatlantic trade liberalisation agenda with no counterbalancing voices from civil society. The TACD was the main network linking consumer groups in the US and the EU, although some key individuals also worked together on GM food in other fora.

TACD member organisations had a consumer rights agenda, expressed in slogans like “the right to know, the right to choose”. They had diverse views about the need for agbiotech and its potential benefits, but they more readily found agreement on issues of safety and consumer rights. Eventually TACD members formulated common positions, so that they could speak with a single voice in discussions with government.

TACD’s first policy statement on GMOs demanded a comprehensive mandatory approval process (TACD, 1999). A second statement, released soon after, raised doubts specifically about substantial equivalence:

It is important to consider the limitations of an approach based on “substantial equivalence” and consider whether more robust methods for assessing the unintended consequences of genetic modification are available or could be developed... TACD calls for the development of methods

for assessing GM foods, which unlike “substantial equivalence” can help to give a clearer idea of the potential unintended consequences of genetic modification. (TACD, 2000: 2, 4)

Meanwhile consumer NGOs extended their criticisms of regulatory practice. In their view, regulators had a weak basis on which to identify any differences between a GM food and a non-GM counterpart. On behalf of consumer groups worldwide, a consultancy report emphasized the inadequate baseline information on conventional food and the patchy data submitted on GM food: “it is hardly plausible that compositional data have been analysed in a statistically sound way” (SBC, 2001: 5). European consumer organisations reiterated their previous proposals that ‘More resources need to be made available for independent, unbiased scientific research’, especially ‘for further nutritional, toxicological and immunological evaluation where there are differences in the composition of a GM crop and its non-GM reference, whether intended or unintended’ (BEUC, 2001: 3-4).

As this quote indicates, consumer groups framed the problem as reducible uncertainties which could be clarified by better data and new test methods. Through the TACD, consumer NGOs communicated this view directly to policymakers in the US and EU administrations.

## *5.2 EU-US Consultative Forum*

In May 2000 Presidents Prodi and Clinton launched the EU-US Consultative Forum on Biotechnology (the EU-US Forum). It was comprised of 20 expert members including representatives from industry, environmental and consumer groups. It had a remit to “consider the full range of issues of concern in biotechnology in the United States and the European Union, most of which relate to... food and agriculture”. Strategically, it was designed to find a route beyond the trans-Atlantic trade conflict.

The EU-US Forum implicitly redefined substantial equivalence. According to the final report, GM food products should “be subject to a mandatory pre-market examination by the appropriate regulatory authorities” (EU-US Forum, 2000: 4, 8). It describes substantial equivalence in a relatively modest way:

The concept of substantial equivalence should only be used to structure a safety assessment. The fact that a biotechnology food is held to be substantially equivalent to a conventional food should not be taken automatically to mean that it needs less testing or less regulatory oversight than “non-substantially” equivalent biotechnology foods. The concept of substantial equivalence should be improved by the development and application of new techniques, which can help to identify unintended and potentially harmful changes. (ibid: 10; Recommendation 5).

The EU-US Forum thereby suggested that more scientific tests were needed to make the concept robust.

Both administrations accommodated the final report in their responses. The European Commission pointed out that it was funding numerous projects to develop new techniques for substantial equivalence (CEC, 2001a; cf. DG Research, 2001). The US government stated:

Substantial equivalence is sometimes wrongly characterized as an attempt to avoid applying approval procedures to bioengineered food products. This is not the case. In the U.S., we use this concept as a starting point in our risk assessment process (U.S. Dept of State, 2000: 3).

That statement implied a level of scrutiny which did not exist; the US government did not (and at the time of writing still does not) require producers to seek pre-market approval of GM food.

Within the EU-US Consultative Forum, the problem of consumer-public confidence allowed consumer groups to find common ground with a wider network. One participant reflected later

that “The whole point of it was to try and look at what changes are needed to gain greater consumer confidence in GMOs...” (interview, European consumer representative, 11.10.02). A report from a US NGO, directed at the US FDA, used a similar language: feeding studies “might detect problems and they would add public confidence to safety determinations of a new technology with less-than-perfect testing protocols” (CSPI, 2003: 21).

### *5.3 Codex Alimentarius Commission*

The FAO/WHO Codex Alimentarius Commission sets global food standards. After the WTO was created in 1995, its adjudication procedures raised the political stakes associated with Codex standards, which could play a role in a trade dispute. In the late 1990s, when GM food was being blocked in the EU, some member states raised the need for Codex standards in this area. At its 23rd session in June-July 1999, the Codex Alimentarius Commission initiated an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology.

Before the first meeting of the Task Force, the host representative broadly defined the problem that the governments faced:

We are required to promote biotechnology based on consumer understanding about the safety of the technology. We have to reach an international consensus on the safety of foods derived from biotechnology. – Shingo Haketa, Vice-Minister for Health and Welfare, Japan (Reuters, 2000).

