THE JEAN MONNET PROGRAM

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Jean Monnet Working Paper 04/04
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European Regulation of GMOs: Thinking about ‘Judicial Review’ in the WTO

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Abstract

This paper examines the role of ‘judicial review’in the WTO, by reference to a case study on the European regulation of GMOs. It argues that ‘judicial review’ may, in this setting, be conceived as re-enforcing rather than negating democracy, by enhancing accountability, and in particular the external accountability of states. It draws on the work of Robert Keohane, who understands external accountability as accountability to people who while situated outside of a given polity are affected by decisions adopted within it. The paper supports this argument with reference to cases such as Shrimp/Turtle and, more recently, GSP. It concedes, however that as the Appellate Body of the WTO comes to elaborate stronger substantive benchmarks for review – rationality or proportionality type tests – ‘judicial review’ also raises a democracy dilemma for the WTO. One aspect of this dilemma concerns the place of public opinion in risk regulation, and the legal entitlement of Member State governments to be responsive, in their regulation, to such opinion. This democracy dilemma presents an audacious challenge for the WTO, and one which admits of no easy or absolute answers.

European Regulation of GMOs

The European approach to the regulation of genetically modified organisms (GMOs) is predicated upon the concept of prior approval. The legal framework for prior approval is finally in place. Amidst a mass of legislation, two instruments stand out as central, viz.
the 2001 Deliberate Release Directive,¹ and the 2003 GM Food and Feed Regulation.² As may be exemplified by specific reference to the latter, European Union law performs a three-fold function in relation to the prior approval of GMOs.

1 Reader in European Law, University of Cambridge. Visiting Professor, Columbia Law School (Spring 2004). This paper is based upon a lecture given at University College London in December 2003. It will be published in (2004) Current Legal Problems which is published on behalf of the UCL Faculty of Law. Many thanks to Jane Holder and Michael Freeman for the invitation to present this lecture, and to Lord Hope of Craighead in his capacity as Chair. Thanks also to them and to all present for their thoughtful comments and questions. Gráinne de Búrca, Jeffrey Dunoff, Rob Howse, Maria Lee, Petros Mavroidis, Bill Simon and Margaret Young kindly read a draft of this paper and provided valuable comments; not all of which I have been able to take on board in this paper. Errors and misconceptions definitely remain my own.

First, European Union law identifies the objectives which may legitimately be pursued by the system of prior approval. The range of objectives is somewhat expanded in the GM Food and Feed Regulation. Alongside the critical internal market objective, this is concerned not only with the protection of human life/health and the environment, but also with animal health and welfare and ‘consumer interests in relation to genetically modified food or feed’. Though expanded, the range of underlying objectives nonetheless remains finite. No authorization shall be granted or refused other than on the grounds set out in the Regulation. The paradigm for prior approval is fixed and closed. Viewpoints which cannot be accommodated within this paradigm will be excluded, and voices which do not resonate within this paradigm will not be heard. To take an example, there is provision in the GM Food and Feed Regulation for consultation with the European Group on Ethics in Science and New Technologies. Yet, other to the extent that ethical concerns may be packaged as integral to the attainment of the above objectives, their place in prior approval is not clear. Similarly, it is for the European Commission to draw up a draft of the authorization decision in respect of GM food or feed. In so doing, it shall take account not only of the opinion of the European Food Safety Authority (EFSA), but also of ‘other legitimate factors relevant to the matter under consideration’. In view of the strictures above – requiring that no authorization be granted or refused other than on the grounds set out in the Regulation – the place of ‘legitimate factors not integrally connected to the closed list of stated objectives remains, at best, uncertain.

The second function performed by EU law in relation to GMOs is to structure the governance arrangements according to which prior authorization will proceed. The arrangements are elaborate. Every detail was contested in the course of legislative enactment. The system is:

- multi-level, involving actors across different levels of government, from the local to the European. In a multi-level system of governance, the question of balance of power is all important. All participate but all are not equal. In the GM Food and Feed Regulation, as noted, it falls to the Commission to draw up a draft of the authorization decision. The final decision will be taken in accordance with a regulatory committee procedure, implying an overall supervisory function for the Member States, via their representatives in the Standing Committee on the Food Chain and Animal Health, and ultimately via their representatives in Council.8

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3 Supra n. 2, Article 1. This contrasts with Article 1 of the deliberate release directive which is concerned only with the protection of human health and the environment. It is interesting to observe that neither the environment nor the consumer protection legal bases were included among those upon which the 2003 Regulation rests. Given the centrality of these objectives to the regime established this seems strange. One explanation might lie in the fact that the Regulation seeks to achieve exhaustive harmonization which would not be in keeping with the minimum harmonization approach laid down in the areas of environment and consumer protection.

4 Supra n. 2, Article 4(5).

5 Supra n. 2, Article 33.

6 Supra n. 2, Article 7(1).

7 Supra n. 2, Article 35(2).

8 See generally, supra n. 2, Article 7.
this way, power does not accrue exclusively to any one level of governance, but is shared across the different levels. Significant too, in assessing power relations between the different levels, is the question of the residual autonomy enjoyed by Member States, or by regions, following the conclusion of a European wide position on authorization. This autonomy may flow from the EC Treaty – by way of the Article 95 ‘environmental guarantee’ for example. It may flow also from the text of the governing legislation, and in particular by virtue of the inclusion therein of a safeguard clause conferring emergency powers. It is notable that the safeguard powers of the Member States are significantly have been significantly curtailed in the 2003 GM Food and Feed regime, relative to earlier measures.

- multi-actor, in that it establishes a role for political and expert actors. The expert dimension has been given a glossy new exterior with the establishment of EFSA. This is to operate in accordance with certain foundational values; notably independence, scientific excellence, transparency and diligence. This new agency is charged with issuing an opinion on any application for the authorization of GM Food or Feed. It shall give reasons for this opinion and include information upon which it is based. Responsibility for the provision of this opinion will rest with the EFSA scientific panel on genetically modified organisms. Where the Commission’s decision is not in accordance with this opinion, it must provide an explanation for the differences. It is at least arguable, on the basis of the case law, that any such explanation must give reasons for departure which operate at a ‘scientific level at least commensurate’ with that of the EFSA opinion. The role for public opinion in the GM Food and Feed authorization process is small. The public may make comments to the Commission on the EFSA opinion. No further provision is made as to the manner in which these comments are to be taken into account. As a form of public participation, these provisions are notably weak. They stand in contrast to

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9 For an example of the Commission denying the lawfulness of recourse to Article 95(5) in respect of GMOs, see Commission Decision 2003/653 OJ [2003] L230/34. This concerned a notification put forward by Austria concerning a blanket ban on GMOs in North Austria.
10 See supra n. 2, Article 34 which is parasitic upon the emergency measures laid down in the Regulation laying down the general principles and requirements of food law, and establishing the European Food Safety Authority. Regulation 178/2002 OJ [2002] L31/1. See specifically Articles 53 and 54. The bottom line here is that Member States may only make autonomous recourse to emergency measures where the Commission has not acted, and even then only for a period of ten days within which time the matter must go to the Standing Committee on the Food Chain and Animal Health for extension, amendment or abrogation.
12 Supra n. 2, Article 22(7). This speaks of the ‘scientific and technical quality of the opinions which it issues’ for which I have substituted ‘excellence’ above. This language of excellence derives from the case law of the CFI. See Case T-13/99 Pfizer [2002] ECR II-3305.
13 Supra n. 10, Regulation 178/2002, Article 6(6).
14 This is a standing panel, the membership of which is listed on the web.
15 Supra n. 10, Regulation 178/2002, Article 7(1)
16 Supra n. 12, Pfizer.
17 Supra n. 10, Regulation 178/2002, Article 6(7).
more ambitious experiments in public participation in EU environmental law more generally.\textsuperscript{18}

The \textit{third} function of European law in relation to GMOs is a disciplinary one. It serves as a basis to discipline the recalcitrant, be they Member States or Community institutions. This discipline may seek to prise open the markets of reluctant Member States. It may serve to ensure compliance with established procedures for the authorization of GMOs. Conceivably at least, it could serve also to question the adequacy of the level of protection pursued.\textsuperscript{19}

To date, this disciplinary dimension has taken a back-seat. This is surprising in view of the fact that the entire system for the authorization of GMOs ground to a halt in 1998.\textsuperscript{20} Neither the Commission, nor private companies, have exploited the legal avenues open to them in a bid to kick-start the system on the books. The Commission has long desisted from deploying Article 226 in mounting actions against recalcitrant Member States. It has sought instead to engage in a constructive exercise in regime building, hoping to buy the trust and support of the Member States through the elaboration of a new framework for authorization. The new framework is now in place and still a majority of Member States is refusing to step into line. The Commission’s patience has run out and in 2003 it initiated proceedings against fourteen Member States for their failure to implement the 2001 Deliberate Release Directive.\textsuperscript{21} Still it has taken no action in respect of repeated instances of legally-suspect Member State recourse to safeguard powers. This reticence of the Commission, in deploying legal enforcement tools, is made possible by virtue of its unfettered discretion in respect of Article 226 EC. The Commission may decide to proceed against an allegedly offending Member State. Or it may decide not to. The existence of such discretion has often provoked the fury of environmentalists. On this occasion though, it has served them well by allowing the Commission to stand back in the face of blatant and repeated illegality. It has served to allow the law to stand aside, pending political resolution.

