TAKING CONSUMERS SERIOUSLY: THE SWISS REGULATORY APPROACH TO GENETICALLY MODIFIED FOOD

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INTRODUCTION

Switzerland was among the first states to require the labeling of food products containing genetically modified organisms (GMOs).[1] Moreover, Switzerland has employed unique approaches to regulation of GMOs. For example, Swiss regulation establishes as an objective the protection not only of environmental and economic interests, but also of the "dignity of creation."[2] Concern for the latter led to the creation of an Ethics Committee. The Swiss regulation is the product of a broad public debate within the Swiss population, which led to a consensus that was itself confirmed in two referenda in 1992 and 1998.[3] As such, it reflects the fact that because of its participatory political system which directly involves the population in the decision-making process,[4] Switzerland, which not only has "European" environmental sensibilities but also strong pharmaceutical and

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1 Switzerland introduced its first labeling requirement for genetically modified (GM) food in 1995. *See infra* Part II.A.1.

2 "Dignity of creation" refers to the dignity which is inherent in nature and especially in all living things, independent of value to humans. *See infra* Part II.A.1 and sources cited *infra* notes 22-31.

3 See *infra*, Part II.A.

4 *See generally* ULRICH HÄFELIN & WALTER HALLER, SCHWEIZERISCHES BUNDESSTAATSRECHT 287-92 (2d ed. 1988). One of the characteristics of the Swiss participatory political system is the direct influence of the Swiss people on the political process through a popular vote system. Swiss citizens can propose changes to the constitution by presenting an "initiative" signed by at least

biotechnological interests, necessarily had to reconcile several seemingly conflicting interests in order to promulgate these regulations. This institutionalized obligation to find solutions, which—in order to be amenable to a majority of the population—reflect all major concerns, decisively influenced the content of the Swiss regulation.

This Article will explore the Swiss regulatory approach to genetically modified (GM) food. Part I will focus on the events which led to the promulgation of current regulations, with special attention given to the evolution of consumers' concerns over the products used. Part II will demonstrate that the Swiss adopted balanced and prospective regulations by taking into account not only traditional interests and concerns but also this evolution of consumer interests. Finally, Part III and the Conclusion will show that the Swiss regulations are fully compatible with international law and are useful as a model for international GM food regulation.

I
Consumers' Increased Sensibility Towards Environmental and Ethical Concerns

The Swiss approach to GM food is strongly influenced by the fact that consumers' attitudes toward food have shifted considerably. Traditionally, consumers accepted new food products without hesitation; however, they recently began to oppose the introduction of new products like beef treated with growth hormones and food products which include GMOs. Moreover, consumers' interests and concerns are no longer limited to the products themselves but extend also to the processes of production.[5] Hence, many consumers require that products are produced and traded under fair conditions and are grown in a

100,000 voters. Proposals for constitutional amendments are then voted on by the population.

[5] *See generally* Franz Xaver Perrez, *The Efficiency of Cooperation: A Functional Analysis of Sovereignty*, 15 Ariz. J. Int'l & Comp. L. 515, 524-25, 527-48 (1998). The author notes that there are several reasons why one might be interested in the process and production method (PPM) of a specific product, even if they do not affect the physical characteristics of the end-product. Typically, these reasons include pollution and other forms of environmental degradation resulting from a specific method of production; other reasons may relate to non-physical externalities such as social, competitive or "psychic" externalities. However, it must be emphasized that GM food does not involve a typical non-product related PPM-issue where like products are treated differently, merely

sustainable manner. This shift began about twenty years ago and led to the strong rejection of GM food in Switzerland. Consumers in the European Union (E.U.) have expressed similar concerns. As a result, major European supermarkets have decided not to sell GM food products.[6]

There are many reasons why consumers oppose GM food; however, four fundamental issues generally motivate consumer concerns: health, environmental, ethical, and socio-developmental issues. First, consumers reject GM food because they fear that GM food involves risks to their health. This fear may be related to direct negative impacts of eating GM food;[7] however, it may also be attributed to indirect risks such as the risk that use of antibiotic resistance marker genes in crops may lead to microbial resistance to antibiotics, which would render the latter useless.[8] Second, consumers reject GM food not only because they are afraid that the food itself or its production methods threaten their health, but also because GMOs may put entire ecosystems at risk.[9] Other consumer concerns involve ethical questions. For example, consumers have questioned the ethical adequacy of including "terminator" genes in crops. These genes prevent harvested seeds from germinating and thus preclude farmers from reserving a certain amount of harvested seed for the next planting.[10] Consumers also worry that genetic engineering reduces

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because there is normally a physical difference between GMO food and traditional food products.