At its first meeting the Task Force mandated a new expert consultation. Amongst other issues, this expert consultation had to consider questions related to substantial equivalence (CAC, 2000). Only scientists were appointed to the expert group but some of these discussed the issues with consumer NGOs. In the Codex deliberations that followed, important roles were played by non-state actors, e.g. Consumers International and the Bio-Industry Organisation (e.g. CI, 2000a). They were admitted officially as ‘observers’ but in practice were more active.

CI proposed that the expert group’s report should abandon the concept of ‘substantial equivalence’ altogether (CI, 2000b). However, this was impossible, because leading governments were committed to the concept in some form. The CI representative then supported moves to redefine it in ways that weakened the emphasis on similarity with conventional food.

The expert report accommodated this proposal. For example, it attributed deep conflicts to “the mistaken impression that the determination of substantial equivalence was the end point of a safety assessment”. It argued instead that the concept should be used “to identify similarities and differences...” and that a compositional comparison “was not the sole basis for determining safety”. When comparing a GM food and a conventional counterpart: “If the differences exceed natural variations, a nutritional and toxicological assessment is required” (FAO/WHO, 2000: 7).

Moreover, the report emphasised unknown risks: “Present approaches to assess possible unintended effects are based, in part, on the analysis of specific components (targeted approach). In order to increase the probability of detecting unintended effects, profiling techniques are considered as useful alternatives (non-targeted approach)” (ibid: 6). At the same time, the report acknowledged that more work was required to develop such techniques, e.g. metabolomics and proteomics (ibid: 20).

The Task Force basically accepted the expert consultation report, including the prospect of “unintended effects”, which may be either predictable or unexpected (CAC, 2001; also CAC, 2002). Some disagreements arose over risk-assessment criteria. For evaluating the composition of GM food, the US government initially proposed that the “conventional counterpart” could

itself be a GM food, but this was not accepted (CAC, 2001). There were also disagreements on appropriate methods for evaluating evidence of allergenicity. Some European experts expressed views similar to consumer NGOs; they favoured a “decision tree”, whereby a single piece of evidence could be used to reject a product. By contrast the US-led view favoured “the preponderance of evidence”, whereby all available evidence would be considered together.

Despite such disagreements, the Task Force agreed guidelines, which were then adopted by Codex. They mention various test methods that might be deemed necessary for a risk assessment. For example, for compositional tests to be meaningful, the crop should be grown under relevant agronomic conditions in a variety of sites. Beyond conventional toxicology studies, “Additional in vivo or in vitro studies may be needed on a case-by-case basis to assess the toxicity of expressed substances” (CAC, 2003a: 30; see Table II).

The final document was widely welcomed as articulating international standards, from quite diverse standpoints. NGOs expressed the view that the new standards could protect consumer rights vis à vis US pressures against more stringent regulation elsewhere. Indeed, governments now had “... a protective shield for any strong risk-assessment system which may be challenged at the WTO” (interview, Consumers International, 30.10.02).

Beyond mandating more stringent criteria, the redefinition of substantial equivalence opened up technical criteria to wider accountability. This implicitly shifted the boundary between science and policy. In a parallel development, “risk-assessment policy” was made an explicit issue for food safety in general (CAC, 2003b).

Meanwhile some experts suggested renaming substantial equivalence as “the comparative approach”. Indeed, an OECD staff member retrospectively gave this name to proposals in the 1991 FAO/WHO expert consultation report, while implying that the concept always had a modest meaning (Kearns, 2002: 12). Likewise EU experts later articulated “the comparative approach” for risk assessment of GM food (EFSA 2004a: 12-13). The new name implied more scientific uncertainty and a greater burden of proof required to demonstrate similarity with a safe food.

## **6. Re-interpreting “Substantial Equivalence” in EU practice**

As outlined in the previous section, transatlantic governance processes ran in parallel with EU efforts to regain control of GM food regulation, especially by separating safety from wider issues. Consumer groups participated in discussions about the scientific uncertainties that needed to be clarified through better knowledge. Through a scientification process, risk-assessment criteria became more open-ended, dependent on further test results and debate over their significance. In the late 1990s doubts had been raised about the available test methods, along with proposals to improve them and to develop more sensitive tests (shown in Table II). At stake for governments was how to redraw a science/policy boundary whilst avoiding further politicisation. This section shows how changes in European regulatory practice had difficulties in stabilising a ‘science’ on which to base safety judgements (see Table I.4).

[Insert Table II]

### *6.1 Concept as Dynamic*

In European regulation of GM foods, a turning point came in August 2000, when the Italian government suspended the sale of products derived from four varieties of GM maize. These

products had already gained EU-wide approval under the simplified procedure, based on a claim for substantial equivalence. According to the Italian government, however, the notifiers had not shown that the GM maize was substantially equivalent to conventional maize. They argued that the products should undergo a full risk assessment.