The reluctance of the disciplinary dimension should not, however, be allowed to conceal the very great activity of the European courts in the area of risk regulation. While, bar \textit{Monsanto},\textsuperscript{22} the case law is not specifically concerned with the issue of GMOs, the findings of the courts nonetheless bear directly upon this question. Notable in this respect are the pronouncements of the courts on the so-called precautionary principle.\textsuperscript{23} These have served to delineate in some detail, the circumstances in which Community

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\textsuperscript{18} The example of environmental impact assessment is exemplary in this respect. See, especially Directive 2003/35 OJ [2003] L156/17 and especially Article 3.
\textsuperscript{19} See Case C-236/01 \textit{Monsanto} judgment of 13 March 2003.
\textsuperscript{20} See the Institute of International Economic Law at Georgetown site for an excellent overview of developments in the EU and in the WTO as regards GMOs: http://www.law.georgetown.edu/iel/current/gmos/
\textsuperscript{22} Supra n. 19.
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institutions (or Member States) may enact protective measures to guard against risk. Two aspects are particularly striking. First, while the courts grant a wide margin of discretion to the political branch, this discretion is made contingent in two important respects. First, and in language strikingly resonant of the WTO Appellate Body, ‘a preventive measure cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically verified’. The precautionary principle can therefore apply only in situations in which there is a risk, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated. Second, legality will be assessed having regard to a wide range of procedural criteria. For example, a scientific risk assessment must be carried out which is based on the principles of excellence, transparency and independence. While, for reasons of ‘democratic legitimacy’ the decision-maker may disregard scientific advice, it must give specific reasons for so doing, and the statement of reasons must be ‘of a scientific level at least commensurate with that of the opinion in question’. It must fight science with science.

As noted, the language of the Court of First Instance is strongly resonant of that of the WTO Appellate Body, notably in the Hormones case. Here, it lays emphasis upon the fact that ‘theoretical uncertainty’ of the kind that arises ‘since science can never provide absolute certainty that a given substance will not ever have adverse health effects’ is not the kind of risk which can ground protective measures under Article 5.1 of the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). The WTO Agreement does not have direct effect in Community law, but it does enjoy indirect – or interpretative – effect. The evolving understanding of the precautionary principle in Community law represents a single and striking example of this. The salience of this extends beyond the sphere of risk regulation. It is of constitutional importance. Direct effect was denied on the basis of a need to preserve the autonomy of the political and legislative branches, notably in view of the room for manoeuvre which they enjoy under the WTO Dispute Settlement Understanding. In the event that WTO ‘recommendations and rulings’ are not implemented within ‘a reasonable period of time’, ‘compensation and the suspension of concessions or other obligations are temporary measures available’ as alternatives. Yet, this room for manoeuvre may be just as effectively – if frequently less visibly – undermined by way of interpretative fidelity to the WTO.

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24 Pfizer, supra n. 12, para. 143.
25 Pfizer, supra n. 12, para. 146.
26 Pfizer, supra n. 12, para. 172.
27 Pfizer, supra n. 12, para. 199. On the democratic legitimacy point, see para. 210 where the CFI observes that ‘That finding can also be justified on grounds of principle relating to the political responsibilities and democratic legitimacy of the Commission. While the Commission’s exercise of public authority is rendered legitimate, pursuant to Article 155 of the EC Treaty… by the European Parliament’s political control, the members of SCAN [Scientific Committee on Animal Nutrition], although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority’.
28 EC – Hormones (WT/DS26/AB/R).
29 Ibid, para. 187.
31 Article 22, WTO Understanding on the Settlement of Disputes.
This takes us on to the WTO. In this domain we do not find any bespoke regime devoted to the regulation of GMOs. There is no WTO side agreement on GMOs. Instead, what we find is a series of agreements containing broad and open-ended obligations; obligations which are characterized by the kind of deep ambiguity which is often the hallmark of consensus-based drafting. It may be, nonetheless, that the same tripartite division of functions outlined above will serve us also in the case of WTO law.

The WTO Agreement serves to identify the objectives which may be legitimately pursued by the Member States. Article XX GATT, for example, lays down a series of general exceptions. These relate, for example, to the protection of human, animal or plant life or health, and the conservation of exhaustible natural resources. The SPS Agreement represents an elaboration of GATT, Article XX(b) and is concerned only with measures which are applied to protect human, animal or plant life or health. The Technical Barriers to Trade is more open-ended. Here, Member States may adopt measures which are necessary to fulfill a legitimate objective. While the agreement identifies some such objectives, the list is not exhaustive.

It is clear that the nature of the objective pursued will have a bearing upon the legal framework according to which an assessment of conformity will proceed. Thus, for example, an SPS measure is functionally (as well as territorially) defined. These are measures which are applied with a view to protecting human, animal or plant health from certain specified risks. These include risks to human or animal life or health arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs. The nature of the objective pursued is thus critical in classifying a measure as an SPS measure. Uncertainty remains as to whether the underlying objective is to be ascertained by reference to considerations of subjective intent, or on the basis of objective factors embedded in regulatory design or text. The locus of protection must be the


33 See recital 2 of the preamble to this agreement and Article 2.1. See also Annex A for a long and convoluted definition of what constitutes an SPS measure. This is defined not only in terms of the objectives being pursued but also on the basis of the nature of the risk which the Member State is seeking to guard against. It also has a territorial dimension in that a measure will only be classified as an SPS measure if it seeks to protect the objective in question within the territory of the regulating state.

34 Article 2.2 TBT.

35 Annex A.1 SPS.

36 Australian Salmon (WT/DS18/AB/R). On a different point, the AB, in its application of the Article 5.5 consistency requirement the AB looked to Australia’s explicit (stated) level of protection as regards ocean-
territory of the regulating state. To the extent that any EU import restriction or approval decision is applied in pursuit of any other objective, that measure will fall outside of the SPS Agreement. Technical regulations, on the contrary, are not functionally (or territorially) limited in this way. Nor would they seem to have their basis in subjective intent. What is not clear is the manner in which a measure is to be characterized where it pursues a range of objectives which cut across two (or more) distinct agreements, with their distinct—and very different—disciplines. This issue would seem likely to arise as regards the 2003 GM Food and Feed Regulation itself, and in respect of specific authorization decisions adopted thereunder. This issue may be approached in one of at least two ways.

First, and in a manner reminiscent of the European Court in its legal basis case law, the dispute settlement bodies might adopt a ‘principal-ancillary’ objective approach. According to this they would search out the ‘centre of gravity’ of the measure, where possible singling out its primary purpose in a bid to identify the applicable agreement. Thus, decisions relating to the prior authorization of GM food will contain reasons, and the EFSA opinion issued in relation to that application will be made public. It may be possible, extrapolating from these, to determine the primary purpose of the contested measure. Nonetheless, as the legal basis case law shows, this is not always easy to do and, on occasion, simply not possible. It is at any rate an artificial solution in the context of a regulation which pursues multiple objectives, and in the context of authorization decisions which may seek to serve diverse aims. It conceals the multi-faceted nature of the regulation, in a bid to accommodate the formality of law.

Alternatively, the dispute settlement bodies might acknowledge the multiplicity of the objectives pursued, and desist from ranking these in order of importance. They might seek to disentangle the various components co-existing within a given measure, placing the different bits in different WTO boxes, according to the objective being pursued. Thus, in so far as a measure is predicated upon public health concerns of the kind contemplated by the SPS Agreement, it would fall for scrutiny according to the terms of this agreement. In so far, however, as it pursues consumer welfare goals, it would escape the strictures of SPS, and fall for consideration under the TBT Agreement and/or the GATT.

This approach presents practical and legal challenges. Taking labeling by way of characteristically complex example. The labeling provisions of the GM Food and Feed

caught Pacific salmon on the one hand, and to the level of protection ‘reflected in’ Australia’s treatment of herring used as bait and live, ornamental finfish (para. 158), the latter seemingly in the absence of any explicit statement. This might seem to suggest that it is only in the absence of stated intention that the panel/AB will seek to ascertain intent on the basis of the actual measure and perhaps its surrounding context. See also the report of the panel at para. 8.107.

37 Annex 1.1 TBT.
38 See, for example, C-155/91 Commission v. Council [1993] ECR I-139.
39 In the (in)famous Titanium Dioxide case (Case 300/89 Commission v. Council [1991] ECR I-2867, para. 13) the European Court found that the contested measure was ‘indissociably’ concerned with the two objectives in question, namely the protection of the environment and the elimination of disparities in conditions of competition.
Regulation are said (in the preamble) to pursue multiple objectives. Some of these are such that they would tend in the direction of the application of the TBT Agreement (consumer information, fairness of commercial transactions, religious or ethical concerns). Others are such that SPS might apply (nutritional value, protection of public health of certain sections of the population). The labeling provisions in the Regulation, or the labeling dimension of any authorization decision, would have to be dissembled yet further simply with a view to identifying the applicable disciplinary regime. A single concrete measure may be, at once, an SPS measure and a TBT measure in view of the multiplicity of objectives which underpins it. The measure is only an SPS measure in so far as it pursues a public health objective. In so far as that same precise requirement is imposed in the name, for example, of consumer information or market transparency, it constitutes a technical regulation. The measure may be justifiable as one, but not as the other. It may, in its SPS guise, constitute a breach of that agreement, while at the same time be acknowledged as necessary to fulfill a legitimate objective, and thus as acceptable under the TBT Agreement.