[6] *See, e.g., Ein Faktisches Gentechnik-Moratorium*, NEUE ZÜRCHER ZEITUNG, March 25, 1999.

[7] *See, e.g.*, Arpad Pusztai, *Report of Project Coordinator on Data Produced at the Rowett Research Institute (RRI)* (arguing that the consumption by rats of genetically modified potatoes had significant effects on organ development, body metabolism and immune function) (visited May 30, 2000) <http://www.rri.sari.ac.uk/gmo/ajp.htm>. *But see Royal Society Rejects Latest Claims in the* Lancet *on GM Potatoes* (visited May 30, 2000) <http://www.royalsoc.ac.uk/templates/press/showpresspage.cfm?file=1999101400.txt>.

[8] *See, e.g.*, Florianne Koechlin, *Antibiotika-Resistenz und der Novartis-Mais: Spiel mit gefährlichen Keimen*, DIE WOCHENZEITUNG, Nov. 7, 1997, at 3.

[9] *See, e.g.*, Brian Halweil, *The Emperor's New Crops*, WORLD WATCH, July/August 1999 at 21, 25 (discussing the "leaking" or "escaping" of modified genes from transgenic crops to other plants); Carol Kaesuk Yoon, *Pollen From Genetically Altered Corn Threatens Monarch Butterfly*, N.Y. TIMES, May 20, 1999 (discussing a study from Cornell University which provided the first evidence that pollen from a transgenic plant can be harmful to nonpest species).

[10] *See, e.g.*, Halweil, *supra* note 9, at 26-27; Adi Sollberger, *Das "Terminator"-Gen Geht um*, WELTWOCHE, Feb. 4, 1999, at 46. *See also* Barnaby J. Feder, *Monsanto to Bar a Class of Seeds*, N.Y. TIMES, Oct. 5, 1999, at A1 (discussing the Monsanto company's decision in October 1999 to make no effort to market

the value of nature to its utility for humans and subjects it to short-term human interest. They also fear that man has begun to act like God or that the dignity of nature might be threatened.[11] Moreover, consumers worry that patenting transgenic seeds will create a new feudalism in which farmers, especially those in developing countries, will be dependent upon a few multinational companies from the northern hemisphere.[12] There is also concern that biotechnology will increase income disparities between large- and small-scale farmers.[13]

Finally, because of these concerns about safety and impact, a "new" consumers' concern has emerged: the concern to be informed whether a product is produced through genetic engineering. Most importantly, this concern to be informed relates not only to the physical characteristic of the end-product but also to its production and process method. Any regulatory approach to GM food, not only the Swiss approach, has to take this evolution in consumers' concerns into account.

On the other hand, genetic engineering may also provide new opportunities and prospects. Thus, many people believe that biotechnology is one of the most promising sectors of the economy, providing not only new highly skilled jobs[14] but also

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seeds that produce infertile crop plants, thus removing itself from a debate harmful to its public image).

[11] *See infra* note 23 and accompanying text.

[12] *See, e.g.*, Halweil, *supra* note 9, at 25-29. On the other hand, there are also attempts to share benefits from biotechnology with those who have contributed to these benefits; for example, indigenous people or farmers in developing countries. *See*, *e.g.*, Alwin R. Kopše et al., Swiss State Secretariat for Economic Affairs, Swiss Federal Institute of Intellectual Property, & Swiss Agency for the Environment, Forests & Landscape, Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources 4 (2000) (unpublished Swiss submission to the Fifth Conference of the Parties to the Convention on Biological Diversity, May 15-26, 2000) (on file with the *N.Y.U. Environmental Law Journal*).

[13] *See, e.g.*, Matin Qaim, *Transgenic Virus Resistant Potatoes in Mexico: Potential Socioeconomic Implications of North-South Biotechnology Transfer*, ISAAA BRIEFS No. 7, 1998, at iv, 35 (proposing a subsidized seed distribution mechanism in order to prevent such an increase in income disparities).

