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**Judging GMOs: Judicial Application of the
Precautionary Principle in Brazil**

by

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JUDGING GMOs: JUDICIAL APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN BRAZIL

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The precautionary principle is included in many international environmental laws, but there is little consensus regarding its meaning and how it should be incorporated into governmental decisionmaking. With a focus on a landmark lawsuit in Brazil that prevented the federal government from approving the use of genetically modified organisms (GMOs) in commercial agriculture, this article analyzes how national courts should apply the precautionary principle. The article argues that the precautionary principle is best understood to mean that decisionmakers should identify and consider risks with caution when faced with scientific uncertainty about potentially serious environmental harms and that courts should apply the precautionary principle as a procedural requirement when they review governmental decisions. The article contributes to a growing literature about compliance with international environmental norms and the role of national courts in the international legal system.

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INTRODUCTION

The use of genetically modified organisms (GMOs) in agriculture provides fertile ground for debates about the precautionary principle. The precautionary principle embraces the idea that full scientific certainty should not be required before governments take preventative action against potentially serious environmental harms.¹ Some urge the need for a precautionary approach toward GMOs because of their uncertain environmental and human health implications.² Others, however, warn that applying the precautionary principle to GMOs will limit or delay the use of a new technology that promises economic, environmental, and human health benefits.³ Despite these conflicting viewpoints, most recent international environmental agreements

1. See *infra* Section I.A.

2. See, e.g., John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEG. STUD. 207 (Fall 2001); Julie Hill, *The Precautionary Principle and Release of Genetically Modified Organisms (GMOs) to the Environment*, in INTERPRETING THE PRECAUTIONARY PRINCIPLE 172 (Timothy O'Riordan & James Cameron eds., 1994); Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L. J. 297 (2002); Katherine Barrett & Carolyn Raffensperger, *From Principle to Action: Applying the Precautionary Principle to Agricultural Biotechnology*, 4 INT'L J. BIOTECH. 4 (2002).

3. See, e.g., INDUR M. GOKLANY, *THE PRECAUTIONARY PRINCIPLE: A CRITICAL APPRAISAL OF ENVIRONMENTAL RISK ASSESSMENT* (2001); Henry I. Miller & Gregory Conko, *Genetically Modified Fear and the International Regulation of Biotechnology*, in RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE 84 (Julian Morris ed., 2000); Jonathan H. Adler, *The Cartagena Protocol and Biological Diversity: Biosafe or Bio-Sorry?*, 12 GEO. INT'L ENVTL. L. REV. 761 (2000); Deborah Katz, *The Mismatch Between the Biosafety Protocol and the Precautionary Principle*, 13 GEO. INT'L ENVTL. L. REV. 949 (2001); Frank Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996); Edward Soule, *Assessing the Precautionary Principle in the Regulation of Genetically Modified Organisms*, 4 INT'L J. BIOTECH. 18 (2002).

incorporate the precautionary principle, including the Cartagena Protocol on Biosafety that regulates GMOs in international trade.⁴

As the precautionary principle becomes part of international law, national courts are increasingly called upon to interpret and apply it. In Brazil, the precautionary principle was a central aspect of a district court's decision to enjoin the Brazilian government's approval of genetically modified soybeans for use in commercial agriculture.⁵ The decision, first handed down in 1998 as a preliminary injunction, required that the government prepare an environmental impact study prior to approving a GMO.⁶ In 2004, an appellate court reversed the district court and held that the risk analysis that formed part of the government's GMO approval process satisfied the precautionary principle.⁷ This legal controversy drew international attention due to Brazil's importance in the global production and trade of agricultural commodities.⁸ The case also serves as a significant example of the application of the precautionary principle by national courts.

⁶ With a focus on the Brazilian GMO case, this Article addresses the question of when and how national courts should apply the precautionary

4. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 [hereinafter Biosafety Protocol].

5. This case, which is referred to throughout this Article as the "Brazilian GMO case," consists of a preparatory action seeking injunctive relief (*Ação Cautelar*) and a principal action seeking a decision on the merits (*Ação Civil Pública*, or Public Civil Action). See *infra* Section II.A.

6. *Ação Cautelar*, Processo No. 1998.34.00.027681-8, 6ª Vara Federal da Seção Judiciária do Distrito Federal, Juiz Antônio Souza Prudente (decided on August 10, 1999) [hereinafter District Court Decision in the *Ação Cautelar*]; Acórdão, Apelação Cível no. 2000.01.00.014661-1/DF, Original case number: 199834000276818, 2ª Turma do Tribunal Regional Federal da 1ª Região (TRF-1), Juíza Assusete Magalhães (decided on August 8, 2000, published in the *Diário de Justiça* on March 15, 2001, p.84) [hereinafter Appellate Court Decision in the *Ação Cautelar*]. *Ação Civil Pública*, Processo No. 1998.34.00.027682-0, 6ª Vara Federal da Seção Judiciária do Distrito Federal, Juiz Antônio Souza Prudente (decided on June 26, 2000) [hereinafter District Court Decision of *Ação Civil Pública*]. See *infra* Section II.A.

7. Acórdão, Apelação Cível No. 1998.34.00.027682-0/DF, 5ª Turma Tribunal Regional Federal da 1ª Região (TRF-1), do Juíza Selene Maria de Almeida (decided on June 28, 2004, published in the *Diário de Justiça* on September 1, 2004) [hereinafter Appellate Court Decision in the *Ação Civil Pública*]. See *infra* Section II.A.

8. See ROBERT L. PAARLBERG, *THE POLITICS OF PRECAUTION: GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES* 67, 79 (2001); Tony Smith, *Farmers Help Deliver Modified Crops to Brazil*, N.Y. TIMES, Oct. 14, 2003, at W1. In terms of soybean production, which was the focus of the Brazilian GMO case, the United States, Brazil, and Argentina are the three largest producers, producing 43%, 24%, and 16% of the world crop, respectively, in the marketing year 2001-02 (Oct. 2001 to Sept. 2002). USDA, Foreign Agricultural Service, Circular Series FOP 07-04, tbl.5 (July 2004), available at <http://www.fas.usda.gov/oilseeds/circular/2004/04-07/FULL.pdf>. In 2001-02, 71% of the United States soybean crop and 98% of the Argentine soybean crop were Round-up Ready® (RR) soybeans, whereas RR soybeans remained illegal in Brazil. CLIVE JAMES, PREVIEW: GLOBAL REVIEW OF COMMERCIALIZED TRANSGENIC CROPS: 2001, ISAAA (International Service for the Acquisition of Agri-biotech Applications) Brief No. 24-2001 at 9, available at <http://www.isaaa.org/kc/Publications/pdfs/isaaabriefs/Briefs%2024.pdf> (last visited Feb. 10, 2004).

principle. Section I argues that the precautionary principle requires government actors to take scientific uncertainty into account in their decisionmaking process and that courts have an important role in ensuring compliance with this obligation. Section II analyzes the judicial opinions in the Brazilian GMO case and evaluates how each court applied the precautionary principle. Section III argues that, although the Brazilian appellate court correctly focused on the government's decisionmaking process rather than on the government's ultimate decision, the court should have applied greater scrutiny to ensure that the Brazilian government took a "hard look" at the scientific uncertainty associated with GMOs. By using a hard-look approach, national courts can apply the precautionary principle to require that governmental decisionmaking considers risks that remain uncertain without substituting their judgment for that of the decisionmaker. This Article contributes to a growing literature on the role of national courts in the implementation of international environmental laws⁹ and in the international legal system more broadly¹⁰ while focusing on the legal contours of the precautionary principle.

I. THE PRECAUTIONARY PRINCIPLE

This section outlines the meaning of the precautionary principle and the role of national courts in applying it. Although the precautionary

9. INTERNATIONAL ENVIRONMENTAL LAW IN NATIONAL COURTS (Michael Anderson & Paolo Galizzi eds., 2002) (including country studies of Australia, Canada, the European Union, Germany, Ghana, Hungary, India, Italy, Netherlands, Switzerland, the United Kingdom, and the United States). On national compliance with international environmental law generally see ENGAGING COUNTRIES: STRENGTHENING COMPLIANCE WITH INTERNATIONAL ENVIRONMENTAL ACCORDS (Edith Brown Weiss & Harold K. Jacobson eds., 1998) and THE IMPLEMENTATION AND EFFECTIVENESS OF INTERNATIONAL ENVIRONMENTAL COMMITMENTS: THEORY AND PRACTICE (David G. Victor, Kal Raustiala & Eugene B. Skolnikoff eds., 1998).