This conclusion is, however, contingent upon an acceptance that a single measure may, at one and the same time, be an SPS measure and a technical regulation. This may, however, be thought to sit uncomfortably with the text of the TBT Agreement which explicitly provides that it does not apply to SPS measures, as defined in Annex A of the SPS Agreement. A measure which is applied, inter alia, with a view to fulfilling an SPS objective is an SPS measure. As such, it is not technical regulation. And this, in a sense, is the danger against which the AB must guard. It must guard against the imperialism which might be thought to inhere in the SPS Agreement by virtue of this wording. Where a measure is multi-faceted, it must be considered in all its facets. This may require a feat of mental acrobatics as a single measure – pursuing multiple objectives – comes to be conceived at one and the same time as, and not as, an SPS measure. Even then there is a danger that regulatory objectives will be assessed in isolation one from the other, each objective standing or falling alone, unable to gain strength one from the other in conditions of mutual reinforcement rather than isolation. But at the very least, no one objective should be allowed to silence the others on the basis that a measure, once an SPS measure is always, and only, an SPS measure.

Moving on to the second function of WTO law, the WTO Agreement may also be conceived as shaping governance arrangements with respect to the regulation of GMOs. Thus, as will be discussed further below, the various agreements establish a variety of procedural obligations relating to governance. To take a single example for now, the TBT Agreement contains quite detailed notification and consultation requirements. Member States must publish a notice of proposed technical regulations and notify other Members of their scope, objective and rationale. They must, further, allow a reasonable time for other Members to make written comments on these proposed measures, and take these written comments (and the results of any discussions about them) into account.40

Finally, there can be no doubt that the WTO Agreement serves to discipline recalcitrant states. Leaving aside issues of practical compliance, Members must bring their measures

40 See in particular Article 2.9-2.12 and Article 10 TBT.
into conformity with WTO rulings within a reasonable period of time. Where they fail to do so, they must, if requested, enter into negotiations with a view to developing mutually satisfactory compensation. If this is not agreed, the complaining party may request permission to suspend concessions or other obligations under the covered agreement.41

As noted previously, neither compensation or suspension of concessions is to be preferred to full implementation. It may be anticipated that this disciplinary dimension may come to the fore in the coming months. As is well known, the United States, Argentina and Canada have initiated dispute settlement proceedings against the EU in the WTO in the area of GMOs.42 This is directed against the EU’s so-called moratorium on GMOs, whereby applications for authorization are allegedly not being processed even in accordance with the demands of the EU’s own regime. It is directed also at the actions of the Member States in respect of their widespread (and allegedly WTO-incompatible) recourse to safeguard powers established under the relevant legislation.43

Even if – as suggested – this same tripartite division of functions may assist in understanding the role of the WTO in relation to the regulation of GMOs, one crucial difference at least may be identified. This relates to the relative prominence of the role of the ‘judicial branch’ in the WTO, as compared to the EU. The EU’s GM regime has been painstakingly constructed over many years. It establishes a legislative framework which is specific to GM and mind-boggling (or mind-numbing) in its detail and complexity. Its elaboration followed long and fierce debates between the different political branches at EU level and between the different Member States (and their constituents including sub-state actors). Of course, interpretative questions remain. Some have already been alluded to, such as the scope and role of ‘other legitimate factors’ in the course of prior approval. Though ambiguities remain it would, however, be foolish to deny the additional degree of interpretative discretion enjoyed by the WTO’s judicial branch in this sphere. As already observed, the lawfulness of the EU’s regime will, from the perspective of the WTO, be assessed in the light of a series of supremely open-ended pronouncements. In so far as it falls for consideration under the SPS Agreement, these bodies will be charged with assessing whether the contested measure is supported by sufficient scientific evidence, or whether it is based upon a risk assessment.44 To the extent that it falls within the ambit of the TBT Agreement, the ‘judicial organs’ will be required to ascertain whether the contested measure is necessary to secure fulfillment of a legitimate objective.45 As regards the application of the GATT, these bodies may be required to develop and apply criteria on the basis of which the

41 Article 23 DSU.
42 See: European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291/23), p. 1. Note that the complaint is also directed at the actions of the Member States which ‘maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC’. This refers to Member State recourse to their safeguard powers, especially under the (1990) deliberate release directive. As the EC has exclusive competence in trade in goods, it has responsibility regardless of the identity of the state actor said to be committing a breach.
43 The EC has exclusive competence in the area of trade in goods. Hence, the action is taken in the name of the EC even where the wrong-doing is perpetrated by the EC Member States.
44 Articles 2.2 and 5.1 SPS. Subject, of course, to the possibility of adopting provisional measures on the basis of Article 5.7 SPS where there is an insufficiency of scientific evidence.
45 Article 2.2 TBT.
‘likeness’ of GM and conventional products may be assessed.\textsuperscript{46} At the level of the WTO there is no elaborate legislative regime, painstakingly constructed over the course of several decades. At the level of the WTO – a commitment to textual fidelity notwithstanding – the answers will not leap forth from the text, but will flow from the judgment of those charged with its elucidation. In the WTO, the role of the judicial branch is key.

The WTO dispute settlement bodies are called upon to perform a judicial review type function vis-à-vis decisions of the Member States.\textsuperscript{47} This function is performed by a WTO panel, subject to the possibility to appeal on points of law to the Appellate Body (the AB). Contrary to the situation under the GATT, the adoption of panel and AB reports by the inter-governmental Dispute Settlement Body is virtually automatic, requiring consensus against in order to prevent this.

This judicial review function may be performed in respect of executive or administrative acts, but it bites also in respect of legislative acts, including those adopted by democratically elected parliaments within the Member States. In performing this task the AB enjoys extensive interpretative room for manoeuvre. It is called upon to exercise judgment. This fact of judicial review at the level of the WTO presents a profound challenge to the legitimacy of this organization from the perspective of democracy. The challenge is not unique to the WTO. It inheres in the institution of judicial review more generally. For this reason, it may be useful in contemplating the challenge to consider the reactions which it has provoked in domestic debates.

It was Alexander Bickel who coined the – by now almost hackneyed – phrase ‘the counter-majoritarian difficulty’.\textsuperscript{48} Alluding to the power of ‘a handful of unelected and unaccountable judges to strike down laws passed by a representative legislature’,\textsuperscript{49} this difficulty casts doubt upon the compatibility with democracy of judicial review of legislation. It casts doubt upon the very idea of ‘constitutional democracy’, in so far as it is judges who are charged with interpreting and applying the constitution, and with

\textsuperscript{46} Article III.4 GATT.

\textsuperscript{47} The WTO dispute settlement bodies – the panels and the Appellate Body – may be conceived of performing a judicial review type function. Their role is to assess the compatibility of measures adopted by WTO Members with the terms of the WTO Agreement. While the dispute settlement bodies do not annul measures which are incompatible, ‘[p]rompt compliance with recommendations or rulings of the DSB [Dispute Settlement Body] is essential in order to ensure effective resolution of disputes to the benefit of all Members’.Article 21.1 DSU. It is true that compensation and suspension of concessions are available as alternatives to compliance. These are, however explicitly stated to be ‘temporary measures’, and neither is to be ‘preferred to full implementation of a recommendation to bring a measure into conformity with the covered agreements’.Article 22.1 DSU. For a recent discussion of the relationship between these alternatives, see J.H. Jackson, ‘International Law Status of WTO Dispute Settlement Reports: Obligation to Comply or Option to “Buy Out”’ (2004) 98.1 American Journal International Law 109. While this issue concerning the obligations of parties found to be in breach of the WTO Agreement is of great importance, and should be constantly borne in mind, it will does not form the subject matter of discussion in this paper.


\textsuperscript{49} J. Waldron, \textit{Law and Disagreement} (OUP, 1999), p. 286
upholding the rights which it is deemed to protect. Different strategies have been developed to attempt extrapolation from the counter-majoritarian difficulty.

Some seek to disparage the democratic credentials of the legislative branch:

It is surely the case that the assumption that legislatures have a lock on democratic legitimacy is seriously flawed. First, legislative outcomes are not majoritarian: legislative outcomes do not truly manifest majoritarian will and consequently their later setting-aside by courts, whatever it might do, does not upset decisions made by a majority. Individual legislators rarely claim to vote in line with the preferences of their constituents and, when they function as group, there is no evidence to suggest that the outcome on any particular issue will coincide with majoritarianism.\textsuperscript{50}

Christopher Eisgruber agrees. ‘Electorates and legislatures will distort the judgments of the people in predictable ways’, due in part to the incentives faced by voters and legislators ‘to make political decisions on the basis of self-interest’.\textsuperscript{51} Even if the legislative will could be regarded as representative of the majority, still – for some – it should not be equated with democracy. Thus for Eisgruber, for example, majority rule ‘cedes government to a mere fraction of the people’, whereas democracy demands ‘government by the whole people’.\textsuperscript{52}

Many, often building on this, seek to defend the democratic credentials of judicial review. There are versions of this approach galore.\textsuperscript{53} The nuance of the argument need not detain us here. Suffice it to note the existence of two broad schools.