The European Commission sought an expert basis on which to lift the ban. DG Consumer Affairs requested advice from the relevant EU-level expert body, the Scientific Committee on Food (SCF). The SCF advised that the Italian authorities had not provided evidence that the GM maize posed a risk to human health. Citing this advice, the European Commission then demanded that Italy remove the ban; and it requested support from the Standing Committee on Foodstuffs, which represents EU member states. That body instead sided with Italy, stating: “it was unacceptable that GMO-derived products were placed on the EU market under the simplified procedure, without undergoing a full safety assessment” (StCF, 2000: 2).

Such conflicts led the Commission to omit a simplified procedure from its draft Regulation on GM Food and Feed. It stated that:

The use of this regulatory short-cut for so-called “substantially equivalent” GM foods has been very controversial in the Community in recent years... and there is consensus at the international level... that whilst substantial equivalence is a key step in the safety assessment process of genetically modified foods, it is not a safety assessment in itself (CEC, 2001b; cf. EC, 2003: 1).

Thus the Commission cited an international consensus in the reports of the EU-US Forum and the Codex Task Force.

This change in the status of substantial equivalence extended earlier moves to open up risk-assessment criteria as a policy issue. According to a Commission official, substantial equivalence would be kept as a risk-assessment tool, although EU-wide harmonisation might be difficult for this “dynamic concept”, whose interpretation was still under development (Pettauer, 2002: 23). This acknowledges dependence on scientific knowledge yet to be gained.

## *6.2 Policy Shifts in Risk Assessment*

Meanwhile EU scientific advisors were highlighting the lack of agreed assessment criteria and test methods in relation to substantial equivalence. In addition, they argued, available tests could find only whatever they targeted: “Currently applied methods do not provide certainty to detect all new non-targeted plant constituents or an increase of the amount of unintended existing toxic constituents and therefore the methods need to be expanded” (SSC, 2000: 8). Consumer groups continued to emphasise “methodological limitations for obtaining meaningful information” e.g. from animal tests on whole foods, and from compositional tests (Schenkelaars, 2002: 62). At this time EC legislation listed risk-assessment criteria but did not say what tests were needed in which cases (EEC, 1990; EC, 1997a, 1997b). More detailed guidance did not specify exactly what compositional differences would warrant what additional tests, and anyway such documents had no statutory force (e.g. SSC, 2000, 2002).

In the absence of clear statutory guidance at the EU level, some expert advisors took the initiative at the national level and requested more extensive information on products being submitted for approval there. This procedure slowly elaborated assessment criteria and test requirements via case-by-case judgements, sometimes involving discussions with NGOs. For example, Dutch consumer groups and government advisors discussed weaknesses of data packages from companies (Schenkelaars, 2005). After biotechnology companies started submitting requests for GM food authorisation to the Netherlands in 1999, its food safety experts recognised the limitations of compositional data for risk assessment. The authorities asked the companies to document the content of secondary metabolites in the GM crop

compared to those of the non-GM control (SBC, 2001). Industry supplied this information as part of an overall effort to harmonise data requirements across the EU (EuropaBio, 2001; Amijee, 2002: 50).

There are other examples of how a national advisory body shifted EU-wide criteria along more stringent lines. Until 1999 the UK and Germany were the two EU member states that received most notifications for commercial approval of GM foods. When the UK received applications to approve fresh food products derived from new GM maize crops, the company's dossiers already included toxicology and allergenicity data, and so went beyond compositional equivalence. But the advisory committee regarded this as inadequate (ACNFP, 2001: 7-8). More rigorous data were eventually submitted to satisfy the committee. The requirements echoed those that NGO scientists had proposed in the mid-1990s (CI, 1996; Ho and Steinbrecher, 1997; Tappeser & von Weizsacker, 1996).

For generic issues of GM food safety, the UK Royal Society established a working group which included a consumer representative. Echoing NGO proposals, its report emphasized the need to define the 'normal' composition of conventional plants, as a basis for any comparison with GM plants, as well as the need to develop more sensitive tests (Royal Society, 2002: 6). The report reveals tensions around expert authority over regulatory science. The authors agreed "that scientific assessments must inform policy decisions but cannot pre-empt them, and that public opinion must be taken into account throughout". Moreover, "The amount of comparative data required to establish substantial equivalence involves a somewhat subjective judgement" – yet the criteria "should be made explicit and objective" (ibid: 2002: 5-6). Such contradictory language indicates a tension between opening up assessment criteria and maintaining a distinct expert, scientific realm.

Long-standing test methods were recast as near the research frontier and even as methodologically doubtful. Not only NGOs but also expert advisors voiced doubts about compositional comparisons: "Limitations of this analytical comparative approach are the possible occurrence of unknown toxicants and anti-nutrients...", argued a Dutch food safety advisor, who also served on the EU delegation to Codex (Kuiper et al., 2001: 515). Expert advisors also suggested that new safety tests might be necessary to assess future novel products. Scientists in the Netherlands took a lead in proposing more sensitive techniques e.g. messenger RNA and micro-array analysis of its expression. They also emphasised profiling techniques e.g. proteomics for detecting changes in protein content, and metabolomics for detecting changes in metabolic activity (Kuiper et al., 1999). They argued that such methods should be developed further and validated, especially for detecting secondary effects due to more extensive genetic modification of future GM crops (Kuiper et al., 2001: 523).