10. A largely unexamined assumption exists that national courts enforce international laws. See Daniel Bodansky & Jutta Brunnée, *The Role of National Courts in the Field of International Environmental Law*, in INTERNATIONAL ENVIRONMENTAL LAW IN NATIONAL COURTS, *supra* note 9, at 1, 7 ("The importance of national courts in implementing international norms, although generally neglected by political scientists, is regarded as a 'banality' by international lawyers."); PATRICIA W. BIRNIE & ALAN E. BOYLE, INTERNATIONAL LAW AND THE ENVIRONMENT 251 (2002) ("[N]ational law is the medium through which states will usually implement their international obligations... It both serves as the principal source of legal remedies for individual claimants and enables the notion of individual or corporate responsibility to become part of the system of enforcement."). On the emerging role of national courts as actors in the international legal system, see Anne-Marie Slaughter, *Breaking Out: The Proliferation of Actors in the International System*, in GLOBAL PRESCRIPTIONS: THE PRODUCTION, EXPORTATION, AND IMPORTATION OF A NEW LEGAL ORTHODOXY 13 (Yves Dezalay & Bryant G. Garth eds., 2002) (observing that national courts are among the many new actors "above, below, beside, and within" the state that are becoming players "in their own right" in the international legal system).

principle's meaning in international law is widely debated,¹¹ it is best understood to mean that decisionmakers must account for scientific uncertainty about potentially serious environmental harms.¹² Given this meaning, national courts can enforce the precautionary principle as a procedural requirement. If courts rigorously apply this rule, they can play an important role in ensuring that decisionmakers implement the precautionary principle.

A. *The Meaning of the Precautionary Principle in International Law*

Since its first articulation in international law in 1987, the precautionary principle has become a common element in international environmental agreements.¹³ Currently, more than ninety international agreements include the precautionary principle in one form or another.¹⁴ In addition, some courts and academics consider the precautionary principle to be customary international law.¹⁵ Nonetheless, international

11. *Infra* Section I.A. See Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1004 (2003) (challenging the precautionary principle "because, read for all that it is worth, it leads in no direction at all"); Christopher D. Stone, *Is There a Precautionary Principle?*, 31 ENVTL. L. REP. 10790 (2001) (questioning the coherence and meaning of the precautionary principle).

12. On the prevalence and extent of scientific uncertainty in environmental decisionmaking, see, e.g., Daniel A. Farber, *Probabilities Behaving Badly: Complexity Theory and Environmental Uncertainty*, 37 U.C. DAVIS L. REV. 145, 148-52 (2003); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988). The scientific uncertainty that arises in environmental decisionmaking is usefully categorized into three types: relevant environmental information may be (1) available and indefinite; (2) unavailable and theoretically obtainable; and (3) unavailable and theoretically unobtainable. Marcia R. Gelpe & A. Dan Tarlock, *The Uses of Scientific Information in Environmental Decisionmaking*, 48 S. CAL. L. REV. 371, 394 (1974). Much of the relevant environmental information about GMOs seems to fall into the second and third categories.

13. Second International Conference on the Protection of the North Sea: Ministerial Declaration Calling for the Reduction of Pollution, Nov. 25, 1987, pmble; para. XVI, 27 I.L.M. 835, 838-40 (1998). The precautionary principle evolved from a German principle of environmental policy. Sonja Boehmer-Christiansen, *The Precautionary Principle in Germany – Enabling Government*, in INTERPRETING THE PRECAUTIONARY PRINCIPLE 31, 33 (Timothy O’Riordan & James Cameron eds., 1994).

14. ARIE TROUWBORST, EVOLUTION AND STATUS OF THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW 303 (annex A), 329 (annex B), (2000).

15. The ALI Restatement (Third) on International Law, § 102, defines sources of international law as follows: A rule of international law is one that has been accepted as such by the international community of states: (a) in the form of customary law; (b) by international agreement; or (c) by derivation from general principles common to the major legal systems of the world. James Cameron, *The Precautionary Principle in International Law*, in REINTERPRETING THE PRECAUTIONARY PRINCIPLE 113, 122 (Timothy O’Riordan, James Cameron & Andrew Jordan eds., 2001). For arguments that the precautionary principle is customary law, see Trouwborst, *supra* note 14, at 248 (arguing that it is customary law based on state practice in Australia, New Zealand, the United Kingdom, Chile, and India); James Cameron & Juli Abouchar, *The Status of the Precautionary Principle in International Law*, in THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION (David Freestone & Ellen Hey eds., 1996); Owen McIntyre & Thomas

tribunals have declined to definitively rule on the status of the precautionary principle in international law.¹⁶

Despite its prevalence in international law, the precautionary principle's meaning and usefulness remain controversial. Its precise wording varies in international agreements, and it "appears to mean different things in different contexts."¹⁷ The Rio Declaration of 1992 contains the most authoritative formulation of the precautionary principle in international law.¹⁸ Principle 15 of the Rio Declaration states:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.¹⁹

A number of other legal instruments, including the binding Biosafety Protocol, incorporate this version of the precautionary principle.²⁰

Considering the language used in the Rio Declaration, the precautionary principle encompasses at least two distinct meanings.²¹ The

Mosedale, *The Precautionary Principle as a Norm of Customary International Law*, 9 J. ENVTL. L. 222-23 (1997); John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVT. L. & POL'Y REV. 13, 14 (2002) ("At some level of generality, precaution is undoubtedly a customary rule of international law.").

16. In the Beef Hormones case, the WTO Appellate Body found the precautionary principle's legal status to be "less than clear" and declined to take a position. PHILIPPE SANDS, *PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW 277-78* (2d ed. 2003). The precautionary principle has also been argued by parties but not relied upon in decisions by the International Court of Justice, the International Tribunal of the Sea, and the European Court of Justice. For discussion of cases, see *id.* at 273-79; Cameron, *supra* note 15, at 128-30; BIRNIE & BOYLE, *supra* note 10, at 118-19.

17. BIRNIE & BOYLE, *supra* note 10, at 116. For descriptions of variations in the wording of the precautionary principle in international law, see Katz, *supra* note 3, at 957.

18. Applegate, *supra* note 15, at 13.

19. Rio Declaration on Environment and Development, June 14, 1992, U.N. Doc. A/CONF.151/5 (1992), reprinted in 31 I.L.M. 874, 879 (1992) [hereinafter Rio Declaration].

20. In addition to reaffirming and stating its accord with Principle 15 of the Rio Declaration in its preamble and Article 1, the Biosafety Protocol incorporates precautionary language into Articles 10 and 11 of the protocol. The Protocol provides that

[I]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a [GMO] on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regards to the import of the [GMO] in question . . . in order to avoid or minimize such potential adverse effects.

Biosafety Protocol, *supra* note 4, at 1031. For discussions of the meaning of the precautionary principle in the Biosafety Protocol, see, e.g., Applegate, *supra* note 15, at 63-66; Darren Smits & Sean Zaboroski, *GMOs: Chumps or Champs of International Trade?* 1 ASPER REV. INT'L BUS. & TRADE L. 111 (2001).

21. BIRNIE & BOYLE, *supra* note 10, at 116 ("Much of the confusion surrounding [the precautionary principle] stems from a failure to distinguish the identification of risk from the entirely separate question of how to respond to that risk. Thus to suggest that states shall 'apply a precautionary approach (or principle)' may mean that when faced with uncertainty, they must

first possible meaning is that the decisionmaker must take cautious measures when faced with scientific uncertainty about potentially serious environmental harms.²² In other words, the “caution” in the precautionary principle speaks to the ultimate decision about what regulatory response is required. Under this interpretation, the decisionmaker is obligated to prohibit or restrict a new product or activity when there is a high level of scientific uncertainty regarding potentially serious environmental harms.

A second possible meaning of the precautionary principle is that the decisionmaker must identify and consider risks with caution when faced with scientific uncertainty about potentially serious environmental harms.²³ Here, “caution” relates to the decisionmaking process. Under this interpretation, the decisionmaker must acknowledge a given uncertainty and take it into account when determining whether and how to proceed.²⁴ With regard to the ultimate regulatory decision, the precautionary principle would permit – but not require – scientific uncertainty to serve as a basis for governmental restrictions.

Most critics understand the precautionary principle to have the first meaning; they interpret it to require restrictive regulation in the face of scientific uncertainty.²⁵ Professor Sunstein, for example, understands the precautionary principle “to suggest that regulation is required whenever there is a possible risk to health, safety, or the environment, even if the supporting evidence is speculative and even if the economic costs of regulation are high.”²⁶ Professor Sunstein and other critics are accordingly concerned that the precautionary principle will lead governmental decisionmakers to overlook the costs of regulation and the benefits of the proposed product or activity.²⁷ From this perspective, the

be more cautious in identifying risks, or it may mean that they must be more cautious in taking measures to deal with those risks.”).

22. *Id.*

23. *Id.*

24. *Id.* at 117 (“As endorsed in Rio Principle 15, what the precautionary principle does mean is that uncertainties . . . should be acknowledged and taken into account when determining whether to proceed and what controls are needed.”).

25. See, e.g., Adler, *supra* note 3, at 777; Cross, *supra* note 3, at 853. Cf. Applegate, *supra* note 15, at 29.

26. Sunstein, *supra* note 11, at 1018 (classifying this as a “strong” version of the precautionary principle and finding that “this understanding fits with the understandings of many of its most enthusiastic proponents, and that with relatively modest variations, this understanding fits with many of the legal formulations as well” (citations omitted)). Professor Sunstein suggests that “weak versions of the precautionary principle are unobjectionable and important.” *Id.* at 1016. On strong and weak versions of the principle, see *infra* note 38.