For some, the democratic credentials of judicial review lie in its capacity to constitute and perfect the political process, rendering it more authentically democratic. Within this group, some will place emphasis upon the protection of procedural rights (as opposed to substantive values) – and in particular upon ‘the right of rights’, participation,\textsuperscript{54} notably on the part of minorities whose interests may tend to be swamped by open majoritarian processes.\textsuperscript{55} Others within this group may go further, conceiving democracy as more

\textsuperscript{50} A. Hutchinson, ‘The Rule of Law Revisited: Democracy and Courts’ in D. Dyzenhaus, Recrafting the Rule of Law (Hart, 1999), p. 206
\textsuperscript{52} Ibid. p. 8 & p. 7.
\textsuperscript{53} For a discussion and references to the broad literature see Waldron, supra n. 49, chapter 13. Waldron is, of course, the best known and most convincing of the ‘judicial review skeptics’, at least in the context of constitutional review of primary legislation. The best-known and enduring example is the seminal work by J.H. Ely, Democracy and Distrust: A Theory of Judicial Review (Harvard University Press, 1980).
\textsuperscript{54} Waldron, supra n. 49, chapter 11 and p. 283.
\textsuperscript{55} See Ely, supra n 53. Ely places emphasis upon the role of courts in ‘clearing the channels of political change’ in order to ensure an open and effective democratic process. This leads him to charge the courts with the protection of free speech and voting rights, and with the enforcement of the non-delegation doctrine. As noted, a second strand to his theory charges the courts with re-enforcing the representation of minorities within a participatory political process.
than a merely procedural ideal, and as demanding more than actual and equal participation. For them, democracy is said to encompass a substantive dimension which represents ‘conditions for the legitimacy or moral respectability of democratic decision-making’.56 ‘Democratic procedures cannot remain democratic unless they are utilised by people who share some basic equality and liberty’.57

A second, distinct, approach places emphasis not so much upon the instrumental capacity of judges to contribute to improved legislative democracy, as upon the free-standing democratic credentials of the judiciary in the performance of its review function. Such arguments may rest upon the ‘democratic pedigree’ of judges,58 or upon the mode of reasoning which they deploy. As to the latter, the emphasis may be placed upon the moral integrity of judges, or their disinterestedness, or upon their heightened capacity for moral reason or (moral) deliberation.

It is with the thinking of the first of these two groups that this paper is concerned, and specifically with those who conceive the role of the judiciary in terms of its capacity to enhance – through recourse to procedural precepts - the democratic nature of the political process; legislative and executive. Even so, this discussion may, at first sight, seem a long way from the WTO. It may, moreover, seem counter-intuitive as a starting point given that that organization comprises Members which are democracies and members which are not. Nonetheless, it is possible to argue that this ‘democracy-reinforcing’ conception of judicial review has something to offer us in contemplating the activities of the AB in the WTO.

The role of judicial review in constituting or re-enforcing democracy will vary according to context. It will vary according to the origins of the decision under review and according to the dangers or deficiencies which characterize the decision-making process in question. Of course, the judicial conception of these dangers or deficiencies will depend ultimately upon their underlying conception of democracy. Thus, to give a straightforward example, the relationship between democracy and judicial review will vary according to the identity of the body promulgating the contested act. The approach will be different in the case of the review of primary legislation as compared to the review of a regulatory act. Further, taking the latter, the court’s approach will vary according to whether, for example, it adopts a ‘transmission belt’ or ‘deliberative’ perspective on democracy. Whereas the former is ‘backwards-looking’, placing emphasis upon the limited scope of the delegated powers conferred, and upon the democratic authority of the conferring authority, the latter looks forwards to the processes according to which the delegated act was adopted and justified.

The WTO may be thought to operate against the backdrop of a particular kind of democracy deficit; a deficit which arises as a result of the disjuncture which has grown

56 Waldron supra n. 49, p. 283.
57 Hutchinson supra n.50, p. 206.
58 Eisgruber, supra n. 51, p. 29 who points out that (in the US) judges have a democratic pedigree by virtue of their being political appointees, nominated and confirmed by elected officials.
up between ‘jurisdiction’ and ‘impact’.\textsuperscript{59} It is a truism to say that decisions adopted within a given polity frequently spill-over beyond the boundaries of that polity and affect people – often profoundly – who do not form part of the relevant demos. Those so affected cannot be said to be truly self-governing if their fate is determined in (large) part by decision-makers who are not only not representative of them, but who are not in any sense accountable to them. Thus, as Robert Keohane has pointed out, this gap between jurisdiction and impact generates an all-important ‘external accountability gap’;\textsuperscript{60} external accountability being defined as ‘accountability to people outside of the acting entity, whose lives are affected by it’.\textsuperscript{61} Keohane argues that this external accountability deficit represents one of the most pressing normative problems of our time, particularly in so far as powerful states are concerned, immune as they are from established mechanisms of accountability, reputational, economic and so on. For Keohane, organizations such as the WTO represent rare pockets of institutionalized external accountability and it would, he argues, ‘be tragic if the “anti-globalization” movement succeeded in demolishing or diminishing the institutions and networks developed to cope with globalization, without putting comparable institutions in their place’.\textsuperscript{62} For Keohane, from the perspective of external accountability, these organizations represent a ‘glimmer of hope’.\textsuperscript{63}

Viewed from this perspective, it may be interesting to ask whether judicial review in the WTO may be conceived as a tool to mitigate this all important external accountability gap, and hence to re-enforce democracy in an age when the concept of statehood no longer captures all dimensions of power.\textsuperscript{64} The concept of accountability is a multi-faceted and evolving one. It is subject to continuous transformation as it tries to keep up with the challenges posed by the emergence of dramatically new forms of (transnational) governance. This is reflected in the multiplicity of forms and mechanisms for accountability highlighted by Keohane in his work; electoral, legal, reputational, economic and so on. At the core, however, for Keohane accountability, in its many guises, comprises two elements, viz. a requirement on the part of those reaching decisions to report to the individual or group to which they are accountable (a transparency dimension), and the ability of that individual or group to sanction the decision-maker.\textsuperscript{65} Thus, accountability is viewed as a relationship between actors. One rationale for the constitution of accountability relationships is defined in terms of ‘impact’, whereby those


\textsuperscript{60}Keohane, supra n. 59.

\textsuperscript{61} Supra n. 59, p. 141.

\textsuperscript{62} Supra n. 59, p. 151.

\textsuperscript{63} Supra n. 59, p. 150.

\textsuperscript{64} The suggestion here is not that accountability and democracy are synonymous. Indeed, the relationship between these two concepts is complex and contested and is worthy of exploration. For now though, the argument of this paper rests upon the premise that there is a relationship between external accountability and democracy, and that accountability is a necessary though not a sufficient condition for democracy. The point is not that external accountability in the kinds of forms under discussion here could ever ‘close’ the democracy gap, but merely that it can make some contribution in giving voice to ‘outsiders’ in the adoption of decisions which impact upon them, but in respect of which they are normally wholly excluded.

\textsuperscript{65} Supra n. 59, p. 139
who are ‘”choice determining” for some people [should be] fully accountable for their actions’ to those people’.  

Turning first to the obligation to report: this may be weak or strong in form. It may, at minimum, imply an obligation to inform those affected of the existence and content of the decision in question. As we move down the continuum from weak to strong, there may arise also an obligation to explain the basis of the decision adopted; to give reasons for it and to make available the information upon which it is said to be based. The obligation to report may be more than one-way; active on the side of the decision-maker but passive on the side of the recipient. It may necessitate more active engagement on the basis of consultation or dialogue. Any explanation proffered may be required to address the specific concerns raised by the notified parties. Conceivably, participation opportunities may be provided to such parties through, for example, a right to a hearing.

Expressed in this way, it is not hard to see that there may be seeds of an external accountability based approach inherent in the activities of the WTO. As noted previously, the WTO Agreement contains a multitude of notification and consultation obligations, whereby Members proposing to introduce restrictive measures are required to notify other Members of their decisions and to receive and discuss comments put forward by them. Regular fora for consultations are established in the form of committees, and such committees are to encourage consultations or negotiations between states. Transparency, reason giving, and consultation and dialogue emerge as treaty-based instruments of external accountability.

Notable also are the conclusions of the AB in the recent EC Tariff Preferences report. Here the AB was called upon to examine the compatibility with the ‘Enabling Clause’ of one aspect of the European Union’s Generalized System of Preferences (GSP). It was specifically concerned with the Drug Arrangements inherent in this, which operate to grant additional tariff preferences to certain specified developing country members. The current practice of the EC is to concede concessions to twelve beneficiary countries (but not to India, the complaining state). The AB, like the panel, found that the Drug Arrangements operate in a manner which is not consistent with the non-discrimination requirement inherent in Article 2(a) of the Enabling Clause. Unlike the panel, it did so while keeping open the possibility of differentiation as between developing countries in the operation of preferential trading regimes. The conclusions of the AB on the discrimination point were premised upon two key considerations.