Some scientists also initiated a European network on the safety assessment of GM food (DG Research, 2001: 130-32; Entransfood, 2003). Taking part in the discussions, consumer representatives extended their cooperative relation with research scientists and expert advisors. They also became more enthusiastic about efforts to develop profiling techniques. However, some experts anticipated that such methods would generate voluminous data that would be difficult to interpret meaningfully. Industry warned against any premature new requirements to use such tests (EuropaBio, 2004).

Building on earlier documents (SSC, 2000, 2002), the European Food Safety Authority drafted new guidance for risk assessment of GM products. EFSA's experts outlined tests of nutritional content, toxicology and allergenicity. "In the case of newly expressed proteins with an insufficient database and, in particular, if the available data suggest the existence of any cause



for concern”, they requested toxicological tests – a 28-day repeated-dose test for acute effects of the purified novel protein, and a 90-day test of the whole food (SSC, 2003: 19; EFSA GMO Panel 2004: 33). This request conflicted with the industry position that a 14-day acute toxicity test would provide adequate information (EuropaBio, 2001, 2004). In any case, the expert guidance left unclear what GM products or preliminary test results would justify such tests.

European consumer groups welcomed the guidance and proposed further development of test methods, e.g. profiling techniques. Such groups wanted to be consulted about risk-assessment criteria, though they had different views on directly participating in official procedures (BEUC, 2003). They sought accountability for the framing of scientific uncertainty but did not question the safety of GM foods already approved by the EU.

European experts had mixed feelings about their convergence and practical relations with consumer groups around issues of scientific uncertainty. They valued the interaction whilst also lamenting the politicisation of science and accusations of bias. For example:

My relations with consumer groups have been positive and negative. There have been discussions about the types of tests and their usefulness; these discussions have included consumer groups such as the Consumentenbond. On the negative side, some anti-GM people question my credibility (interview, Dutch expert advisor, 2003).

We need to clarify the distinction between legitimate and illegitimate uncertainty. Good scientists can recognise where experiments establish certainty or leave open uncertainty. But uncertainty is a ball played by stakeholders (interview, Austrian food scientist, 2003).

### *6.3 Toxicological Tests in Dispute*

Official experts too have played the uncertainty ball, thus providing scope for the further politicisation of science and scientification of politics. Experts disagreed about the ‘normal variation’ which could provide a baseline for comparing the different test animals, and thus the empirical basis for a judgement on substantial equivalence (Levidow et al., 2005: 269). Earlier difficulties over whole-food toxicology tests became a high-profile controversy around a specific product.

In autumn 2004 Monsanto’s MON 863 maize was moving towards EU approval for import only. Shortly before the EU regulatory committee was to vote on safety approval, journalists leaked a critical report by a French advisory committee from the previous year. It noted statistical anomalies, especially that GM-fed rats had lower kidney weights than the control animals. According to its report, the committee could not definitively conclude that risk was absent (CGB, 2003).

Deficient company science now became a high-profile issue, especially in France and the UK. Speaking to journalists, the CGB President emphasised the need for “sound, validated scientific results” on MON 863. Launching a mass-media campaign, the French NGO Crie-Gen declared, “experts acknowledge that GM food has significant effects on animals” (as quoted in Mennessier, 2004). The relevant German Ministry, headed by a Green Party politician, asked Arpad Pusztai to evaluate the rat feeding tests. Citing the differences in kidney weights, his September 2004 report advocated further studies on the immune response of animals in order to gain essential information. Citing these comments in turn, European environmental NGOs attacked the company’s scientific evidence.

However, EU experts rejected these criticisms. In their view, similar variations were found among animals fed conventional maize and so were unrelated to feeding with GM maize. Consequently, “Whilst some statistically significant differences were observed, these differences were not considered as biologically relevant since they fell within normal variation ranges”. EU experts stated that extra tests would be worthwhile only “if there are indications of the occurrence of unintended effects” from the product, but this was not the case for MON 863 (EFSA GMO Panel, 2004b: 4). The French CGB then reported that it had no concerns about risks to animal health from MON 863.

Despite the greater expert consensus, controversy continued. Some national experts wanted clarity on the normal baseline, as a stronger basis for judgements about biological relevance. According to a dissident member of the CGB, it was unacceptable for the product file to treat each risk issue separately, and the rat study should have been redone (quoted in Foucart, 2004).