27. Cross, *supra* note 3, at 860; Sunstein, *supra* note 11, at 1023; Stone, *supra* note 11, at 10792; Adler, *supra* note 3; Goklany, *supra* note 3. In the context of GMOs, critics argue that the precautionary principle disregards the benefits of greater agricultural productivity. See, e.g., Adler, *supra* note 3 (arguing that GMOs would reduce habitat loss by improving agricultural productivity); Goklany, *supra* note 3, at 48 (arguing that GMOs would improve nutrition and

precautionary principle could result in perverse outcomes that do not maximize social welfare or environmental quality.²⁸

The precautionary principle in international law, however, has developed a meaning closer to the second interpretation. Analyzing changes in articulations of the precautionary principle in international law over time, Professor Applegate finds that the precautionary principle of international law has been “tamed.”²⁹ Most importantly, the precautionary principle does not determine what particular measures a decisionmaker should take when environmental impacts are characterized by scientific uncertainty.³⁰ Consistent with this interpretation, the “consequences of applying a precautionary approach differ widely.... Invoking the precautionary principle or approach cannot in itself determine what those measures should be, or how strong they should be.”³¹ The precautionary principle leaves the question of what measures to take, and indeed whether to take any measures, up to the decisionmaker.³²

In addition, this second interpretation does not require decisionmakers to disregard other decisionmaking principles and techniques. In particular, it does not substitute for or prohibit risk assessment or cost-benefit analysis. The language contained in various international agreements supports this interpretation. For example, the Biosafety Protocol relies extensively on the precautionary principle but also specifies the use of risk assessment techniques.³³ Moreover, the Rio

health in the developing world). Critics are also concerned that the precautionary principle will be used to erect trade barriers. *See, e.g.,* Stone, *supra* note 11, at 10791 (“In the trade area, most prominently, there is concern that, as long as the precautionary principle remains nebulous, trading nations will mask as ‘precautionary health protection measures’ border controls actually designed to shield domestic producers from foreign competition.”).

28. Cross, *supra* note 3, at 859-60; Adler, *supra* note 3, at 764.

29. *See* Applegate, *supra* note 15, at 15-16, 68 (explaining that “the constituent elements of the precautionary principle have been altered over time to be less stringent or to narrow the scope of the principle” and describing the shift from a strong hazard-based precautionary principle to a weak risk-based precautionary principle).

30. *Id.* at 19-20, 30. *See also* David Freestone & Ellen Hey, *Implementing the Precautionary Principle: Challenges and Opportunities*, in FREESTONE & HEY, *supra* note 15, at 250-53.

31. BIRNIE & BOYLE, *supra* note 10, at 119-20.

32. On the range and types of regulatory responses that may be appropriate under the precautionary principle, *see* Applegate, *supra* note 15, at 29-30. Given the extent of discretion it leaves to the decision maker, the precautionary principle is more appropriately characterized as a standard than a rule. *See, e.g.,* Sonia Boutillon, Note, *The Precautionary Principle: Development of an International Standard*, 23 MICH. J. INT’L L. 429, 447 (arguing that the precautionary principle fits the definition of a standard in international law); David Freestone, *International Fisheries Law Since Rio: The Continued Rise of the Precautionary Principle*, in INTERNATIONAL LAW AND SUSTAINABLE DEVELOPMENT, 136 (Alan Boyle & David Freestone eds., 1999); Cameron, *supra* note 15, at 133.

33. Biosafety Protocol, *supra* note 4, at arts. 10(1), 15; Applegate, *supra* note 15, at 63-66; Aarti Gupta, *Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?*, 9 IND. J. GLOBAL LEGAL STUD. 265, 265-66 (2001).

Declaration's precautionary principle explicitly refers to the use of cost-benefit analysis when it speaks of "cost-effective" measures.³⁴ Accordingly, the precautionary principle stands alongside other risk-assessment and management tools used by environmental decisionmakers.³⁵

The precautionary principle not only requires that decisionmakers account for scientific uncertainty, but also provides that they can legitimately invoke scientific uncertainty to restrict a product or activity.³⁶ The precautionary principle makes scientifically uncertain risks "legally significant" but does not require a particular substantive outcome.³⁷ Accordingly, the importance of the precautionary principle is procedural rather than substantive. Interpreting the precautionary principle to speak to the decisionmaking process rather than to the ultimate regulatory decision might be considered a weak rather than a strong form of the precautionary principle.³⁸ However, by reinforcing the value of preventing environmental harms and ensuring appropriate concern for

34. Rio Declaration, *supra* note 19, Principle 15; David A. Dana, *A Behavioral Economic Defense of the Precautionary Principle*, 97 NW. U.L. REV. 1315, 1316 (2003) ("The principle is better understood as a complement to, rather than as a substitute for, cost-benefit analysis."); Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More than Money*, 76 N.Y.U. L. REV. 114, 184 (2001) (arguing that the precautionary principle and other versions of the "safety principle" are "not inconsistent with cost-benefit methodology"). The European Commission's Communication on the Precautionary Principle also makes clear the continued relevance of cost benefit analysis. Commission of the European Communities, Communication from the Commission on the Precautionary Principle, COM(2000)1, at 19, available at http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf (last visited Nov. 27, 2004).

35. For an explanation of how the precautionary principle fits with traditional risk assessment and management tools, see Commission of the European Communities, *supra* note 34, at 18-20. The communication limits the applicability of the precautionary principle to harms that cannot be sufficiently characterized by science and links the precautionary principle to more traditional risk management tools, particularly scientific risk assessment and cost benefit analysis. The communication states that the implementation of the principle should start with a scientific evaluation that is "as complete as possible," including identification of the degree of scientific uncertainty. The communication sets forth five guidelines for measures that are based on the precautionary principle. Such measures should be: (1) proportional to the chosen level of protection, (2) non-discriminatory, (3) consistent with similar measures, (4) based on an examination of costs and benefits, and (5) contingent on future scientific developments. *Id.*

36. United States environmental laws broadly incorporate the idea that scientific uncertainty may serve as a basis for governmental restrictions. See David Vogel, *The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe*, 33 BRIT. J. POL. SCI. 557, 561-62 (2003); Trouwborst, *supra* note 14, at 189-200; Daniel Bodansky, *The Precautionary Principle in US Environmental Law*, in INTERPRETING THE PRECAUTIONARY PRINCIPLE (Timothy O'Riordan & James Cameron eds., 1994).

37. BIRNIE & BOYLE, *supra* note 10, at 119.

38. On the strength of different formulations of the precautionary principle, see Sunstein, *supra* note 11, at 1011-14; Andrew Jordan & Timothy O'Riordan, *The Precautionary Principle in Contemporary Environmental Policy and Politics*, in PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE 30-32 (Carolyn Raffensperger & Joel Tickner eds., 1999); Soule, *supra* note 3, at 18.

scientific uncertainty, the precautionary principle effectively counters the increasingly common call for full or almost full scientific certainty before taking regulatory action.³⁹

B. *Application of the Precautionary Principle by National Courts*

As the precautionary principle has become accepted as a principle of international law, national courts have invoked and applied it in a growing number of cases. For example, courts in several countries have applied the precautionary principle to strike down particular government actions or impose specific duties on the government.⁴⁰ At the same time, national courts face many barriers with respect to applying the precautionary principle and other international environmental law principles. Even where these barriers are overcome, there is disagreement about how to apply the principle, with some courts considering it to mean merely that governmental decisions should be guided by "common sense" and others interpreting it more rigorously to determine substantive policy outcomes.

A recent study showed that while national courts are playing an increasingly important role in implementing international environmental norms such as the precautionary principle, there are also significant barriers.⁴¹ These barriers include restrictive standing rules, judges' and litigants' lack of familiarity with the law, and the indeterminacy of many of the norms.⁴² In several countries, the judicial branch is also unwilling to rule against the government, particularly in matters relating to the implementation of international law.⁴³ In cases where international environmental law did come into play, national courts invoked principles of "uncertain" legal status such as the precautionary principle as sources of international environmental law second only to treaty provisions.⁴⁴ It appears that the indirect application of international environmental law—

39. Applegate, *supra* note 15, at 72-75. On the importance of the values expressed by the precautionary principle, see Dana, *supra* note 34, at 1317 ("Principles can express and reinforce value commitments and procedurally structure decisionmaking without dictating a single set of specific, substantive outcomes.").

40. See *infra* notes 47-49. In a variety of other cases, national courts have discussed or applied the precautionary principle in a less conclusive or less approving manner. See Bodansky & Brunnée, *supra* note 10, at 17, n.83 (citing cases from Australia, Canada, Netherlands, the United Kingdom, and the United States). On German court cases, see PETER H. SAND, *INTERNATIONAL ENVIRONMENTAL LAW: LESSONS IN GLOBAL CHANGE* 135-37 (1999).

41. Bodansky & Brunnée, *supra* note 10.

42. Bodansky & Brunnée, *supra* note 10, at 20-21.

43. Donald R. Rothwell & Ben Boer, *International Environmental Law and Australian Courts*, in *INTERNATIONAL ENVIRONMENTAL LAW IN NATIONAL COURTS*, *supra* note 9, at 23, 43; Daniel Bodansky & Mary Manous, *International Environmental Law in United States Courts*, in *INTERNATIONAL ENVIRONMENTAL LAW IN NATIONAL COURTS*, *supra* note 9, at 238.