First, and procedurally, the EU regime was found to be deficient in that it did not provide any mechanism according to which the list of beneficiaries could be supplemented or amended. Subject to the possibility of amending the primary legislation, the list of

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66 Supra n. 59, p. 141, citing the work of David Held.
67 See, for example, Article 12 SPS Agreement. Jeffrey Dunoff has undertaken work on the crucial role of the SPS Committee.: ‘Lotus Eaters: Reflections on the Varietals Dispute, the SPS Agreement and WTO Dispute Resolution’ (on file with the author).
68 EC – Tariff Preferences (WT/DS246/AB/R).
beneficiaries was ‘closed’. As such, the tariff preferences available under the Drugs Arrangements could not be regarded as ‘available to all GSP beneficiaries suffering from illicit drug production and trafficking’.  

Second, the AB laid emphasis upon the absence of ‘criteria or standards to provide a basis for distinguishing beneficiaries under the Drug Arrangements from other GSP beneficiaries’.  

The approach of the AB in GSP is noteworthy from the perspective of external accountability. It concedes considerable flexibility to the regulating Member State in terms of the choice of objective which it wishes to pursue, and to this end is willing to permit reasoned differentiation as between individual developing countries. Nonetheless, it places heavy emphasis upon transparency on the one hand, and upon procedural propriety on the other. If special benefits are to be made available to third countries, this must be on the basis of criteria which are transparent and which reflect the development, financial or trade need to which the differential treatment is intended to respond. The preferences must be available to all GSP beneficiaries similarly affected by the problem at hand. In the case of the EU Drug Arrangements, there was ‘no indication as to how the beneficiaries …were chosen or what kind of considerations would or could be used to determine the effect of the “drug problem” on a particular requirement’. Related to this is the requirement that procedures must be put in place which render the policy responsive to change; such that the special preferences may over time be extended to similarly situated states, or withdrawn from those which are no longer capable of being regarded as similarly situated. For the AB differentiation is one thing, discrimination another. Absent clear criteria, applied consistently and in a manner which is responsive to change, it is not possible to guarantee that differentiation will not serve to mask discrimination.

Yet more telling perhaps, though not dissimilar in some ways, are the decisions of the AB in Shrimp-Turtle. Here the AB may be thought to be striving after external accountability. The AB focused upon the manner in which the US restriction in question has been applied. In condemning the United States, the AB laid emphasis, inter alia, upon its failure – prior to the enactment of the unilateral measures – to engage in serious, across-the-board and good-faith negotiations with the third countries affected, with a view to reaching multilateral or bilateral agreements with them on the protection and conservation of sea turtles. It laid emphasis too upon the abject failure of the United States to respect the fundamental requirements of basic fairness and due process in the

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70 Supra n. 68, para. 187.
71 Supra n.68, para. 188.
72 Supra n. 68, para. 188..
73 Supra n. 68, para. 183.
74 US – Prohibition on the Import of Shrimp and Shrimp Products (WT/DS58/WT/R) and for the Article 21.5 DSU AB report see WT/DS58/WT/RW.
operation of its import certification scheme. This scheme was condemned as operating in a manner which was singularly informal and casual, requiring no reason giving, no transparency, and providing no right to a hearing at any stage.

In *Shrimp/Turtle*, famously, the AB did not second-guess the policy objectives of the United States. On the contrary, it adopted a permissive stance... Emphasis was laid upon the manner in which the United States had behaved vis-à-vis its trading partners in the operationalization of its sea turtle conservation regime. It might be thought that the United States was condemned for being insufficiently ‘other-regarding’ in its attitude to those situated outside of the polity, but affected by decisions adopted within it. If, as Keohane argues and I accept, external accountability is a key requirement of democratic legitimacy in a globalized order, the decisions of the AB may be thought to have rendered a positive service to democracy; to have re-enforced rather than to have undermined it.

Recall, however, that Keohane’s core conception of accountability includes two elements, not one. The second is concerned with the power to sanction, rather than the duty to report. Consideration of this second dimension raises some interesting, but difficult, questions in the context of the WTO. One thing at least is clear. A failure to comply with the procedural obligations laid down in the WTO Agreement will amount to a breach of that Agreement. Such procedural failures are, in themselves, susceptible to condemnation by the dispute settlement bodies of the WTO. What is less clear is the nature of the consequences which may flow from a finding that a WTO Member has failed to report adequately. In the event of a finding of breach, the recommendations and rulings of the WTO bodies are to be implemented within a reasonable period of time.\(^75\) Failure to do so may – absent mutually acceptable compensation arrangements – generate an entitlement to suspend concessions or other obligations under the WTO Agreements.

It is, however, hard to see how this might apply in the case of a purely procedural failure. ‘The level of the suspension of concessions or other obligations authorized by the DSB shall be equivalent to the level of the nullification or impairment’.\(^76\) The nullification or impairment in the case of a procedural failure is political not economic. It is associated with the existence of an accountability deficit and not, in itself, with economic costs. Neither compensation nor suspension of concessions can begin to capture the nature or consequences of a breach of this kind.

Awareness of this then generates the all important question of whether – and if so in what circumstances - a procedural failure may be construed as depriving the associated substantive measure of its legitimacy. In the EU, for example, a failure to comply with the requirements of the so-called notification directive operates to deprive the regulation in question of all legal effects.\(^77\) In the WTO we know, on the basis of *Shrimp/Turtle*,

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\(^75\) Article 22(1) DSU.

\(^76\) Article 22(4) DSU. See also *US – 1916 Anti-Dumping (WT/DS136/AB/R)* according to which a prevailing party may not impose trade restrictions absent evidence of actual trade impact. Thus, absent real, quantifiable harm, there is no right to discipline – by way of monetary penalties – non-conforming states.

that procedural failures of the kind outlined above may likewise operate to deprive Member States of the possibility of recourse to the GATT, Article XX exceptions. These requirements were construed by the AB as inherent in the ‘chapeau’ to Article XX. Elsewhere in the WTO, it remains an open question as to whether a serious procedural deficiency which is such to undermine the capacity of the WTO to re-enforce external accountability through an obligation to report, might in itself be such to permit condemnation of the resulting substantive measure as non-compliant with the WTO Agreement. A positive answer to this question would serve to instantiate the second of Keohane’s accountability conditions in the WTO, by facilitating the possibility of sanction in the case of an external accountability sapping procedural failure.

**Shrimp/Turtle and GMOs**

An emphasis upon external accountability may frequently serve to dissipate conflict. Evidence from the SPS Committee would seem to bear this out. The specific facts of *Shrimp/Turtle* may also attest to this. Here, where the United States had tried to negotiate, this had led to the conclusion of the inter-American Convention for the Protection and Conservation of Sea Turtles. This required the parties to put in place regulations providing for the use of such turtle exclusion devices in shrimp fishing, such as were ‘jointly determined to be suitable for a particular party’s maritime area’. This, as is evident from the discussion above, stands in stark contrast to the unilateral rules applied by the United States in the absence of any such agreement.

The practical utility of the *Shrimp/Turtle* approach may be further exemplified by returning to the GM example. As is well known, a WTO panel has been established to hear a complaint by the United States (along with Canada and Argentina) concerning an alleged ‘EC moratorium on the importation of ‘biotech products’. It is argued that, according to this, the EC has suspended consideration of applications for approval of agricultural biotechnology products. ‘In particular, the EC has blocked in the approval process under EC legislation…all applications for placing biotech products on the market, and has not considered any application for final approval. The approvals moratorium has restricted imports of agricultural and food products from the United States’.

The indignant protestations of the EU notwithstanding, it is the case that, until 19 May 2004, no new approvals have been conceded since October 1998. Dozens of applications for approval are evidently stalled at various stages in the established procedure. As far as applications under the original 1990 deliberate release directive are

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78 See J. Dunoff supra n. 67.
79 Supra n. 42.
80 European Commission (DG Trade), *WTO Case on GMOs* 17 June 2003 p. 3.
concerned, the majority were simply never submitted by the Commission for consideration to the regulatory committee. More recently, under the revised 2001 directive, EFSA has delivered a number of favourable scientific opinions and the Commission appears to have resumed its processing of applications. On 19 May 2004, the Commission adopted a decision approving the marketing of Syngenta’s GM BT-11 maize, which may not be used a whole fresh sweet corn or as tinned sweet corn.81

This scenario would appear to lend itself to analysis in accordance with Shrimp/Turtle. Other than with respect to the most recent applications, the EC seems to have desisted from actually applying its established and published rules for the consideration of applications for authorization. Even in respect of those products for which a specific risk assessment was undertaken, there is in existence no specific approval decision (negative or positive) which might be claimed to be based upon it. No decision, let alone any reasoned decision, seems to have been issued by the Commission since October 1998 regarding any specific application for authorization. If the approach of the United States in Shrimp/Turtle was condemned as being singularly informal and casual, the EC’s approach would appear to be susceptible to condemnation on the basis of its generalized and unreasoned departure from published criteria and procedures for approval. At the very least, seen from the perspective of any individual applicant, the Commission’s approach would seem to be non-transparent and therefore difficult to contest.82

The point here is not to try to anticipate the outcome in this case. It is rather to illustrate the practical utility of the kind of criteria applied by the AB in Shrimp/Turtle. In the current GM debacle, it seems highly likely that such criteria might once again serve as benchmarks for (negative) evaluation. These benchmarks, it was argued above, might be conceived as bolstering rather than undermining democracy by virtue of their capacity to enhance the external accountability of states.