[14] *See* SWISS NATIONAL SCIENCE FOUNDATION, BIOTECHNOLOGY IN SWITZERLAND (1999) (quoting Pascal Couchepin, Swiss Minister of Economy, at the Annual Meeting of the Association of Swiss Biotechnology Companies in March 1999):

> Biotechnology is one of the most promising sectors for the future of the Swiss economy. In addition to the exciting knowledge that will be gained through research, the biotechnology sector will also be a provider of high value-added products as well as new jobs for people. The small and me-

new insights and knowledge. Biotechnology could help solve major problems, such as world hunger, and could help in discovering cures for diseases which traditional medicine has been unable to fight effectively.[15] Moreover, genetically engineered crops may produce higher yields while requiring fewer pesticides and fertilizers, thus making farming more efficient, while at the same time reducing the negative environmental effects of pesticides and fertilizers.[16]

Governments and legislatures have to consider both the positive and negative aspects of genetic engineering. As a consequence, policy-makers have to reflect and reconcile opposing interests which seem to require different regulations. Moreover, although traditional product regulation had to accommodate two fundamentally different interests—producers' interests in an open and free market and traditional consumers' interests in good, safe, and affordable products—regulators now face many more and various consumer concerns. Today, the issue of genetic engineering in general, and of GM food in particular, includes environmental, ethical, developmental, economic, pharmaceutical, medical, scientific, and the aforementioned "new" consumer aspects. The legislator's task today is to deal with a problem which has at least four or five dimensions. This proliferation of interests and dimensions may be one of the reasons why the regulation of genetic engineering and of GM food products is so difficult and why it generates such a high potential for conflicts.

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dium-sized enterprises that are characteristic of this sector form the backbone of our national economy.

See also BUNDESAMT FÜR STATISTIK, UMWELTSTATISTIK SCHWEIZ: GENTECHNOLOGIE 12-13 (1998) (discussing the economic importance of genetic engineering for Switzerland).

[15] *See, e.g.*, BUNDESAMT FÜR STATISTIK, *supra* note 14, at 3-4; Bernhard Wenger, *Die Fünfte Medizinische "Revolution,"* DER BUND, Dec. 1, 1997, at 2; Andrea Arz de Falco, *Hilft Gentechnologie gegen Krankheiten*?, WENDEKREIS, June 1997, at 16.

[16] *See, e.g.*, BUNDESAMT FÜR STATISTIK, *supra* note 14, at 5-7; M. Qaim, *The Economic Effects of Genetically Modified Orphan Commodities: Projections for Sweetpotato in Kenya*, ISAAA BRIEFS No. 13, 1999, at 13-14. *But see* United States Department of Agriculture, *Impacts of Adopting Genetically Engineered Crops in the U.S—Preliminary Results* (visited May 30, 2000) <http://www.econ.ag.gov/whatsnew/issues/gmo/>.

II
THE SWISS REGULATORY APPROACH

Because the Swiss population directly influences the political process, the Swiss regulatory approach to GM food must respond to and reflect the population's major concerns.[17] A regulation which does not sufficiently reflect these concerns would be challenged and would probably be rejected in a popular referendum. While this system of popular democracy is sometimes seen as cumbersome, it promotes the adoption of regulations which have been discussed in a broad public debate and which are based on widespread support. Moreover, once the Swiss people have taken a decision in a referendum, Parliament and the government have guidance for further regulation on the issue.

The Swiss regulation of genetic engineering and GM food is a typical example of this political decision-making process. The Swiss population has twice clarified the basic direction it wishes to pursue: In a first referendum, it made clear that the regulation of genetic engineering must account for environmental, consumer and ethical concerns. In a second referendum, a majority of the population expressed the opinion that genetic engineering should not be banned generally, so long as a strict regulatory framework responding to the initial concerns was adopted. Since the Swiss regulation of GM food is determined by these two decisions, the following paragraphs will focus on the two referenda and the arguments which most influenced their outcome.