44. Bodansky & Brunnée, *supra* note 10, at 16.

its use as an interpretive aid for national law—is more common than its direct application as the rule of decision.⁴⁵

Most cases in which national courts have applied the precautionary principle have involved challenges of governmental decisions by citizen groups.⁴⁶ In 1993, an Australian court applied the principle to delay the building of a road until the government gathered more information on the population and habitat of an endangered frog.⁴⁷ The Pakistani Supreme Court applied the precautionary principle in a 1994 case to disallow the building of new power stations until further scientific evidence showed that electromagnetic fields from the stations would not be harmful.⁴⁸ In 1996, the Indian Supreme Court invoked the precautionary principle as part of the legal basis for ordering the implementation and enforcement of stringent industrial pollution control measures and the closure of non-complying facilities.⁴⁹ A commentator on the status of the precautionary principle in Australia, where perhaps the greatest of number of precautionary principle cases have been litigated,⁵⁰ views judicial implementation of the precautionary principle as “ideal” because it is sufficiently flexible to tailor the principle’s effect to the particular facts of the case.⁵¹

45. *Id.* at 15.

46. Cf. Elizabeth Fisher & Ronnie Harding, *The Precautionary Principle in Australia: From Aspiration to Practice*, in REINTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 15, at 215, 220 (stating that in Australia “the precautionary principle has been considered in over twenty five court review decisions” in which “applicants have tended to argue (among numerous other arguments) that a particular decision should be struck down because there was a failure properly to apply the precautionary principle”); Bodansky & Brunnée, *supra* note 10, at 18 (“Our study found a number of cases in which international environmental law was used as the basis of a claim against a plaintiff’s own government.”).

47. *Leatch v. Nat’l Parks & Wildlife Serv.*, 81 L.G.E.R.A. 270, 1993 NSW LEXIS 8229 (1993). See Trouwborst, *supra* note 14, at 232-34. *But see* Fisher & Harding, *supra* note 46, at 221 (discussing the *Leatch* case as a “significant exception” to the Australian courts’ tendency to be hesitant to overturn an administrative decision for not utilizing the precautionary principle appropriately). For a description of other Australian and New Zealand cases, see Trouwborst, *supra* note 14, at 234-42.

48. *Shehla Zia v. WAPDA* (1994), available at <http://www.elaw.org/resources/text.asp?ID=280>. See Trouwborst, *supra* note 14, at 223.

49. *Vellore Citizens Welfare Forum v. Union of India* (1996), available at <http://www.elaw.org/resources/text.asp?ID=199>. See Trouwborst, *supra* note 14, at 224-25.

50. See Fisher & Harding, *supra* note 46, at 215 (stating that “Australia has been at the forefront of the implementation of the precautionary principle.”); see also Elizabeth C. Fisher, *The Precautionary Principle as a Legal Standard for Public Decision-making: the Role of Judicial and Merits Review in Ensuring Reasoned Deliberation*, in PERSPECTIVES ON THE PRECAUTIONARY PRINCIPLE 83 (Ronnie Harding & Elizabeth Fisher eds., 1999).

51. Charmian Barton, *The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine*, 22 HARV. ENVTL. L. REV. 509, 547-52 (1998) (commenting on the implementation of the precautionary principle by Australian courts). See also Fisher, *supra* note 50, at 83 (stating “legal decisions are highly influential in furthering definition of the precautionary principle and its implications for administrative action”).

Where national courts are receptive to challenges against governmental actions based on the precautionary principle, the question remains as to how courts should apply it. In many cases, national courts have treated the precautionary principle as a doctrine of “common sense,” interpreting it in a limited way to require that governmental decisions be supported by common sense.⁵² Some courts, in contrast, have found it to require that the government restrict or prohibit an activity characterized by uncertain risks.⁵³ Since the precautionary principle is best understood to require that decisionmakers consider scientific uncertainty about potentially serious environmental harms in their decisionmaking process, national courts should apply it as a procedural requirement. A national court should review the government’s decisionmaking process to determine whether or not it complied with the precautionary principle while leaving the substantive determination to the governmental decisionmaker. The court can thus ensure that the decisionmaker considered the scientific uncertainty of potentially serious environmental damages without dictating the decisionmaker’s regulatory response.

II. JUDICIAL APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN BRAZIL

This section provides an overview of the case and summarizes the decisions of the district and appellate courts. In the Brazilian GMO case, the national courts applied the precautionary principle as a principle of international environmental law. While the courts essentially agreed upon the principle’s status in international law, the district and appellate courts differed in their assessment of what procedures were necessary to satisfy the precautionary principle.

A. Overview of the Brazilian GMO Case

As the first GMO seed for which commercial approval was sought in Brazil, Monsanto’s “Roundup Ready” (RR) soybeans have been at the center of the Brazilian GMO controversy.⁵⁴ In June 1998, Monsanto requested approval for RR soybeans from the responsible federal agency,

52. Bodansky & Brunnée, *supra* note 10, at 15 and n. 66 (citing representative cases).

53. See *supra* notes 47-49 and associated text.

54. Roundup Ready soybeans are genetically modified to be tolerant of “Roundup,” a glyphosate-based herbicide produced by Monsanto. See http://www.monsanto.com/monsanto/us_ag/layout/productivity_traits/rr_soybean/default_um.asp (last visited February 28, 2005). Two related lawsuits constitute the Brazilian GMO case. The first lawsuit was an action seeking injunctive relief (*ação cautelar*). The second lawsuit was a public civil action (*ação civil pública*). Under Brazilian civil procedure, the *ação cautelar* is the “preparatory lawsuit” that is decided immediately based on whether it makes out a prima facie case (*fumus boni juris*) and demonstrates the risk of irreparable damage (*periculum in mora*). The *ação civil pública* is the “principal lawsuit” that is decided on its merits.

the National Technical Commission on Biosafety (CTNBio, *Comissão Técnica Nacional de Biossegurança*) pursuant to Brazil's National Biosafety Law of 1995.⁵⁵ In September 1998, a non-governmental consumer organization, the Brazilian Institute of Consumer Defense (IDEC, *Instituto Brasileiro de Defesa do Consumidor*), filed a lawsuit against the federal government to prevent the approval of RR soybeans.⁵⁶ In the course of the litigation, the environmental organization Greenpeace Brazil joined IDEC as a plaintiff.⁵⁷ Monsanto of Brazil, and its subsidiary, Monsoy Ltd., joined the federal government as defendants.⁵⁸

The first legal action by IDEC was an action for injunctive relief (*ação cautelar*), filed in São Paulo federal district court in September 1998.⁵⁹ IDEC argued that the Brazilian Constitution required the preparation of an environmental impact study (EIA, *estudo de impacto ambiental*) and that CTNBio did not have the power to authorize RR

55. *Lei de Biossegurança*, Lei No. 8.974, de 5 de Janeiro de 1995, D.O.U. de 06/01/1995 (hereinafter, National Biosafety Law). See Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L & COMP. L. 129, 155 (2000); Victor Palaez & Wilson Schmidt, *The Dissemination of Genetically Modified Organisms in Brazil*, 4 INT'L. J. OF BIOTECHNOLOGY 211, 222 (2002). CTNBio is a federal commission of the Ministry of Science and Technology (*Ministério de Ciência e Tecnologia*, or MCT) that was created by the National Biosafety Law of 1995. Under the regulations of the National Biosafety Law, CTNBio's responsibilities included the formulation of a national biosafety policy and an ethics code for genetic manipulation; the establishment of norms and regulations relating to the cultivation, manipulation, use, transport, storage, marketing, consumption, and discard of GMOs; the classification of GMOs according to their degree of risk; and the issuance of "conclusive technical opinions" (*parecer técnico prévio conclusivo*) authorizing the release of GMOs into the environment. Decreto No. 1.752 de 20 de dezembro de 1995, D.O.U. de 21/12/95, arts. 1, 2.

56. See Palaez & Schmidt, *supra* note 55, at 222; Paarlberg, *supra* note 8, at 75; see also Valdir de Oliveira Rocha, *Biotechnology in Brazil: Legal and Economic Aspects*, available at http://www.veirano.com.br/english/conteudo_articles.cgi?ARTIGO=13 (last visited Nov. 27, 2004). IDEC is a Brazilian consumer organization founded in 1987 with approximately 40,000 members. It describes itself as an organization that conducts comparison tests of products and services, informs members of their consumer rights, organizes public campaigns which may include lawsuits and lobbying, and publishes a magazine, Consumers Inc., as well as other pro-consumer guides. See <http://www.idec.org.br/default.asp> (last visited January 26, 2005).

57. Paarlberg, *supra* note 8, at 76. Greenpeace is an international environmental organization founded in 1971 that has 2.8 million members worldwide and offices in 41 countries. See http://www.greenpeace.org/international_en/history/ (last visited Nov. 27, 2004). Greenpeace Brazil began operating in 1992. See Souza, *supra* note 55, at n.97. The federal environmental agency, the Brazilian Institute of the Environment and Natural Resources (IBAMA, *Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis*) also joined as a plaintiff, but was removed from the case by an executive order handed down on June 1, 2000. See Appellate Court Decision in the *Ação Cautelar*, *supra* note 6, at 11.