A few months later similar risk issues were turned into the front-page story of a UK quality newspaper. The story now had extra twists: the company’s refusal to disclose raw data from the rat experiments; Pusztai’s role in criticising the available data; and his marginalisation by the establishment:

Here, environment editor Geoffrey Lean, who has led this paper’s campaign on GM technology for the past six years, examines the new evidence. And he asks the questions that must concern us all: Why is Monsanto, the company trying to sell GM corn to Britain and Europe, so reluctant to publish the full results of its alarming tests on lab rats? Why are our leaders so keen to buy the unproven technology against the wishes of consumers? And why is the man who first raised these concerns six years ago shunned by the scientific establishment and his former political masters? (Lean, 2005).

Such conflicts over company data persisted among member states, which increasingly criticised EFSA’s safety claims. To address this conflict, in April 2006 the Commission invited EFSA to clarify which specific protocols should be used by applicants to carry out scientific studies demonstrating safety, e.g. toxicology tests (CEC, 2006).

In sum, EU procedures moved towards more extensive and rigorous test methods for assessing GM food safety. This move opened up greater scope for expert disagreements about scientific evidence – indeed, for politicisation of science. The regulatory procedure had difficulties in establishing the cognitive authority of official EU experts and thus in stabilising ‘science-based regulation’.

## **7. Analysis: Trans-Atlantic Governance of GM Food Safety**

In the introduction to this paper we set an overall task: to analyse how different policy agendas framed scientific uncertainty around GM food. We also asked three questions about the concept of substantial equivalence: What agendas initially shaped the concept? How has its meaning changed over time? How can these changes be explained? After outlining the diverse framings of risk issues, this section answers the three questions. Overall this section draws on the theoretical concepts and arguments discussed earlier in this paper. We analyse the case over time, focusing on key processes, as follows: scientisation begun and blocked; scientification with politicisation; and governance through collective problems.

## *7.1 Framings of Scientific Uncertainty*

In the late 1990s an intense public controversy around GMOs gave European critics more opportunities to challenge risk-assessment criteria for GM products. In the GM food debate, scientific uncertainty about risk was framed according to three main policy agendas:

- 1) Pro-agbiotech groups: GM techniques are more precise than alternatives and they make GM food risks more predictable than conventional food risks. Risks are readily testable, especially through compositional tests, which can be standardised across countries. Such tests will indicate if additional knowledge is needed to detect unintended effects.
- 2) Anti-agbiotech groups: GM techniques are inherently risky by generating unknown hazards, although these might sometimes be revealed through risk research. Agricultural biotechnology is an extension of the industrial agri-food system, which has already harmed health and the environment. GM products are pollutants, which should not be permitted.
- 3) Mainstream consumer groups: Consumers have “a right to know and a right to choose” safe food. GM food carries uncertain risks which must be clarified through more rigorous methods. Safety depends on adequate, reliable and accountable science. Such science is essential for improving regulatory procedures and thus gaining consumer confidence.

In these frames, risk assessment was associated with regulatory efficiency, wider industrial hazards and consumer rights, respectively. Each framing had its own view of substantial equivalence as a basis for risk assessment. Together these frames constituted the uncertainties to be debated and clarified.

## *7.2 Scientisation Begun and Blocked*

When the concept of substantial equivalence was introduced, it provided a technocratic basis for scientising risk-assessment policy. The concept drew a line between science and policy, as if risk-assessment criteria lay on the side of science (cf. Jasanoff, 1987). The concept was then used to compare GM foods with their non-GM counterparts and to confirm their similarity as regards safety. At least initially, risk assessment emphasised tests of physico-chemical composition as the means to detect any unintended changes, while acute toxicity tests targeted the known novel protein. The concept was used to justify no or minimal regulatory scrutiny. It facilitated safety claims, limited demands for scientific information and avoided arguments over methodological difficulties.

In addition, substantial equivalence was used to standardise risk-assessment criteria across countries. This served the general OECD remit for efficient, harmonised regulatory regimes and thus trade liberalisation (cf. Newell, 2003). The US and the EU both adopted the concept in the 1990s. At the same time, it could be flexibly interpreted to accommodate different national contexts and new issues, thus making an inter-governmental consensus possible. Thus the pro-agbiotech frame informed early risk-assessment procedures, which facilitated trans-Atlantic commercialisation and trade liberalisation of GM products.

When European controversy over GM food erupted from 1997 onwards, however, substantial equivalence was vulnerable to attack by long-standing and new policy actors. This vulnerability had its origins in the policy agendas that had shaped the concept. Critics raised various doubts, which expressed of socio-political conflict over a contentious innovation. They drew analogies between biotechnological models of intensive agriculture and other health risks, especially mad

cow disease. They criticised substantial equivalence for playing down the novelty of GM food, for helping companies to bypass a risk assessment, and for minimising evidence of safety.

In the late 1990s protestors were opposing the use of scientific rationality to conceal political choices as technical ones, by analogy to previous technoscientific-risk controversies (cf. Nelkin, 1979). Safety approval was cast as an undemocratic submission to the US government and multinational companies; European activists turned GM food into an ominous symbol of ‘globalisation’ (cf. Lipschutz, 1997; Paterson et al., 2003). These developments undermined the public legitimacy of risk-assessment procedures, especially in Europe. The intense controversy blocked efforts to scientise policy through the concept of substantial equivalence.