A. *The Historical Background*

1. *First Referendum: Approval, Labeling, and Respect for the "Dignity of Creation"*

Switzerland began in the early 1990s to address GM food and genetic engineering issues. The Swiss people voted on a first referendum in 1992, which resulted in the adoption of a constitu-

[17] *See generally* HÄFELIN & HALLER, *supra* note 4, at 286, 281, 297, 320-21. On the federal level, there are three instruments which enable the direct participation of the Swiss population in the political decision-making process: "Initiative" (*see supra* note 4), "facultative referendum" (the adoption of a new law, the revision of an existing law or the adoption of certain international treaties can be challenged by 50,000 voters; if this happens, the new law or treaty or amendment has to be voted on by the population), and "obligatory referendum" (each constitutional amendment and certain international treaties have to be voted on by the population).

tional amendment establishing the basis for future regulation. In this referendum, the Swiss population made clear that regulation of genetic engineering must ensure the safety of humans, animals, and the environment, as well as the protection of the diversity of animal and plant species.[18] As a consequence, Switzerland adopted a regulatory framework which prescribed that GMOs must be handled safely, that the government must be notified of and approve GMO work which involves risks for humans and the environment, and that a GMO's release into the environment requires approval.[19] In 1995, Switzerland adopted regulations requiring a GM food to be approved before it was introduced into the market and that GM food be labeled.[20] Interestingly, the fact that Switzerland was one of the first countries to introduce labelling requirements for genetically modified food was an important stimulant for the development of methods and techniques to detect GMOs, and the Swiss industry has meanwhile gained a leading position in the GMO-detecting technology.[21]

However, the constitutional amendment adopted in 1992 required the federal government to consider not only the safety of humans, animals, and the environment, but also the "dignity of creation" when regulating genetic engineering and GMOs.[22] This new element reflects the concern that the new genetic engineering technology gives mankind the means to "act like God"[23]

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[18] *See* SWITZ. CONST., art. 24.III (art. 120.II revised Swiss Constitution).

[19] *See* Bundesgesetz über den Umweltschutz, Umweltschutzgesetz (USG), arts. 29(b)-(f) (SR 814.01, October 7, 1983); Verordnung über den Umgang mit Organismen in geschlossenen Systemen, Einschliessungsverordnung (ESV, October 25, 1999); Verordnung über den Umgang mit Organismen in der Umwelt, Freisetzungsverordnung (FrSV, October 25, 1999); Verordnung über den Schutz der Arbeitnehmerinnen und Arbeitnehmer vor Gefährdung durch Mikroorganismen (SAMV, October 25, 1999).

[20] *See* Bundesgesetz über Lebensmittel und Gebrauchsgegenstände (LMG), art. 9 (SR 817.0, October, 1992); Lebensmittelverordnung (LMV), arts. 15 and 22 (SR 817.02, March 1, 1995); Verordnung über das Bewilligungsverfahren für GVO-Lebensmittel, GVO-Zusatzstoffe und GVO-Verarbeitungshilfstoffe (VBGVO, SR 817.021.35, Nov. 19, 1996).

[21] See on this: Josef Syfrig, *Analytik gentechnisch veränderter Organismen (GVO): "Dank technologischem Vorsprung messen wir GVO-Anteile präziser,"* BIOTECH FORUM, Sept. 99.

[22] *See* SWITZ. CONST., art. 24.III (art. 120.II revised Swiss Constitution). The term used in the Swiss constitution ("Würde der Kreatur," "dignité de la créature," or "dignità della creatura") may also be translated into English as "dignity of non-human species." *See also infra* note 31.

[23] *See, e.g.*, Peter Sloterdijk, *Regeln für den Menschenpark*, DIE ZEIT, Sept. 1999, at 15, 20-21 (reprinting July 1999 speech at the castle of Elmau addressing the possibility of modern biotechnology enabling an elite of humans to plan and

and that humans will misuse the technology by subjecting it to short-term interests, thereby neglecting the interests of future generations.[24] Moreover, the new consideration for the "dignity of creation" recognizes that each individual living species has an inherent dignity. Humans must avoid causing a member of a species pain, suffering, and humiliation, and must not view species solely based upon their utility to mankind.[25] Finally, the new consideration acknowledges an important shift from an anthropocentric to a biocentric approach. Therefore, the obligation to respect "dignity of creation" requires that nature and especially all non-human species must not be reduced to their basic utility for humans, and entails an acknowledgement that each has a value and dignity of itself, independent of its utility for mankind.

By requiring the government to consider creation as a value independent of its value and utility for mankind, the constitutional amendment of 1992 clearly prescribed a non-anthropocentric approach to genetic engineering. There are different types of non-anthropocentric ethics which maintain that nature has rights independently of its utility for humankind:[26] rights could be extended from humans to other animals with the neurophysiological capacity for experiencing pain and happiness and their opposites;[27] rights could be extended further to all animals or liv-

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determine the character and genetic information of future generations). *See also* Ronald Dworkin, *Die Falsche Angst, Gott zu Spielen*, DIE ZEIT, Sept. 16, 1999, at 15, 17 (trans. Meinhard Büning). Dworkin argues that humans have always acted like God and tried to influence destiny, for example, by protecting themselves against natural catastrophes or by inventing and using penicillin to fight diseases. The real challenge is not that man acts like God, but that biotechnology provides mankind with new possibilities with which traditional ethics and value-systems are unable to deal.