58. IDEC, *Transgenicos 3* (a document written shortly after September 1, 2003, to summarize the legal history of the case), available at www.idec.org.br/files/relatorio_transgenicos.doc. See also Souza, *supra* note 55, at 156; Paarlberg, *supra* note 8, at 76-77.

59. *Transgenicos*, *supra* note 58, at 1-2. See also Souza, *supra* note 55, at 156. For further explanation of the "ação cautelar" in Brazilian civil procedure, see *supra* note 6.

soybeans without one.⁶⁰ The district court granted the preliminary injunction,⁶¹ which was affirmed and made permanent by a federal district court in Brasilia in August 1999.⁶² In August 2000, the Federal Regional Tribunal (TRF, *Tribunal Federal Regional*) upheld the injunction on appeal.⁶³ The injunction invalidated the governmental approval of RR soybeans, ordered Monsanto and Monsoy to refrain from marketing RR soybeans, and required Monsanto and Monsoy to prepare an EIA prior to any future approval of RR soybeans.⁶⁴ The injunction remained in force throughout the adjudication of the case.⁶⁵

In October 1998, IDEC filed the principal legal action in the case, a public civil action (*ação civil pública*).⁶⁶ IDEC again argued that the

60. Souza, *supra* note 55, at 156. The Brazilian GMO case also involved allegations that the government failed to enact product labeling regulations as required by the Consumer Defense Code. *Id.* Aspects of the case dealing with product labeling are beyond the scope of this article.

61. Decision by Juiz Raquel Fernandez Perrini, 11^o Vara Federal da Seção Judiciária de São Paulo federal district court, September 1998. See Palaez & Schmidt, *supra* note 55, at 222. See also District Court Decision in the Ação Cautelar, *supra* note 6, at 1-2 (transcribing a portion of Judge Perrini's decision). After granting the injunction, Judge Perrini requested that the case be transferred to a federal district court in Brazil's capital, the 6^a Vara Federal da Seção Judiciária do Distrito Federal, where Greenpeace had filed another lawsuit regarding GMOs in 1997. See Souza, *supra* note 55, at 156; District Court Decision in the Ação Civil Pública, *supra* note 6, at 1; District Court Decision of the Ação Cautelar, *supra* note 6, at 2-3.

62. District Court Decision in the Ação Cautelar, *supra* note 6. The courts issued two other rulings before the final ruling in August 1999. In November 1998, Judge Antônio Oswaldo Scarpa, a substitute judge in the 6th federal district court (6^a Vara Federal da Seção Judiciária) issued a ruling that partially revoked the injunction that had been conceded by Judge Perrini. See *Id.* at 3. See Paarlberg, *supra* note 8, at 77. In June 1999, Judge Prudente issued a ruling that reinstated and expanded the initial injunction. The final decision of August 1999 made this injunction permanent. See District Court Decision in the Ação Cautelar, *supra* note 6, at 6-7; Paarlberg, *supra* note 8, at 77.

63. Appellate Court Decision in the Ação Cautelar, *supra* note 6.

64. District Court Decision in the Ação Cautelar, *supra* note 6, at 56-58. On September 24, 1998, CTNBio approved RR soybeans for commercial use. Palaez and Schmidt, *supra* note 55, at 223. See CTNBio Communication No. 54 (Comunicado No. 54), Published in the Diário Oficial da União N^o 188 de 01.10.98, Seção 3, página 56, available at <http://www.ctnbio.gov.br/ctnbio/legis/comunicados/054.htm>.

65. While the injunction remained in place, it was partially undermined by an executive order that legalized the harvest of RR soybeans in the 2002-2003 season and the planting and harvest of RR soybeans in the 2003-2004 season. Medida Provisória No. 113 of March 26, 2003, Published in the D.O.U. de 27.03.2003, art. 1, seção I, 1^a página, converted into Lei n^o 10.688, de June 13, 2003, available at http://www.mct.gov.br/legis/mp/mp113_2003.htm; Medida Provisória No. 131 of September 25, 2003, published in the D.O.U. de 26.09.2003, seção I, 1^a página, converted into Lei n^o 10814, de 15 de Dezembro de 2003, available at http://www.mct.gov.br/legis/mp/mp131_2003.htm. The Federal Attorney General challenged the constitutionality of Medida Provisória No. 131 in a Direct Action of Unconstitutionality filed in the Federal Supreme Court in January 2004. See <http://www.pgr.mpf.gov.br/pgr/3camara/portarias/ADINFontelessojatransgenicaLei10814.htm>.

66. IDEC, *supra* note 56, at 7. The Public Civil Action Law of 1985 (*Lei de Ação Civil Pública*) authorizes civil society organizations and a wide range of governmental entities to file public civil actions (*ação civil pública*) in order to defend environmental and other "diffuse and collective interests." Lei No. 7.347 de 24 de julho de 1985, D.O.U. de 25.07.85; see also Antonio Gidi, *Class Actions in Brazil - A Model for Civil Law Countries*, 51 AM. J. COMP. L. 311, 327

Constitution required the preparation of an EIA prior to governmental approval, and it asked the court to prohibit CTNBio from approving RR soybeans or any other GMO without one.⁶⁷ In June 2000, the district court decided the case in favor of the plaintiffs.⁶⁸ In addition to maintaining the injunction that had applied specifically to RR soybeans, the court held that the CTNBio could not approve any GMO without an EIA.⁶⁹ In June 2004, the appellate court reversed the decision, finding that CTNBio had adequately evaluated the GMO without preparing an EIA.⁷⁰

In reaching their decisions, the district court and the appeals court considered two key issues: (1) the constitutionality of CTNBio's action and (2) the application of the precautionary principle. The constitutional question was whether CTNBio violated the Constitution's environmental provisions by approving RR soybeans without requiring an EIA. The relevant provision of the Constitution states, "it is the responsibility of the Government to... require, in the form of the law, a prior environmental impact study, which shall be made public, for installation of works or activities that may cause significant degradation of the environment."⁷¹ The district court found that GMOs may cause

(2003); Matt Handley, Comment, *Why Crocodiles, Elephants, and American Citizens Should Prefer Foreign Courts: A Comparative Analysis of Standing to Sue*, 21 REV. LITIG. 97, 129-35 (2002); Edesio Fernandes, *Collective Interests in Brazilian Environmental Law*, in PUBLIC INTEREST PERSPECTIVES IN ENVIRONMENTAL LAW 118, 123-25 (David Robinson & John Dunkey eds., 1995) (with translation of law into English at 130-34).

67. *Transgenicos*, *supra* note 58, at 7; see also District Court Decision in the Ação Civil Pública, *supra* note 6, at 2.

68. *Transgenicos*, *supra* note 58, at 8.

69. District Court Decision in the Ação Civil Pública, *supra* note 6, at 50.

70. Appellate Court Decision in the Ação Civil Pública, *supra* note 7. In the appellate decision, Judge Antônio Ezequiel da Silva concurred with Judge Almeida while Judge João Batista Gomes Moreira dissented. See TRF Derruba Decisão que Proíbia Soja Transgênica, GAZETA MERCANTIL, June 29, 2004; Justiça Mantém Veto para Soja Transgênica, GAZETA MERCANTIL, June 30, 2004, available at http://agenciact.mct.gov.br/index.php?action=/content/view&cod_objeto=18632 (last visited Nov. 27, 2004). Plaintiffs appealed the decision to a larger panel of the appellate court, and future appeals may be made to the Supreme Tribunal of Justice (STJ, *Supremo Tribunal de Justiça*), and, ultimately, the Federal Supreme Court (STF, *Supremo Tribunal Federal*). On civil procedure and the structure of the federal courts in Brazil generally, see José Carlos Barbosa Moreira, *Brazilian Civil Procedure: An Overview*, in A PANORAMA OF BRAZILIAN LAW 183-205 (Jacob Dolinger & Keith S. Rosenn eds., 1992). For more information on the structure of Brazilian courts, see José Reinaldo de Lima Lopes, *Social Rights and the Courts*, in FROM DISSONANCE TO SENSE 567 (Thomas Wilhelmsson & S. Hurri eds., 1998); Megan J. Ballard, *The Clash Between Local Courts and Global Economics: the Politics of Judicial Reform in Brazil*, 17 BERKELEY J. INT'L L., 230, 245-46 (1999).