It is worth emphasizing too, that here it is the EU regulator which has failed to process applications in accordance with the procedures and values established by the EU legislature. The executive branch – in its complex multi-level form – has departed over a long period of time from the governance precepts laid down by the legislature. Such willful non-application of established rules might be thought to pose a threat not only to the external accountability of states, but also to internal accountability within states. In thinking about internal accountability, one might look also to US – Lamb by way of example.83 Here the AB, in the context of a claim under Article 4.3 of the Safeguards Agreement, found that it is for a panel to evaluate ‘as a formal matter’ whether the


82 It is however telling that there has been no action for judicial review concerning the alleged moratorium. No company which has submitted an application has challenged the failure of the EC Commission to act in accordance with its duties under the deliberate release directive. This seems unlikely to be associated with standing concerns, but to reflect rather public relations concerns about being seen to force GM food on reluctant European consumers.

Member in question has evaluated all relevant factors and, ‘as a substantive matter’ whether the Member has provided a reasoned and adequate explanation of how the facts support the determination.\textsuperscript{84} The disciplines inherent in this and other cases may be construed from a perspective of external accountability, in that they serve the interests of transparency and, ultimately, contestability on the part of trading partners. So too may they be viewed from a perspective of internal accountability, in that they promote executive fidelity to democratically determined processes and values and, again, decision-making which is transparent and contestable – from the inside as well as from the out.

Returning though to Shrimp/Turtle and to the notion that, as far as the GM moratorium is concerned, the benchmarks which it lays down might serve as a substitute for any more fully fledged substantive evaluation, thus allowing the dispute settlement bodies to sidestep the need for more sensitive ‘rationality’ or ‘proportionality’ type tests.

Any such conclusion should, however, be viewed in the light of two cautionary remarks.\textit{First}, and at some length, any relief that this approach might offer to the dispute settlement bodies would surely be short lived. With the new legislative package in place, it seems only a matter of time before the premises underpinning that package come directly to form the subject of scrutiny in the WTO. In evaluating the WTO-compatibility of eventual, actual authorization decisions, it seems unlikely that the AB will adopt an approach which is purely procedural. In many cases – Shrimp/Turtle and GSP included – the dispute settlement bodies have self-evidently moved beyond a mere focus on the procedural dimension. In these cases, the basis for their evaluation lies in substantive not procedural norms. These substantive bench-marks vary widely in nature and intensity. In GSP non-discrimination formed the substantive focus for analysis. In Shrimp/Turtle, the AB focused not merely upon the due process failure of the United States, but also upon the substantive nature of its certification regime. It focused in particular upon the ‘rigid’ and ‘unbending’ nature of the US rules, such that other WTO members were obliged to adopt ‘essentially the same policies and enforcement measures’ as the United States, regardless of the conditions prevailing within these states. Standards which were different, but comparable in their effectiveness, would not be such to meet the requirements of the US regime. Thus, an additional benchmark against which the legality of the US measures was assessed was that of flexibility. ‘[A] measure should be designed in such a manner that there is sufficient flexibility to take into account the specific conditions prevailing in any exporting Member’.\textsuperscript{85} This demand for flexibility may be viewed through the lens of external accountability. Accountability to peoples situated outside of the regulating state may be thought to demand that where states seek to protect their vital interests, they should do so in a manner which generates the least possible negative external effects. It would not be appropriately other-regarding for states to impose costs needlessly upon their trading partners. Protective measures which, though not identical, are equivalent in the level of protection which they offer must be recognized in order that unnecessary costs can be avoided.

\textsuperscript{84} Ibid, para. 141.
\textsuperscript{85} Article 21.5, para. 149.
Though substantive in nature, flexibility (and equivalence) and non-discrimination fall on the weak side of the substantive continuum. They acknowledge the autonomy of Members in setting their own standard of protection, placing demands only in relation to the manner in which these standards are to be attained. Other substantive benchmarks would go further. These might demand, for example, not merely that Members report as to the content of their measures, and as to the epistemic basis upon which they rest, but also that there be a ‘rational’ or ‘objective’ relationship between the premises said to underpin the measure and the measure itself. As is well known, such a requirement is imposed in respect of sanitary and phytosanitary measures, whereby protective measures must be reasonably or rationally sustained by the results of a risk assessment.86

This rationality requirement may be differently construed, and even more intensive in the scrutiny which it implies. It may be deemed, for example, to encompass a proportionality dimension. This dimension might extend beyond the least restrictive means test already inherent in the concept of flexibility discussed above. It might, in addition, imply a balancing of costs and benefits, such that the negative consequences associated with restrictions on trade must be justified having regard to the scale of the positive benefits said to ensue. There are signs that the AB is moving in the direction of a substantive benchmark of this kind, albeit – for now at least - not in cases concerning risks to public health.87

As we move from the procedural to the substantive and from the weak substantive to the strong, it might be thought that the WTO comes to present a challenge to our conception of judicial review as democracy re-enforcing. Whatever the external accountability gains may be, substantive discipline of this kind may be thought to pose a threat to the internal accountability of states. According to Keohane, internal accountability is owed by rulers to those who authorize the regime in question, and to those who support it, notably through taxation.88 Keohane seems relatively untroubled by any such threat to internal accountability. ‘Globalization’, he asserts, ‘may weaken internal accountability within democracies, but is political institutionalization a condition for external accountability’.89 He conceives of a competition between internal and external accountability claims, implying a clear recognition that one may be gained at the expense of the other.90

This vision of an external/internal accountability trade-off may be too absolute in the case of the WTO. We saw previously that existing WTO jurisprudence may be thought to serve internal accountability by enhancing fidelity to established procedures and values, and by virtue of the introduction of good governance precepts such as reason giving and transparency requirements. Nonetheless, the tension remains; particularly but not only in

86 See Article 2.2 and 5.1 of the SPS Agreement and EC – Hormones supra n. 28.
87 See, in the context of the GATT, Korea Beef (WT/DS161 and 169/AB/R) and, more recently, in the context of the SPS Agreement, Japan Apples (WT/DS245/AB/R). The former may have implications also for the TBT Agreement where a necessity test also applies in Article 2.2.
88 Supra n. 59, p. 140.
89 Supra n. 59, p. 151.
90 Supra n. 59, 146.
respect of the review of legislative acts. And the more intrusive the judicial review tools, and the more intensive the standard of review, the more clearly this tension will come to the fore. This may be a dilemma which the dispute settlement bodies may succeed in dodging as regards the moratorium. It is, however, not one which they can dodge indefinitely.

The second cautionary observation may be more succinctly put. It is not entirely unrelated in the dilemma which it throws up. Put simply, is important to recall the backdrop to the EC moratorium. This came into being by virtue of the reluctance of a majority of Member States to play any constructive role in the established system for prior authorization. Over time the Commission bowed to this concerted campaign of disobedience, and began to desist from even submitting applications received to the relevant committee, comprising representatives of the Member States. At least on one reading, this Member State defiance was a result of strong public antipathy to the use of GM technology in agriculture. It was born of responsiveness to European-wide public opinion.91

Whatever the truth of this as regards the EC moratorium, it might seem a poor excuse for behaviour which is non-transparent and inadequately reasoned, as well as out of synch with the EC’s established normative framework. However, it does bring to the fore a fundamental issue of immense importance; namely the place of public opinion in the regulation of GMOs. Within the framework of this discussion, this question has two dimensions. The first relates to the place of public opinion within the evolving European framework for the regulation of GMOs. The second is concerned to ascertain the extent to which responsiveness to public opinion is, or ought to be, relevant to an assessment of the WTO-compatibility of Member State protective measures.

As noted at the start of this paper, the 2003 GM Food and Feed Regulation is notably reticent in reaching out to involve the public in governance. Admittedly, the public may make comments to the Commission following the publication of EFSA’s opinion.92 Neither the scope nor the salience of such comments is outlined. The public is nowhere defined, and there is a conspicuous absence of accountability mechanisms such that might induce these comments to resonate within the decision making process. The Commission is not specifically mandated to take these into account. Though it incurs a general obligation to give reasons, and must explain any departure from the EFSA opinion, the Commission is not required to justify its stance with specific reference to the content of the public comments received. In drafting its approval (or non-approval) decision, the Commission is required to take account of the EFSA opinion, together with ‘any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration’.93 The place of public opinion under these headings would

91 For evidence from the UK, following an innovative experiment in public consultation, see the results of ‘GM Nation’: http://www.gmnation.org.uk/. Eurobarometer surveys offer an insight into public attitudes to biotechnology in respect to agriculture and other matters. See, for example, http://www.vib.be/TechTransfer/EN/Flanders+Assets/Public+opinion/ and http://europa.eu.int/comm/research/press/2001/pr2312en.html
92 Supra n. 2, Article 6(7).
93 Supra n. 2, Article 7(1).
be a matter for legitimate debate. The concept of relevant, legitimate factors is not defined in the 2003 Regulation. To the extent that this concept is parasitic upon the broader normative framework for the regulation of food safety constituted by the EFSA Regulation, it might be thought to extend to those factors identified in the preamble thereto. These are said to ‘include’ ‘societal, economic, traditional, ethical and environmental factors and the feasibility of control’.  Though this list may properly be regarded as indicative rather than exhaustive, public opinion is not singled out.