### *7.3 Scientification with Politicisation*

The GM food controversy stimulated greater scrutiny of available test methods, thus challenging the initial meaning of substantial equivalence. Available tests were recast as being at or near the research frontier (cf. Weingart, 1999). The 1991 FAO/WHO expert consultation had warned governments about the weaknesses of compositional tests and any comparisons based on them, but the 1993 OECD report had ignored this warning. In the late 1990s compositional tests were then subjected to greater criticism, particularly on the grounds that they led to deceptive comparisons. Consumer groups sponsored their own expert reports, which challenged inconsistencies and weaknesses in the test data submitted by companies.

Under these circumstances European governments became more dependent upon scientific progress to justify their risk-assessment procedures. Long-standing tests became newly contentious (e.g. physico-chemical composition) and newly relevant (e.g. whole-food toxicology), even for GM foods similar to those already approved. This scientification process generated an abundance of knowledge which was open to diverse expert interpretations. This in turn created more opportunities to politicise science. Policy actors became engaged in an adversarial, inflationary competition – for expert claims, for the latest research results, for new test methods, and for any weaknesses in inconvenient results – on both sides of the controversy. This contest undermined the cognitive authority of science for regulatory purposes.

These dynamics are illustrated by methodological difficulties in testing whole foods on animals, as a non-targeted means to detect unintended effects. As discussed above, the UK government funded Pusztai’s research to improve such test methods, yet the experiments led to unexpected results, which were cited to raise doubts about GM food safety in 1998-99. This in turn polarised international expert networks, creating opportunities for NGOs and others to contest safety claims. Again in 2004 the results of whole-food toxicology tests became contentious for Monsanto’s MON 863 maize, as experts disagreed about the ‘normal variation’ as a meaningful comparator for GM-fed animals.

Through the processes of scientification and politicisation, therefore, public-scientific controversy broke the earlier link between science and policy. Various expert disputes undermined any separate realm of ‘science’, which had been central to the pro-biotech framing and early concepts of substantial equivalence. Contending policy agendas had effectively politicised regulatory science and thus weakened it as a basis for risk assessment. This contest left an unstable basis for distinguishing between reliable and unreliable knowledge for the safety assessment of GM foods. By contrast to the agro-environmental issues of cultivating GM crops, GM food safety had a relatively greater potential for scientific progress which could facilitate an expert consensus, but its realisation and legitimacy depended upon expert-stakeholder relations.

#### *7.4 Governance through New Collective Problems*

In the context of the European legitimacy crisis and trans-Atlantic trade conflict, various international fora were created or extended, e.g. the EU-US Forum, FAO/WHO expert consultation and the Codex Task Force. These fora began to accommodate the framing of mainstream consumer groups, which suggested that a more precautionary, rigorous and accountable form of risk assessment was necessary to gain consumer-public confidence. That new problem-definition created a broader common ground for more stringent criteria, while potentially transcending disagreements about their prior ‘scientific’ rationale in biotechnological risks.

In this way the arguments being made by consumer groups, which emphasised reducible uncertainties, converged with European expert proposals for more rigorous test methods. Based mainly in Europe, this convergence provided a basis to govern the societal conflict at national, EU and trans-Atlantic scales. Stakeholder relations were governed by constructing a new collective action problem – restoring consumer-public confidence – which did not obviously exist beforehand (cf. Young, 1997).

International processes and fora like the EU-US Forum extended informal alliances which were already arising within some European countries. The new Codex standards in particular exemplify governance as the result of “alliances between coalitions in global civil society and the international governance arrangements associated with the UN system” (cf. Lipschutz, 1997: 96). In these processes, leading roles were played by key individuals from the US and EU, just as policy actors from these jurisdictions had played leading roles in the earlier agenda of trade liberalisation. Thus this process can be seen as trans-Atlantic governance of GM food.

The new collective problem of restoring consumer-public confidence marginalised the anti-agbiotech frame, e.g. the problem of “GM pollution” imposing unknowable risks. Even when environmental protest groups participated in relevant events and consultations, risks were framed as reducible uncertainties. Through this process, more difficult political issues could be mediated or displaced by risk-assessment criteria, which remain open-ended. A focus on food safety separated biophysical risk issues from deeper conflicts over ‘GM food’ – a phrase symbolising an ominous form of globalisation, trade liberalisation and the further industrialisation of agriculture. In this way consumer groups participated in governing the conflict around a product that they did not welcome. Thus a governance process can render politics obsolete, leaving only managerial and procedural issues (cf. Pestre, 2006).