71. Constituição Federal (1988), art. 225, § 1, para. IV. Translation from JACOB DOLINGER & KEITH S. ROSENN, A PANORAMA OF BRAZILIAN LAW 492-93 (1992). In Portuguese, Article 225 states:

Art. 225. Todos têm direito ao meio ambiente ecologicamente equilibrado, bem de uso comum do povo e essencial à sadia qualidade de vida, impondo-se ao poder

significant degradation and that the Constitution thus obligated CTNBio to prepare an EIA for RR soybeans and for any other GMO proposed for commercial use.⁷² The appellate court disagreed, and found that the Constitution allows for governmental discretion in deciding whether a particular activity may cause significant degradation.⁷³ The court held that the National Biosafety Law granted CTNBio such discretionary power and that CTNBio had not violated the Constitution by approving RR soybeans without an EIA.⁷⁴

The district court and the appellate court also based their decisions on their respective interpretations of the precautionary principle. Importantly, both courts considered the precautionary principle to be binding international law applicable to the question of GMO approval. Observing its inclusion in the Convention on Biological Diversity and suggesting that it had attained the status of customary international law, the district court called the precautionary principle a “fundamental rule of international environmental protection law.”⁷⁵ The appellate court similarly noted that the precautionary principle was binding international

público e à coletividade o dever de defendê-lo e preservá-lo para as presentes e futuras gerações.

§ 1º - Para assegurar a efetividade desse direito, incumbe ao poder público: ...

IV - exigir, na forma da lei, para instalação de obra ou atividade potencialmente causadora de significativa degradação do meio ambiente, estudo prévio de impacto ambiental, a que se dará publicidade; ...

For a discussion of the Brazilian constitution's environmental provisions, see Edesio Fernandes, *Constitutional Environmental Rights in Brazil*, in HUMAN RIGHTS APPROACHES TO ENVIRONMENTAL PROTECTION 265, 276-79 (Alan E. Boyle & Michael R. Anderson eds., 1996).

72. While IDEC's original complaint involved only the authorization of RR soybeans, the final decision of the district court in the public civil action applied to any GMO. More specifically, the judge ruled that CTNBio did not have the legal authority to authorize any GMO without the preparation of an environmental impact statement. See District Court Decision in the Ação Civil Pública, *supra* note 6, at 37.

73. The court found that the phrase “in the form of law” permitted the establishment of infra-constitutional laws to establish “what is meant by ‘significant environmental degradation’” and “how and when, an EIA must be done.” Appellate Court Decision in the Ação Civil Pública, *supra* note 7, at 100.

74. *Id.* at 110-11, 118-31. The regulations of the National Biosafety Law stated that CTNBio has the authority “to require, as additional documentation, if determined necessary, an Environmental Impact Study of projects and applications involving the release of GMOs into the environment, beyond the specific requirements for the applicable level of risk.” Decreto No. 1,752 de 20 de dezembro de 1995. DOU de 21 de dezembro de 1995. Cap. 2, Art. 2, XIV. The district court ruled this regulatory provision unconstitutional. District Court Decision in the Ação Civil Pública, *supra* note 6, at 37-38.

75. *Id.* at 7-9. The decision does not directly state that the precautionary principle is part of customary law but refers favorably to writings by the commentator Phillippe Sands: “With specific regard to the precautionary principle, Sands has no doubt in stating that this principle, expressed in the Rio Declaration and appropriately incorporated into the Conventions on Climate Change and Conservation of Biological Diversity, is part of customary international law, being as such, a rule of *jus cogens* that, in countries like the United Kingdom, are incorporated automatically into internal national law.” *Id.* at 12.

law based on its inclusion in the Convention on Biological Diversity and the Framework Convention on Climate Change, but it rejected the notion that it was customary law.⁷⁶

Both courts also held that the precautionary principle had been incorporated into the environmental provisions of the Brazilian Constitution.⁷⁷ The district court found it embodied specifically in the constitutional provision requiring the EIA.⁷⁸ The appellate court cited two other environmental provisions that require the government to preserve the country's genetic diversity and integrity⁷⁹ and to control the production, marketing, and use of techniques and substances that pose risk to life, the quality of life, and the environment.⁸⁰ Both courts thus viewed the precautionary principle as applicable in this case, not only as international law but also as national law. However, they reached different conclusions about what the precautionary principle requires of the government in deciding whether to allow GMOs.

B. District Court Decision: The Precautionary Principle Requires an EIA

The district court held that CTNBio violated the precautionary principle by not requiring the preparation of an EIA for the approval of RR soybeans and other GMOs. The court first determined that GMOs presented a significant risk of harm, which it found triggered the precautionary principle.⁸¹ The court concluded that preparing an EIA was necessary to carry out the precautionary principle, as an EIA would “enable real-world predictions of the possible environmental harms caused by the use of GMOs.”⁸² The court explained that “[t]he application of the precautionary principle is closely related to the evaluation of the impacts of human activities. The EIA incorporates precaution and prevention of environmental degradation in its methodology.”⁸³ For the district court, the preparation of the EIA represented compliance with the precautionary principle.

76. Appellate Court Decision in the *Ação Civil Pública*, *supra* note 7, at 403.

77. District Court Decision in the *Ação Civil Pública*, *supra* note 6, at 22. “The precautionary principle, as seen, results from the protective strength of the constitutional text with its requirement to protect the environment as the inheritance of all of humanity.” *Id.* at 26. Appellate Court Decision in the *Ação Civil Pública*, *supra* note 7, at 405.

78. Art. 225, *supra* note 71, § 1º, para. IV.

79. *Id.* para. II.

80. *Id.* para. V.

81. District Court Decision in the *Ação Civil Pública*, *supra* note 6, at 14.

82. *Id.* at 7.

83. *Id.* at 23.

The district court found that other forms of environmental assessment could not substitute for the EIA.⁸⁴ “To apply the precautionary principle, it is essential that a process of prior impact assessment occur, given the uncertainties of harm, and this process is the ‘Environmental Impact Statement.’ As thorough as other assessments may be, they cannot substitute for this process.”⁸⁵ The court concluded that “[a]s the ‘essential procedural tool to evaluate impacts in the face of uncertainties of harm,’ the EIA fulfills the requirement to make the precautionary principle effective.”⁸⁶ On this basis, the district court found that CTNBio’s reliance on environmental assessments conducted in other countries did not meet the requirements of the precautionary principle.⁸⁷ According to the district court, the precautionary principle required that an EIA be conducted in the climatic and ecological context of Brazil.⁸⁸

The district court also found that the slow and lengthy nature of the EIA process was consistent with the precautionary principle.⁸⁹ Under Brazilian law, the EIA process requires that the private or public entity seeking to undertake a potentially harmful project or activity engage a “multidisciplinary team” that proceeds systematically through four phases: an initial planning phase, a technical study phase, a reporting phase, and an evaluation phase. There are public notifications and hearings throughout the process. As the court stated, “[t]he precautionary principle, to be applied effectively, has to take the place of rushing, of precipitous behavior, of insensible rapidity and the desire for immediate results.”⁹⁰ The court criticized the speed of CTNBio’s decision, observing that its approval of RR soybeans was granted after only one year of experimental planting.⁹¹

The district court’s treatment of the constitutional issue and precautionary principle issue reinforced and complemented each other. The court resolved both issues by determining that RR soybeans, and indeed any GMO, presented the potential of significant environmental degradation.⁹² The potential of significant harm triggered both the constitutional EIA requirement and the precautionary principle, which the court deemed to be satisfied exclusively by an EIA.

84. In contrast to the opinion of the appellate court, the district court opinion does not discuss the relative strengths and weaknesses of risk assessment techniques and environmental impacts statements in characterizing the effects of GMOs. *Id.* at 25.

85. *Id.*

86. *Id.* at 29.

87. *Id.* at 9.

88. *Id.* at 8.

89. *Id.* at 35-43.

90. *Id.* at 21.

91. *Id.* at 9.

92. *Id.* at 10, 37.

C. *Appellate Court Decision: CTNBio Satisfied the Precautionary Principle*

Unlike the district court, the appellate court determined that the Brazilian government satisfied the precautionary principle in its approval process for RR soybeans. It found that the Biosafety Law and its regulations incorporated the precautionary principle and that CTNBio had properly established and followed guidelines for GMOs pursuant to this law. The court further found that CTNBio's analysis pursuant to these guidelines was sufficient to satisfy the precautionary principle. Crucial to this conclusion was the appellate court's acceptance of CTNBio's reliance on the technical information provided by Monsanto based on studies in foreign countries rather than studies specific to Brazil.⁹³ The court therefore concluded that the government had satisfied the requirements of the precautionary principle.

The appellate court observed that the National Biosafety Law and its regulations incorporated the precautionary principle.⁹⁴ In the court's view, the law accounted for scientific uncertainty in its requirement that CTNBio certify biotechnology organizations, authorize GMOs on a case-by-case basis, and receive notification of any accidents or sicknesses possibly related to GMOs.⁹⁵ The court noted that the law also directs CTNBio to stop a biotechnology-related activity immediately if there are serious risks to human, animal, plant, or environmental health.⁹⁶

The court noted that CTNBio had established and followed administrative guidelines for approving GMOs for commercial use. As set forth in the CTNBio guidelines, the proponent of a new transgenic plant must first apply to CTNBio for approval.⁹⁷ The applicant must include information about the genetic and agronomic characteristics of the transgenic plant as well as information pertaining to its environmental and health risks.⁹⁸ CTNBio makes the application public by publishing it in the country's official reporter (DOU, *Diário Oficial da União*) and submits it to one or more of its internal committees for study.⁹⁹ CTNBio then issues a "conclusive technical opinion" (*parecer técnico conclusivo*), which it publishes in the DOU.¹⁰⁰

93. Appellate Court Decision in the *Ação Civil Pública*, *supra* note 7, at 431-33, 705.

94. *Id.* at 109.