[24] *See, e.g.*, PETER SALADIN & CHRISTOPH ANDRES ZENGER, RECHTE KÜNFTIGER GENERATIONEN (1988); Philippe Sands, *Protecting Future Generations: Precedent and Practicalities*, in FUTURE GENERATIONS & INTERNATIONAL LAW 83, 92 (Emmanuel Agius & Salvino Busuttil eds. 1998); Edith Brown Weiss, *Our Rights and Obligations to Future Generations for the Environment*, 84 AM. J. INT'L L. 198, 199 (1990).

[25] *See, e.g.*, EIDGENÖSSISCHE ETHIKKOMMISSION FÜR DIE GENTECHNIK IM AUSSERHUMANEN BEREICH, STELLUNGNAHME ZUR KONKRETISIERUNG DER WÜRDE DER KREATUR IM RAHMEN DER GEPLANTEN REVISION DES TIERSCHUTZGESETZES, November 17, 1999 at §§ 1.1, 1.2.

[26] *See generally* ROBERT ELLIOT, *Introduction, in* ENVIRONMENTAL ETHICS, 8-12 (Robert Elliot ed., 1995).

[27] *See, e.g.,* BERNARD E. ROLLING, ANIMAL RIGHTS AND HUMAN MORALITY (1992); STEPHEN R. L. CLARK, THE MORAL STATUS OF ANIMALS (1977); PETER SINGER, ANIMAL LIBERATION (1975).

ing things independently of their psychological capacities;[28] finally, rights could even be attributed to natural entities, whether or not they are living.[29] Yet another approach would attribute values and rights not to the individual animals, plants or rocks, but to ecosystems and to the biosphere itself.[30] The provision in the Swiss Constitution which requires the government to take into account the "dignity of creation," when regulating genetic engineering and GMOs, surpasses the "limited" non-anthropocentric approach extending rights only to animals with neurophysiological capacity for experiencing pain and happiness and accepts that at least all living species have intrinsic value.[31] A recent proposal for an amendment to the Federal Law on the Protection of the Environment tries to limit the constitutional principle to respect the "dignity of creation" to animals and plants.[32] Nevertheless, the proposal acknowledges that, under a "less anthropocentric approach," all living organisms could be covered by the term "dignity of creation" as well, and good arguments could be made to include also the biosphere and ecosystem as a whole.[33]

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[28] *See, e.g.,* Holmes Rolston, III, *Duties to Endangered Species*, *in* ENVIRONMENTAL ETHICS, *supra* note 26, at 60; Christopher D. Stone, *Should Trees Have Standing?—Toward Legal Rights for Natural Objects*, 45 S. CAL. L. REV. 450 (1972).

[29] *See generally* Robert Elliot, *Faking Nature*, *in* ENVIRONMENTAL ETHICS, *supra* note 26, at 76.

[30] *See, e.g*., J. Baird Callicott, *Animal Liberation: A Triangular Affair, in* ENVIRONMENTAL ETHICS, *supra* note 26, at 29 (distinguishing "holistic environmental ethics," which locates ultimate value in the biotic community, from "ethics of animal rights," which locates moral value only in some "individuals").

[31] It is noteworthy that during the formal revision of the Swiss Constitution in Spring 1999 the French formulation "tenir compte de la dignité de la créature" was replaced by "respecter l'intégrité des organismes vivants," while the German and Italian formulations "Würde der Kreatur" and "dignità della creatura" were not changed. It could be argued that the new French formulation "integrity of living organisms" limits the possibility of construing the term "dignity of creation" in a large, holistic approach including also the biosphere and the ecosystem as a whole into the scope of protection. However, the modification in the French text was never acknowledged as a material change of the constitutional provision dealing with genetic engineering. According to the translation service of the Swiss Government, this modification has merely "linguistic reasons" as the formulation "dignité de la créature" seems to be "odd if not ridiculous" to "French ears."

[32] Draft Art. 29a.1(c) Bundesgesetz über den Umweltschutz, *reprinted i*n: BBl 2000 2435.