### **8 Conclusion: Science/Policy Boundary Shifts**

In sum, substantial equivalence has been recast in at least three ways: (1) it has been implicitly redefined, through extra phrases in official documents, to focus on looking for differences between a GM food and its non-GM counterpart; (2) it has been re-interpreted, as risk-assessment procedures have addressed more scientific uncertainties and have required more evidence of safety than before, especially in Europe; and (3) it has been demoted in EU regulatory procedures so that it can no longer be used to justify the claim that a risk assessment is unnecessary. By 2003 official experts were further softening the concept by calling it “a comparative approach”, as if it always had this more modest meaning.

In recasting substantial equivalence, the original boundary between science and policy was redrawn (cf. Jasanoff, 1987). A broadly defined ‘science’ informed early risk-assessment procedures, but later those ‘scientific’ criteria were recast as policy-laden or at least as mixed

issues. This shift involved and implied legitimate scope for the involvement of non-specialists, e.g. through consultation with NGOs and wider publics. At least in Europe, governments became less able to invoke a separate realm of ‘science’ to justify safety claims. Some regulatory authorities imposed more data requirements, although for various reasons, e.g. to demonstrate greater scientific rigour or to justify regulatory delays.

In European procedures more recently there has been a tension between two aims: re-establishing an ‘objective’ scientific basis for decisions, versus leaving risk-assessment criteria open for further policy debate with stakeholders. Expert advisors in particular faced the challenge of expanding their cognitive authority over a broader range of ‘science’ than before. They requested more rigorous data from a wider range of tests than before (see again Table II). Such pressures circulated among member states, often leading to further conflict over the data necessary for risk assessment and difficulties in stabilising such requirements.

Any science/policy boundary becomes less stable in the shift towards non-targeted approaches, which lie at research frontiers in looking for unknown changes. Consumer groups and expert advisors in Europe have welcomed this prospect, but industry has warned against any premature requirements, which could generate yet more ambiguous data. Indeed, further scientification could readily bring more politicisation of science.

This paper has extended interdisciplinary approaches to the study of technoscientific-risk controversies, especially by linking analytical perspectives on regulatory science and governance. Through the interaction of three contending risk frames, the consumer “right to safe food” converged with the problem of consumer-public confidence and expert moves towards more precautionary, rigorous risk assessment. A governance process played many roles including: facilitating interactions between stakeholders; accommodating some critics rather than others; managing conflicts over safety claims; and displacing fundamental conflicts over technological choices. In these ways a governance process can help legitimise an expert basis for regulatory decisions, but this basis remains vulnerable to further politicisation.

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**Table I****Key Events in the Changed Meaning of Substantial Equivalence****I.1 Implementing the concept (early to mid 1990s)**

1990: EC Directive 90/220 on deliberate release of GMOs into the environment.

1992: US FDA guidelines emphasise analytical tests of chemical composition, as a basis to establish the ‘substantial similarity’ of a novel food with a familiar one Generally Recognised as Safe (GRAS).

1993: OECD guidelines present ‘substantial equivalence’ as the international consensus on how to assess the safety of GM food. They ignore expert warnings about absent information for comparisons with a conventional counterpart.

1996: FAO/WHO expert consultation endorses OECD approach.

1997: EU Novel Food Regulation 258/97 includes a simplified procedure which allows companies to avoid a risk assessment if they can show that a GM food is ‘substantially equivalent’ to an existing safe food.

1998: Trans-Atlantic Economic Partnership is created. Its Action Plan proposes a pilot project on ‘simultaneous scientific assessments’ of a GM product in the US and the EU, thus following an agenda from the Trans-Atlantic Business Dialogue (TABD).

**I.2 Challenging the concept (mid to late 1990s)**

1996: Consumers International publish a report critical of ‘substantial equivalence’.

1996/97: Europe receives first shipments of US maize and soya containing GM grain, leading to public protests.

1997: For implementing EU Regulation 258/97, UK Advisory Committee on Novel Foods (ACNFP) accepts ‘substantial equivalence’ for the simplified procedure only in cases where no intact GM DNA or protein remains after processing.

1998: EU regulatory committee adopts UK’s more stringent criteria for the simplified procedure.

1998: Trans-Atlantic Consumer Dialogue (TACD) is created as a counter-weight to the TABD.

1998: Arpad Pusztai announces unexpected alarming results of his GM lectin experiments on a UK television programme. The Royal Society attempts to undermine his claims, even before publication, and *The Lancet* criticises the Royal Society.

1999: EU Environment Council members begin an unofficial de facto moratorium on authorising additional GM products. They demand that the authorisation procedure be made transparent, based on precaution.

1999: Millstone et al. criticise substantial equivalence as ‘unscientific’ in an article in *Nature*. Others defend the concept as a risk-assessment tool.

1999: Arpad Pusztai publishes experimental results which are cited to undermine safety claims for GM food., leading to polarisation between international expert networks

### **I.3 Recasting the concept (late 1990s to early 2000s)**

1999: Codex Alimentarius sets up an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology.

2000: TACD criticises substantial equivalence and calls for ‘more robust methods’ to test safety.

2000: EU-US Consultative Forum on Biotechnology issues its report, which accepts the concept of ‘substantial equivalence’ but highlights the need for better methods to identify unintended and potentially harmful changes in GM food.