95. *Id.* at 408-09. See also Articles 2, 8, and 10 of the National Biosafety Law, *supra* note 55.

96. Appellate Court Decision in the *Ação Civil Pública*, *supra* note 7, at 409. See also Article 16 of the National Biosafety Law, *supra* note 55.

97. CTNBio Instrução Normativa No. 03 de 12 de novembro de 1996, D.O.U. de 13.11.96.

98. *Id.* at 323-24. For the particular types of information that the applicant must submit, see CTNBio Instrução Normativa No. 03, *supra* note 97.

99. Appellate Court Decision in the *Ação Civil Pública*, *supra* note 7, at 322.

100. *Id.* at 321-23.

The appellate court found that CTNBio had conformed with these guidelines, and it laid out the process that CTNBio followed.¹⁰¹ The court observed that Monsanto's request for approval of RR soybeans¹⁰² was considered by CTNBio subcommittees (*Comissões Setoriais Específicas*) specialized in the areas of plant, animal, and environmental health.¹⁰³ The court explained that CTNBio used the following elements in making its decision: Monsanto's original request; Monsanto's response to public comments; expert opinions by consultants; and documentation from regulatory agencies in Argentina, Canada, Japan, the United States, the United Kingdom, and the European Union.¹⁰⁴ "After analysis of the available information, CTNBio concluded through its process of risk evaluation, that RR soybeans did not present evidence of risk greater than that of conventional soybeans."¹⁰⁵ CTNBio issued its conclusive technical opinion approving Monsanto's request in September 1998.¹⁰⁶ The court found that the administrative record was sufficiently compelling to conclude that, even if the defendants had the burden of proving that RR soybeans are safe, they would prevail.¹⁰⁷

The court concluded that this administrative process was sufficient to satisfy the precautionary principle. As the court stated, "[t]he principle requires that before the activity [occurs] there should be an assessment that permits the decision maker to determine [the necessity of] studies in order to avoid eventual harms to people and the ecosystem."¹⁰⁸ In contrast to the district court, the appellate court held that the preparation of an EIA was not the only type of assessment that could satisfy the principle. The court pointed out that legal and scientific authorities outside Brazil had evaluated GMOs primarily using environmental risk assessment techniques rather than through the preparation of an EIA.¹⁰⁹ "The precautionary principle is not respected simply by the preparation of an EIA. Rather, the measures necessary to apply the principle depend

101. Appellate Court Decision in the Ação Civil Pública, *supra* note 7, at 411-12 ("Most important is the factual question of whether the precautionary principle was observed through the methodology called environmental and health risk assessment by CTNBio and the foreign agencies that previously evaluated the product for commercial use. This question is one of fact and does not permit conclusions without an analysis of the facts, of the procedures, and of the scientific studies done in Brazil and in other countries regarding the environmental and health safety of the specific product.").

102. *Id.* at 450. See CTNBio Communication No. 54, *supra* note 64.

103. Appellate Court Decision in the Ação Civil Pública, *supra* note 7, at 450.

104. *Id.* at 525.

105. *Id.*

106. *Id.* at 83.

107. *Id.* at 425-35.

108. *Id.* at 410.

109. *Id.* at 324-35 (discussing the similarities and differences between scientific risk assessment and environmental impact statements and finding that the former is more appropriate to GMOs than the latter). The court also endorses the use of the substantial equivalence method. *Id.* at 378.

unequivocally on the analysis of the potential harms of the proposed activity by the competent governmental agency.”¹¹⁰ For the appellate court, the relevant question was whether CTNBio considered and assessed the environmental risks, not whether it prepared an EIA.¹¹¹ Ultimately, the court found that CTNBio did in fact evaluate and consider the environmental risks with respect to RR soybeans. The court therefore held that CTNBio satisfied the requirements of the precautionary principle.

III. EFFECTIVE JUDICIAL REVIEW FOR THE PRECAUTIONARY PRINCIPLE

This section considers how national courts can ensure that government actors satisfy the precautionary principle in their decisionmaking process. It proposes that the “hard-look” doctrine of United States environmental law should serve as a model for effective judicial review of a government’s compliance with the precautionary principle. It then discusses the extent to which the Brazilian district and appellate courts ensured the Brazilian government’s compliance with the precautionary principle in the GMO case. This section concludes that the district court erred by substituting its own opinion of the necessary regulatory measures for that of the governmental agency. It also concludes that a harder look by the appellate court at CTNBio’s decisionmaking process would have strengthened its holding that CTNBio had satisfied the precautionary principle.

A. A Hard-Look Doctrine for the Precautionary Principle

The hard-look doctrine of U.S. environmental law offers certain lessons on how courts can ensure the procedural adequacy of governmental decisions without allowing courts to determine the substantive outcome of the decisionmaking process.¹¹² Applying the hard-look doctrine, U.S. courts require agencies to offer detailed explanations of their decisions. Agencies must demonstrate that they have given adequate consideration to the arguments of all parties, treat like cases similarly, and otherwise avoid arbitrary determinations.¹¹³ Courts examine the administrative record to exercise a “supervisory role” over

110. *Id.* at 410.

111. *Id.* (“[CTNBio] has the autonomy to decide if this study [the EIA] is necessary and when. CTNBio is required to do a risk assessment regardless.”).

112. The development of the hard look doctrine in United States environmental law signaled a change in the willingness of courts to supervise the exercise of agency discretion when environmental values were at stake. Harold Leventhal, *Environmental Decisionmaking and the Role of the Courts*, 122 U. PA. L. REV. 509, 512-13 (1974); Cass R. Sunstein, *Deregulation and the Hard-Look Doctrine*, 1983 SUP. CT. REV. 177, 181 (1983).

113. Cass R. Sunstein, *In Defense of the Hard Look: Judicial Activism and Administrative Law*, 7 HARV. J. L. & PUB. POL’Y 51, 52 (1984).

the administrative process.¹¹⁴ Courts do not, however, substitute their judgment for that of the administrative agencies.¹¹⁵ The ultimate regulatory decision is left to the discretion of the administrative agency.¹¹⁶ Accordingly, “[t]he court does not make the ultimate decision, but it insists that the official or agency take a ‘hard look’ at all relevant factors.”¹¹⁷ The hard-look doctrine serves as a model for ensuring “effective but appropriately deferential” judicial review.¹¹⁸

As explained above, the precautionary principle requires that government decisionmakers consider the extent of scientific uncertainty with respect to potentially serious or irreversible environmental damages. It further requires that a government refrain from using scientific uncertainty as a reason for not taking preventative measures. While the precautionary principle does not dictate the regulatory measure that a government must choose, it may serve as a legitimate basis for taking such preventive measures. According to this interpretation, the precautionary principle imposes certain procedural obligations on governmental decisionmakers.

Courts can similarly apply the hard-look doctrine with respect to the precautionary principle to ensure that government agencies consider scientific uncertainty while leaving discretion to choose the appropriate

114. Leventhal, *supra* note 112, at 511.

115. See, e.g., *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21, 412 (1976) (stating that neither [NEPA] nor its legislative history contemplates that a court should substitute its judgment for that of the agency as to the environmental consequences of its actions” and determining that the environmental decision at issue required “a high level of technical expertise and is properly left to the informed discretion of the responsible federal agencies).

116. *Id.* at 410 n.21, citing *Natural Res. Defense Council v. Morton*, 458 F. 2d 827, 838 (1972) (stating that a court cannot “interject itself within the area of discretion of the executive as to the choice of the action to be taken”). See also *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (“If the adverse environmental effects of the proposed action are adequately identified and evaluated, the agency is not constrained by NEPA from deciding that other values outweigh the environmental costs.”).

117. Leventhal, *supra* note 112, at 514. See also *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971) (finding that the Secretary’s decision should be reviewed to ensure that it was not “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” and that the court would make this finding through a “searching and careful” inquiry into the facts to determine “whether the decision was based on a consideration of relevant factors”).