[33] Botschaft zu einer Änderung des Bundesgesetzes über den Umweltschutz, *reprinted in*: BBl 2000 2391, 2405.

In response to the adoption of this constitutional amendment, the Swiss Government established an Ethics Committee which is to discuss ethical questions resulting from new developments in genetic engineering.[34] The Ethics Committee does not fulfill a regulatory but rather an advisory function. However, its work is not without significance: a negative recommendation by the Committee was one of the factors which led to the denial of a request for scientific field testing of GM crops. The Committee argued that the scientific benefits that could be gained through this field testing did not justify the risks involved for the environment and the ecosystem as a whole.[35] Moreover, it maintained that the lack of transparency of the testing process, the insufficiency of information included in the request, and the inadequate involvement of the public in the process, weighed against granting the field release.[36]

2. *Second Referendum: Rejection of a General Ban on Genetic Engineering*

In June 1998, the Swiss population rejected by a two-to-one vote a constitutional amendment prohibiting all transgenic animals, all releases of transgenic crops into the environment, and the patenting of certain biotechnological inventions. While at the beginning of the campaign on this referendum, sixty-two percent of the Swiss population generally opposed genetic engineering, the opposition weakened to only thirty-three percent.[37] A variety of events contributed to this change in public opinion.

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[34] On the work of the Ethics Committee, see, for example, "*Da Muss Noch Viel Nachgedacht Werden . . .",* PRO NATURA, Nov. 12, 1999 (quoting an interview with Arz de Falco, President of the Ethics Committee); Mario Tuor, *Madame Ethik*, FACTS, Feb. 4, 1999, at 40. *See also Im Dschungel der Bioethik-Kommissionen*, NEUE ZÜRCHER ZEITUNG, Feb. 6, 1999 (criticising the proliferation of ethics committees).

[35] *See* Verfügung des Bundesamte für Umwelt, Wald und Landschaft vom 16. April 1999, betreffend das Gesuch der Plüss-Staufer AG, um Bewilligung eines Freisetzungsversuchs mit gentechnisch verändertem Mais T25 in Oftringen/AG, § B.2.1 [hereinafter Plüsss-Staufer].

[36] *See* Stellungnahme der Eidgenössische Ethikkommission für die Gentechnik im ausserhumanen Bereich zum Gesuch der Firma Plüss-Staufer um einen Freisetzungsversuch mit T25-Mais in Oftrignen, chapters 1 and 2 (March 17, 1999).

[37] *See* Task Group on Public Perception of Biotechnology, European Federation of Biotechnology, Briefing paper 8, *Lessons from the Swiss biotechnology referendum*, August 1998, at 1, 3 [hereinafter *Lessons*]; BUNDESAMT FÜR STATISTIK, *supra* note 14, at 17.

While proponents of a general ban on genetic engineering claim that their limited financial resources were the major factor leading to the rejection of their proposal, several events initiated by the opponents of the proposed constitutional amendment seem to have strongly influenced public opinion:[38] First, all Swiss Nobel prize laureates, even those not working in biology, held a press conference in which they decried the loss of research potential and suggested that standards in Swiss universities would be lowered should the ban be adopted. Second, scientists organized demonstrations in the streets of Zürich and Geneva, where about 2000 researchers acknowledged their opposition to a general ban on genetic engineering. Third, during the campaign proponents of modern biotechnology were able to shift the discussion away from the impact of genetic engineering on food, plants, and animals to its potential benefits in medicine, science, and education,[39] and scientists immediately challenged the validity of claims about the potential dangers of biotechnology which were made by those who opposed it and published their findings in "shoot-backs."[40] Finally, this major shift to the acceptance of genetic engineering was possible only because of the willingness of the Parliament and the government to respond to the population's concerns by committing itself, prior to the vote on the referendum, to enacting a strict regulatory framework for genetic engineering.

The broad and intense debates that took place during the two referendum campaigns, especially those that accompanied the June 1998 vote, have outlined the political limits and clarified the general conditions of Switzerland's regulation of genetic engineering: While there is a broad acceptance of genetic engineering for pharmaceutical, medical, and scientific purposes in Switzerland, a majority of the citizenry still strongly rejects genetic engineering in the context of food.[41] Thus, while the Swiss

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[38] *See Lessons*, *supra* note 37, at 3; VOX-Analyse der eidgenössischen Abstimmungen vom 7 Juni 1998 (visited May 30, 2000) <http://www.gfs.ch/publset.html>.