2000: FAO/WHO expert consultation emphasises that substantial equivalence should guide efforts to look for differences and similarities between a GM food and its non-GM counterpart.

2003: Codex adopts standards based on the FAO/WHO expert report, thus implicitly redefining substantial equivalence.

2004: EU experts emphasise ‘a comparative approach’ as the meaning of substantial equivalence.

### **I.4 Changing regulatory practice in the EU (early 2000s)**

2000: Italy invokes safeguard clause of Regulation 258/97 to suspend the authorisation of GM products, on grounds that substantial equivalence was not demonstrated under the simplified procedure. European Commission asks Italy to lift the ban and requests support from other member states, who instead criticise the simplified procedure in the Regulation.

2001: European Commission proposes a new Regulation on GM Food and Feed, which does not include a simplified procedure based on substantial equivalence, partly on grounds that it has “been very controversial in the Community in recent years”.

2002: EU’s Scientific Steering Committee circulates draft guidance for GM products, specifying tests for food safety.

2003: As new product files circulate among EU member states, some criticise weaknesses in available data. on GM food safety. Results of whole-food toxicological tests generate disagreements among member states, leading to mass-media coverage in 2000-05.

2004: EU experts consult stakeholders before finalising new guidance for GM products.

2006: The European Commission invites EFSA to clarify which specific protocols should be used by applicants to carry out safety tests, e.g. for toxicology.

**Table II Safety Tests for Novel Foods: Methodological Uncertainties and Changes**

Since the late 1990s doubts have been raised about the test methods available for testing the safety of novel foods, especially those derived from GM crops. There were proposals to improve the tests and to develop more sensitive or rigorous ones. Expert advisory bodies proposed changes which gave more complex meanings to the concept of substantial equivalence. Non-target approaches were developed to detect unintended changes and unknown risks. Documents cited below indicate how such changes responded to doubts and criticism of available test methods.

Risk issue and test	Doubts raised	Proposed changes
Physico-chemical composition: establishing a 'normal' baseline of conventional products, for evaluating equivalence of a GM food	<p>Incomplete data available on non-GM counterparts (CI, 1996; Schenkelaars, 2002)</p> <p>Normal baseline has great variation, linked to field conditions during cultivation. (Haslberger, 2002; Schenkelaars, 2002)</p> <p>Doubts about how to specify acceptable degrees of compositional differences (Kuiper et al., 1999)</p>	<p>Collect more systematic data on conventional products, to gain a reliable baseline of natural variation (EFSA, 2004a).</p> <p>Evaluate any compositional differences vis à vis the range of natural variations (CAC 2003a)</p> <p>Use standard and/or varied conditions for cultivating the crop, to test a range of contexts (SSC, 2002; CAC 2003a).</p> <p>Provide data on secondary metabolites (CAC, 2003a; EFSA, 2004a).</p> <p>Develop new profiling techniques such proteomics and chemical fingerprinting (Noteborn et al., 2000; EFSA, 2004a)</p>
Toxicity: testing a novel protein by acute toxicity tests on lab animals	<p>Difficult to obtain a large amount of plant-derived pure protein; easier to use a microbe-derived substitute, which may be different.</p> <p>Test can detect only known novel proteins, not unintended or pleiotropic effects (SSC, 2000).</p>	<p>Must demonstrate equivalence of any microbial substitute.</p> <p>Use 28-day repeated-dose test (SSC, 2002) [contrasts with industry proposal for 14-day test as an adequate method]</p> <p>Non-targeted approaches could detect unintended effects (FAO/WHO 2000).</p>
Toxicity and/or nutritional quality: testing whole foods on lab animals	<p>Difficult to feed/consume large quantities of a whole food, which itself can yield anomalous results.</p> <p>Difficult to maintain equivalent nutritional content across GM and controls (US FDA, 1992).</p>	<p>If warranted, use a 90-day test avoiding any nutritional imbalance (FAO/WHO, 2000; SSC, 2002; EFSA, 2004a).</p> <p>Develop new profiling techniques such as metabolomics (Noteborn et al., 2000; EFSA, 2004a)</p>
Allergenicity: searching for similarity to a known allergen	<p>Small difference in sequence homology or structural similarity can make a large difference in allergenicity (Donabauer &amp; Valenta, 2002; Spök et al., 2005).</p>	<p>Search method for allergens must be scientifically justified, to avoid false positives or negatives (SSC, 2002; CAC 2003a).</p> <p>Use relevant validated immunochemical tests (CAC 2003a; EFSA, 2004a)</p>
Allergenicity: digestibility-degradation tests of protein stability	<p>Test results can give false negatives (CI, 1996).</p> <p>Results are contingent on the experimental design, e.g. timespan and concentration of pepsin exposure (CSPI, 2003)</p>	<p>Degradation test must be well-validated (SSC, 2002; CAC 2003a).</p>