118. The quoted phrase is borrowed from Celia Campbell-Mohn & John S. Applegate, *Learning From NEPA: Guidelines For Responsible Risk Legislation*, 23 HARV. ENVTL. L. REV. 93, 130 (1999). Not all commentators agree that the hard-look doctrine produced effective or appropriately deferential review. See especially MARTIN SHAPIRO, WHO GUARDS THE GUARDIANS?: JUDICIAL CONTROL OF ADMINISTRATION 53-54 (1988) (arguing that the hard-look doctrine also enabled courts to substantively review agency decisions); Thomas W. Merrill, *Capture Theory and the Courts: 1967-1983*, 72 CHI.-KENT. L. REV. 1039, 1095 (1997) (discussing the decline of the hard-look doctrine after 1983 with changing conceptions of the administrative state).

regulatory response to the decisionmaker.¹¹⁹ The ultimate decision about how to weigh scientific uncertainty in applying the precautionary principle is best resolved in the political sphere. "Judging what is an 'acceptable' level of risk for society is an eminently *political* responsibility."¹²⁰ The courts, however, may use their power of judicial review to ensure that the decisionmaker has considered scientific uncertainty with respect to potentially serious environmental damages and has not inappropriately relied on scientific uncertainty in rejecting a particular regulatory measure. By applying the hard-look doctrine in precautionary principle cases, courts can steer the narrow course between giving too much deference to administrative decisions and substituting their own judgment for that of the executive branch.¹²¹

B. *A Hard Look at the Brazilian GMO case*

In the Brazilian GMO case, the district court erred by substituting its judgment for that of the political decisionmaker. The court interpreted the precautionary principle to require a particular regulatory measure, namely a governmental ban on RR soybeans until after the preparation of an EIA. The court did not examine the administrative record to determine the basis upon which CTNBio determined that RR soybeans did not present a significant risk. Rather, by enjoining the approval of RR soybeans until after the preparation of the EIA, the court made the inherently political judgment that the risks associated with RR soybeans outweighed the benefits. The district court required that CTNBio take a cautious approach rather than requiring that CTNBio identify and consider risks with caution.¹²²

In contrast, the appellate court focused on the actual decisionmaking process of CTNBio. It observed that CTNBio had established guidelines for approving GMOs and that it had followed these guidelines in its approval of RR soybeans. However, the court did not examine CTNBio's

119. For similar argument drawing on Australian administrative law, see Fisher & Harding, *supra* note 46, at 225 ("The principle is a procedural requirement. The decision maker cannot simply ignore the problems of risk, uncertainty, and environmental degradation but must show that they have considered them and that that consideration is reflected in the decision making process."); see also Fisher, *supra* note 50, at 86 (A reviewing court "would analyze how a decision was made and in particular how a decision-maker dealt explicitly with the problem of scientific uncertainty and adapted their decision accordingly.").

120. Commission of the European Communities, *supra* note 34, at 4 (emphasis in original). See also BIRNIE & BOYLE, *supra* note 10, at 119 (The level of risk that is acceptable to society is "a policy question best answered by politicians and society as a whole, not courts or scientists.").

121. *Cf.* Marsh v. Or. Natural Res. Council, 490 U.S. 360, 378 (1989) (explaining that automatic deference "would not simply render judicial review generally meaningless, but would be contrary to the demand that courts ensure that agency decisions are founded on a reasoned evaluation 'of the relevant factors'").

122. See *supra* Section I.A for discussion of the alternative meanings of the precautionary principle.

decisionmaking process to determine how CTNBio had specifically accounted for the problem of scientific uncertainty. The court was satisfied by the fact that CTNBio had considered environmental risks generally, and did not ask the more difficult questions of whether and how scientific uncertainty regarding such risks had been factored into its regulatory decision. Notably, the appellate court was also very deferential to the executive branch. For example, it opened its opinion with the statement that “members of this Federal Court did not receive a popular mandate to decide public policies. We judges, in this or any court, do not represent the interests of the majority or the minority.”¹²³ With a deferential approach, the appellate court’s review did not ensure that CTNBio had taken a hard look at the scientific uncertainty surrounding environmental risks.

The most significant area of scientific uncertainty in this case arguably involved the lack of environmental testing within Brazil. As noted by the appellate court, CTNBio relied on the environmental assessments that had been performed in other countries, including the United States, Canada, Argentina, Japan, the United Kingdom, and the European Union.¹²⁴ Field tests conducted in Brazil had dealt only with the agronomic characteristics of RR soybeans.¹²⁵ A recent report by the U.S. National Research Council on the environmental effects of GMOs makes the relevant point that the assessments of transgenic plants performed by the United States government are limited to “whether and how transgenic plants are moved and released in the United States,” and that environmental risks and impacts not considered in the United States might be important to consider in other countries.¹²⁶ Although a thorough evaluation of CTNBio’s consideration of scientific uncertainty is beyond the scope of this Article, the lack of environmental studies within Brazil suggests that the appellate court should have examined not only whether CTNBio evaluated the environmental risks of GMOs but also whether

123. Appellate Court Decision in the Ação Civil Pública, *supra* note 7, at 2. Later in its decision, the court expresses its deference with reference to the precautionary principle: “it is enough that [CTNBio] has the competency and technical knowledge to adopt the measures that it understands to be necessary and applicable to guarantee the preservation of the environment and, as such, to respect the precautionary principle.” *Id.* at 410.

124. *Id.* at 525. See also District Court Decision in the Ação Civil Pública, *supra* note 6, at 7 (finding that CTNBio had relied heavily on information provided by Monsanto to the United States government).

125. See Appellate Court Decision in the Ação Civil Pública, at 541-42. After the district court issued the injunction, Monsanto began field tests to assess environmental impacts. *Id.* at 544-54.

126. National Research Council, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS 176 (2002). In addition, this report and other recent work broadly criticizes the U.S. government’s environmental assessments of GMOs. See especially Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167 (2004); Bratspies, *supra* note 2.

CTNBio looked at the extent of the scientific uncertainty associated with these risks.

In order to satisfy the hard-look doctrine, CTNBio should have been more explicit about the effects of scientific uncertainty on its decisionmaking process. Taking a hard-look approach, United States courts require that “when there is incomplete or unavailable information, the agency shall always make clear that such information is lacking.”¹²⁷ United States federal regulations state that if the costs or scientific limitations preclude gathering full information, the agency must: (1) explain how the information would help evaluate reasonably foreseeable significant adverse impacts on the human environment, (2) summarize existing credible scientific information on such impacts, and (3) assess these impacts based on generally accepted theoretical approaches or research methods.¹²⁸

Similarly, the Brazilian court should have required that CTNBio identify the areas of scientific uncertainty implicated in its decision on RR soybeans. In particular, the court might have required CTNBio to consider whether there were relevant areas of scientific uncertainty and to show how such uncertainty affected CTNBio’s decision to approve RR soybeans.¹²⁹ Requiring governmental decisionmakers to explicitly identify and assess areas of scientific uncertainty would ensure effective judicial oversight and compliance with the precautionary principle. Ultimately, it would prevent governmental agencies from ignoring or disregarding scientifically uncertain but potentially serious environmental harms.

CONCLUSION

The precautionary principle stands for the proposition that decisionmakers must take scientific uncertainty about potentially significant environmental harms into account in their decisionmaking process. Understood in this way, the precautionary principle translates into a procedural requirement that national courts may impose to ensure governmental compliance. The hard-look doctrine of United States

127. 40 C.F.R. § 1502.22 (2003). *See, e.g., Robertson*, 490 U.S. at 373; *Mid States Coalition for Progress v. Surface Transp. Bd.*, 345 F.3d 520 (8th Cir. 2003); *Sierra Club v. Marita*, 46 F.3d 606, 623 (7th Cir. 1995).

128. 40 C.F.R. § 1502.22(b) (2003). The regulations define “reasonably foreseeable” to include impacts “which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason.” *Id.*

129. Some evidence indicates that CTNBio did take scientific uncertainty into consideration. CTNBio’s approval of RR soybeans included a requirement that commercial plantings of RR soybeans be monitored for a period of five years “with the objective of producing comparative studies of the plant, insect, and microorganism species present in the plantings.” The approval specified that if the study found significant ecological alterations, CTNBio could immediately suspend commercial plantings. Communication No. 54, *supra* note 64.

environmental law provides lessons for how courts can effectively review the decisionmaking process without substituting their opinion on substantive outcomes for that of the decisionmaker. Applying the precautionary principle as a procedural requirement, national courts can help make it more effective and meaningful at the national level.

In the landmark Brazilian GMO case, the district and appellate courts differed in their interpretation of the precautionary principle's requirements. The district court held that the precautionary principle compelled the preparation of an environmental impact statement. The appellate court held that the precautionary principle required the government to consider environmental risks. While the appellate court was correct in determining that the precautionary principle does not require a particular regulatory measure such as an environmental impact statement, its review did not ensure governmental compliance with the precautionary principle. In particular, the appellate court failed to examine how CTNBio assessed scientific uncertainty in its decisionmaking process. By requiring CTNBio to evaluate areas of scientific uncertainty explicitly, the appellate court could have ensured that the government had taken a hard look at scientific uncertainty concerning potentially serious environmental harms.

While the Brazilian GMO case continues to be litigated, the center of the debate about governmental approval of GMOs in Brazil has moved to the legislature. In November 2003, the Brazilian president proposed a new National Biosafety Law to clarify the authority of CTNBio and otherwise reform the regulatory process.¹³⁰ Although legislative decisions may ultimately override judicial decisions in determining the fate of GMOs in Brazil, the Brazilian GMO case will continue to offer important lessons about how national courts can effectively review governmental compliance with the precautionary principle.

130. Projeto de Lei 2401/03. The proposed law showcases the precautionary principle, providing in Chapter I, Article 2, that GMO-related activities must abide by this law and the National Environmental Policy Act "to effectively prevent and mitigate threats to human health and the environment, observing the Precautionary Principle." The full text of the bill is available at <http://www.agrisustentavel.com/trans/lei2401.htm> (last visited Nov. 1, 2004).