The 2003 Regulation, developed against the backdrop of the alleged moratorium, does not seem to be fundamentally concerned with eliciting public participation. Its transparency requirements make much of the relevant information available to the public, and the labeling requirements may be thought to empower the public in its marketplace activities. But still the Regulation is strikingly weak in the public participation for which it provides.

A further question arises in examining the place of public opinion in the European system for the approval of GM food. This may be posed as a negative. Are there, as a matter of Community law, limitations upon the extent to which decision-makers may have regard to public opinion in reaching their approval decisions? This speaks not to any positive requirement to have regard to public opinion, but to the legal limitations in their entitlement to do so.

Here it is important to recall that approval decisions are to be granted or refused only on the grounds set out in the GM Food and Feed Regulation. It is not precisely clear to what the concept of ‘grounds’ refers, but it would seem to suggest that such decisions must be in the service of the ‘requirements’ laid down, whereby the food or feed must not have adverse effects on human or animal health or the environment, mislead the consumer, or differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer. The Regulation is intended to serve certain specified ends. Responsiveness to public opinion or the mitigation of public fears are not in themselves included among these ends. Any decision premised principally upon these latter concerns, disassociated from the specific objectives explicitly laid down, would seem vulnerable to challenge as a misuse of powers.

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94 Maria Lee makes this point in her forthcoming book on environmental law and risk regulation in the EU. See supra n. 10, recital 19 EFSA Regulation.
95 Supra n. 2, Article 4(5).
96 See also ibid, Article 1.
97 This is defined by the European Court in the following terms: “…misuse of powers is defined by settled case-law as the adoption by a Community institution of a measure with the exclusive or main purpose of achieving an end other than that stated or evading a procedure specifically prescribed by the Treaty for dealing with the circumstances of the case”. See Case C-180/96 United Kingdom v. Commission, para. 64. See also Case T-13/99 Pfizer v. Council, supra n. 12, where the CFI finds that ‘where the measure at issue is a measure taken for the purpose of protecting public health….the findings made by the institutions, which differ from those set out in the SCAN opinion must be founded on that purpose alone’ and rejecting the argument that the Council had allowed itself ‘to be influenced, as regards the risk assessment, by concerns expressed in the media’. (paras. 203 and 207). It is, however, important to recall once more than
Equally, it is necessary to recall the recent and repeated insistence of the European courts that ‘a preventive measure cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically verified’.98 This statement seems uncompromising and the threshold which it establishes absolute. Absent specific evidence of risk, such that transcends this ‘merely hypothetical’ threshold, it is not open to the relevant institution to act, regardless of the manner in which the public views that hypothetical risk, and regardless of the intensity of the public fears which the existence of the ‘merely’ hypothetical risk provokes.

By contrast, while above this threshold the autonomy of the political branch is preserved,99 it remains subject to over-arching principles of Community law. Among the most important is the principle of proportionality which, in the sphere of risk regulation, also encompasses a requirement to engage in cost-benefit balancing.100 Ambiguity persists as to the extent to which public attitudes to risk may properly be reflected in decision making and relevant from the perspective of proportionality. Even if public opinion is to be regarded as a factor which may legitimately be taken into account, it is critical also that it be allowed to resonate within the framework of a proportionality analysis.

Turning now, and in a manner which is necessarily speculative, to the place that public opinion could (and to some extent does) play in the WTO. The issue here is to ascertain the extent to which WTO law might accommodate Member State responsiveness to public opinion. Three modes of accommodation may be contemplated.

First, the capacity of Member States to respond to public opinion in regulation will depend upon the stringency or the intensity of the WTO benchmarks for review. To the extent that these are construed and applied in an expansive manner, they will be capable of accommodating diverse responses and diverse conceptions of appropriateness in terms of regulatory response. This will remain true regardless of the motivations which underpin that regulatory response, in so far as these benchmarks are not concerned with subjective intent. Thus, for example, we saw above that the rationality requirement which underpins the risk assessment requirement in SPS is sufficiently open ended to permit the adoption of measures to protect public health even in the face of scientific disagreement as to the nature and magnitude of the risk. The limits to this lie in the requirement that there be positive evidence of the existence of a risk, rather than merely the kind of ‘theoretical’ presupposition of risk which flows from the impossibility of securing absolute, enduring, scientific certainty. In the regulatory space above that threshold, Member States remain free to be more or less responsive to public opinion, on the basis of their own precepts as to the processes – democratic or otherwise – according to which regulatory outcomes ought to be determined. In this sense, it will be apparent that the

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98 Pfizer supra n. 12, para. 143. See also Monsanto, supra n. 19.
99 See Pfizer, supra n. 12, para. 201.
100 Supra n. 12.
salience of the issue of public opinion will increase, along with the intensity or intrusiveness of the ‘normal’ benchmarks for review.

Second, it is possible to contemplate circumstances in which the relevant benchmarks for review will themselves be infused with a sensitivity to public opinion; in which their very construction will serve to accommodate this dimension. Three concrete examples may be given by way of illustration:

- In the context of the SPS Agreement, Article 5.1, the AB drew up its substantive benchmark for review in the light of what ‘responsible and representative [my emphasis]’ governments sometimes do (namely act on the basis of divergent scientific opinion). The parameters of what is to be considered as reasonable in this setting, appear to be shaped by the AB’s understanding of the way in which representative governments operate. Here, what democratic governments in fact do is allowed to infuse the AB’s normative conception of what such governments ought to be allowed to do.

- In the context of the application of the ‘national treatment’ principle in GATT, Article III, the question of ‘like’ products is critical. To the extent that products are not alike, they may be treated differently, without this differentiation amounting to discrimination. The AB has accepted that ‘consumers tastes and habits’, as expressed on the market-place, is one relevant criterion in the analysis of likeness. Though the weight of this criterion, and its relationship with other relevant criteria remains uncertain, public opinion as mediated through market-place behaviour is accepted as playing a role in the construction of the national treatment principle, by virtue of its role in an assessment of likeness.

- Article 5.5 SPS lays down a ‘consistency’ requirement, whereby Members may not institute arbitrary or unjustifiable distinctions in the level of SPS protection sought as between different risk situations, where these distinctions result in discrimination or a disguised restriction on trade. There remains considerable uncertainty as to the kinds of reasons which might be accepted as rendering distinctions non-arbitrary or justifiable. In Hormones the AB stated that Article 5.5 does not impose an absolute consistency requirement; this by virtue of the fact that governments ‘establish their appropriate levels of protection frequently on an ad hoc basis and over time, as different risks present themselves at different times’. Yet the connotations of this remain unclear. The extent to which differences in the public perception of risk may serve to justify distinctions in level of protection is of critical importance, but as yet unsettled.

One area where this issue of the relevance of public opinion may come to fore is in respect of the labeling of GM Food. As noted above, the 2003 Regulation instantiates a

102 Hormones (AB), supra n. 28, para. 214.
broad and demanding labeling regime. This encompasses a public health dimension, but extends well beyond it. It is premised more generally upon the assertion of ‘the right of consumers to information’ in the interests of their being able to make an ‘informed choice’.103 It operates in the interests of market transparency, to use the language of the AB in the Sardines case.104 While at first sight it might seem hard to quibble with information-based demands of this sort, as many have observed labeling regimes raise a host of difficult trade related questions.105 As the European Court has implied, labeling may serve to facilitate consumers’ indulgence of their irrational prejudices.106 Also, conceptually, there is almost no limit to the kinds of information which Members might demand by way of labeling requirements. These could range from the palpably reasonable (the presence of nuts for example, or the presence of extraneous DNA which might raise religious concerns) to the palpably absurd (the colour of the uniforms worn by those in the factory in which the product was manufactured). Yet, in terms of market transparency, the basis for distinguishing between these is not clear. Significantly, one factor to which the EU turns in a bid to justify its labeling regime is public opinion. The Preamble to the 2003 Regulation provides:

The labeling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labeling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers [my emphasis], facilitates informed choice and precludes potential misleading of consumers as regards methods or manufacture or production.107

Thus, in seeking to distinguish the reasonable from the absurd the EU cites, among other things, the existence of a prior public demand to know. The strength of public feeling is such that labeling may be viewed as responding to public concerns. It may be, as an empirical matter, that labeling will further stoke these concerns, but still it is responding to prior concerns. It might be argued that this fact of responsiveness to public opinion might serve to nudge the regime in the direction of the reasonable as opposed to the absurd.

All of this is well and good. It contemplates public opinion as an element in the application of the rules. In view of the open-endedness of the text of the WTO Agreement this route offers considerable potential in injecting sensitivity to public opinion into the terms of the agreement. It might be that it is a sensible place to stop!

Yet a third mode of accommodation may be contemplated in respect of public opinion in the WTO; one which is more direct and more extreme. According to this third mode, the

103 Supra n.2, recital 17.
104 EC – Sardines (WT/DS231/AB/R).
105 For an example in the area of GMOs, see: Arthur E. Appleton, The Labeling of GMO Products Pursuant to International Trade Rules, 8 N.Y.U. ENVTL. L.J. 566-578 (2000).
107 Supra n. 2, recital 21.
WTO might recognize a specific and explicit public opinion style defense. That is to say that, subject no doubt to safeguards, it would (according to this mode of accommodation) be open to Members to justify restrictions on the basis that the protective measures in question are necessary precisely, and conceivably exclusively, because the public considers them to be so. The objections to any such suggestion spring readily to mind. The objections are so numerous and so intense that it may be misconceived to even contemplate traveling down this road. Public opinion is harder to ascertain than it is to manipulate. Adept at the strategic framing of issues, Members may contrive to achieve results which merely shroud their choices in the garb of democracy. Public opinion is rarely uniform and less often static. Even where policies do, unequivocally, command public support, these policies may rest upon assumptions which are ignorant and prejudiced. To this list, one must add arguments about the nature of a properly functioning democracy. Even for those for whom democracy is essentially a procedural ideal, the ideal tends to add up to more than the mere, uncritical, aggregation of ill-informed public preferences.

The work of Cass Sunstein stands as a powerful reminder of the limits of populism in thinking about risk. He celebrates the ‘centrality of science and expertise to the law of risk’, defending an approach which is explicitly ‘technocratic’ and ‘sharply skeptical of populism’. Sunstein examines and explains the mistakes that people make in evaluating risk. He argues that these flow, on the whole, from the mental shortcuts – or heuristic devices – upon which we rely, from the social pressures or influences to which we are exposed, and from our tendency to neglect ‘tradeoffs’ according to which protective measures generate their own, different –invisible or unanticipated - risks.

Sunstein’s many examples are compelling and his insights of crucial importance.

Even Sunstein though feels compelled to qualify his celebration of technocracy. His qualifications flow in part from a form of reasoning which is consequentialist. He points to the negative consequences which may flow from the failure of the state to respond to public perceptions of risk. ‘A sensible approach to risk will attempt to reduce public fear even if it is baseless’. ‘Public alarm, even if ill-formed, is itself a harm, and is likely to lead to additional harms, perhaps in the form of large scale ‘ripple effects’. Similarly, ‘technocrats tend to ignore the fact that to work well, a regulatory system needs one thing above all – public support and confidence’. This is so whether or not a lack of confidence is fully rational.

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108 Risk and Reason: Safety, Law and the Environment (CUP, 2003), p. 294. Eisgruber’s study, supra n. also provides a particularly good account of why democracy should not be equated with majoritarianism. He focuses upon the incentives which bear upon both legislatures and voters to act out of self-interest, rather than on the basis of moral judgment.


111 Ibid.

112 Supra n. 108, p. 294.
Sunstein’s qualifications are, however, not only rooted in consequentialism. They are rooted also in his conception of democracy; deliberative democracy. He is not a populist but he is a democrat. Whereas it is not appropriate for governments to capitulate in the face of vociferous but wrong-headed public demands, it is appropriate for governments to respond to people’s values, at least where these values ‘can survive a process of reflection’ according to the precepts of deliberative democracy.

This tension between technocracy and democracy is one which Sunstein approaches constructively, or positively. He seeks to outline the contours of a solution such that governments may do better in regulating risk. For the WTO, the challenge is somewhat different. The dispute settlement bodies will be called upon to delimit, in a manner which may be universally applied - in states which are (deliberative) democracies and in states which are not - the circumstances in which additional latitude is to be granted to Members to respond to public opinion, even when in so doing the Member in question will fall foul of the ‘normal’ benchmarks for review. What Sunstein’s position does reveal, however, is that even those who are in general technocratic in their leanings, are willing to admit of circumstances in which ‘right answers’ must acknowledge public opinion and respond to the fears and the values which underpin it. It cautions as much against complacent and uncompromising disregard for public opinion, as it does against complacent and uncompromising acceptance of it.

The issue of the role of public opinion presents a audacious challenge for the WTO, especially in the context of this third form of more direct accommodation. It is in part a textual challenge. In certain respects the text of the Agreement would seem to be permissive. A free-standing public opinion style defense could be integrated into the range of legitimate objectives contemplated by TBT, Article 2.2. In other respects the Agreement seems less open. The introduction of a defense of this kind would be more difficult to secure in the context of the GATT, where the list of Article XX exceptions is deemed exhaustive.

Though the textual challenge is important, especially in view of the AB’s literal approach to interpretation, it is, however, the normative challenge which is most daunting; even for those who accept that governments do, and indeed sometimes ought to, take steps to respond to ‘irrational’ public opinion. This is a challenge which has received little attention in the WTO, due no doubt to the multiplicity and the intensity of the objections which spring so readily to mind. But given that even commentators such as Sunstein desist from an uncompromising disavowal of the relevance of public opinion, we should perhaps be modest in acknowledging and confronting this dilemma.

In reflecting upon this issue, we should recall the AB case law discussed above. This reminds us that, in its articulation and application of core concepts, the AB has devised a

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113 Supra n. 108, p. 64.
114 Likewise Eisgruber observes: ‘I do not, however, suggest that it would be acceptable if the Supreme Court (or any other aspect of democratic government) were unresponsive to public deliberation. On the contrary, I insist that democratic institutions, including courts, must be sensitive to public deliberation about justice’. See C.L. Eisgruber supra n. 51 (San Francisco Law Review) p. 58.
range of devices which allow it to be permissive of state autonomy, but not uncompromisingly or uncritically so. In Shrimp/Turtle, it opens the door of the environmental exception to measures concerned with production process standards. Yet flexibility (in the sense of openness to equivalence), due process and a commitment to multilateral co-operation intervene to guard against abuse. In GSP the AB proves more forgiving than the panel of differential tariff treatment of developing countries. But safeguards are introduced to guard against abuse. Such differentiation must be based on objective criteria relating to the development, financial or trade needs of similarly situated developing countries, and the scheme in question must be sufficiently transparent and adaptable in its mode of operation to connect authentically to the objective pursued.

Perhaps then the challenge for the WTO in relation to public opinion is not to exclude it as uncompromisingly irrelevant, but to instantiate with care the conditions according to which its entry into the justification equation may be mediated. Such conditions must be such that the WTO neither foists internal democracy on reluctant Member States, nor undermines it its wide variety of prevailing guises. Most obviously, any such conditions would be concerned with the nature of the evidence required to substantiate claims relating to public opinion. Equally though, additional safeguards could be introduced. These might relate to transparency, both in terms of the fact of reliance upon public opinion as an element in the defense, and in terms of the evidential record upon which this element rests. Any such safeguards might, moreover, acknowledge the peculiarly volatile and contingent nature of public opinion. Thus, measures which purport to rest upon this, might reasonably be required to be regarded as provisional, to be re-visited on a regular basis in order to verify the continuing validity of their evidential base. Additional positive obligations could be incurred by states as pre-conditions for recourse to a public-opinion style defense. To re-iterate, the language of the TBT Agreement, with its focus upon necessity in the fulfillment of legitimate objectives, is highly permissive in this regard. Such pre-conditions might oblige states to explore and to communicate, pro-actively and vigorously, the costs and benefits of its regulatory stance rooted in public opinion. Awareness of costs should extend not only to those endured within the territory of the regulating state, but also to external costs and to the manner and consequences of their distribution. To the extent that Members choose to fall back on arguments from public opinion to justify their regulatory choices, such Members might reasonably be expected to incur a duty to seek to stimulate informed and critical reflection on the part of the fearful or objecting public. To the extent that Members are passive in the face of public opinion which is not demonstrated to be rooted in those forms of rationality which resonate in the WTO, the ‘necessity’ of their measures may be open to doubt.

The salience of this discussion may be exemplified by reference to recent experience in the United Kingdom. Here, as noted previously, the government instituted an ambitious and self-consciously deliberative ‘public debate’ on genetic modification in agriculture. The message was clear. ‘People are generally uneasy about GM’. The

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115 Supra n. 91. The aim of the debate was ‘to promote an innovative, effective and deliberative programme of debate on GM issues, framed by the public, against the background of the possible commercial production of GM crops in the UK and the options for possibly proceeding with this. Through the debate,
more people engage in GM issues, the harder their attitudes and the more intense their concerns’. ‘The debate was welcomed and valued’. However ‘there was a widespread suspicion that the debate’s results would be ignored by government’. It would be a brave government which would set in motion a far-reaching experiment in public deliberation of this kind, were its hands tied at the outset by the WTO. And it would be a diminished WTO which would act as deterrent to such public deliberation.

If the challenge posed by public opinion is complex, it is not one which can or should be avoided. There are problems on both sides of the line. Problems confront those who favour responsiveness (the institution of a dangerously limitless loophole) and those who do not (the severing of connection between governors and governed). This is an issue which has received surprisingly little attention to date, and these last remarks should be regarded as nothing more than an invitation for further reflection on a topic of immense and, in the context of the GM debate, pressing importance.

provide meaningful information to Government about the nature and spectrum of the public’s views, particularly at grass-roots level, to inform decision-making’ (p. 55). Note that the subject of the debate was limited to the commercialization of GM in agriculture in the UK and not with the importation of GM food.