[39] *See Lessons*, *supra* note 37, at 2-3.

[40] *See id*. at 4.

[41] *See* BUNDESAMT FÜR STATISTIK, *supra* note 14, at 17. *See also* Kurt Bisang & Peter Knoepfel, Umweltschutz: Politische Prioritäten, Persönlich Einstellungen und Verhaltensweisen der Stimmerberectigen, *UNIVOX Umwelt 1999* (visited Apr. 29, 1999) <http://www.gfs.ch/univox_umwelt.html> (indicating that approximately 55% of the Swiss population believes that government should do more about the risks of genetic engineering).

population rejects a complete ban on all genetic engineering, it requires at least legislation which ensures that consumers have the opportunity not to buy GMO food. Based on these political conditions, the Swiss government's strategy in this area has involved six principal elements: information; safe regulation; use of a precautionary approach; an emphasis on ethical considerations; prospective regulation which is open for future developments; and, finally, respect for international rules.[42] The goal of this strategy is to reflect all dimensions of the GMO issue, to isolate extreme positions, and to reconcile the different interests and concerns involved. The achievement of these objectives provides a balanced and well-founded regulatory framework that promotes the safe use of genetic engineering.

B. *Swiss Regulations Concerning GM Food*

With regard to GMOs, the Swiss government has adopted the following four types of regulations: (1) regulations for the approval of GMOs for food products; (2) labeling requirements; (3) regulations for the release of GMO products into the environment; and (4) liability regimes for GM crops.

1. *Regulations for the Approval of GMOs for Food Products*

All GMOs must be formally approved before introduction into the Swiss market.[43] Approval is not granted unless there is certainty, based on actual scientific knowledge, that the product poses no threat to human health.[44] It must be noted that approval of a GMO for use as a food product or ingredient does not authorize its general release into the environment. A GMO food approved by this process could not, for example, be used as seeds for planting.

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[42] *See Von der IDA-Gentech Erarbeiteter Entwurf für ein Einleitendes Kapitel zur Gen-Lex-Vorlage*, Oct. 21, 1999, at 1-4.

[43] *See* LMV, art. 15, *supra* note 20; Verordnung über das Bewilligungsverfahren für GVO-Lebensmittel, GVO-Zusatzstoffe und GVO-Verarbeitungshilfstoffe (VBGVO, SR 817.021.35, Nov. 19, 1996). Concerning the approval procedure in Switzerland for GMO-foodstuff, see also Stefan Kohler and Alessandro Maranta, Regulation von gentechnisch veränderten Lebensmitteln: *Die revidierte schweizerische Lösung im internationalen Kontext,* 11/99 AJP 1402, 1406-1407 (1999).

[44] *See* LMV, art. 15, *supra* note 20.

2. *Labeling Requirements*

Since June 1999, a food product must be labeled "produced with GMOs" if any of its ingredients contain more than 1% of GMOs.[45] The motivation for this requirement is to prevent deceptive practices and allow consumers the ability to make choices in accordance with their interests and concerns.[46] Prior to June 1999, regulations required all food products containing GMOs to be labeled. However, as more sensitive testing technologies have emerged, it has become possible to detect GMO contaminations of less than 0.01%.[47] Yet because products may be contaminated unintentionally with GMOs during their growth, production, transportation, and processing, it is impossible to guarantee that even traditionally grown food products that are totally segregated from GMO products are 100% GMO free. In an effort to reflect this practical concern, a threshold labeling requirement of one percent became effective in June 1999 and, since then, food products containing more than one percent GMOs must bear a label reading "produced with GMOs."[48] It is generally believed that in order to fall below this one percent threshold, traditionally grown products must be harvested, transported, and processed separately from those that have been genetically modified.[49]

On the other hand, a food product may be labeled "produced without genetic engineering" if three criteria are met: no GMOs were used during the production and processing of the food or its ingredients; none of its ingredients contain more than one percent GMOs; and a similar GM food product or ingredient which may be used for the production of this product has been approved for the Swiss market.[50] Thus, for example, as long as the market does not present Swiss consumers with the option of a genetically modified salad, no salad may be labeled as "produced without genetic engineering."

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[45] *See* LMV, art. 22b, *supra* note 20. If no GMOs are detectable, as in the case of soya oil, no labeling is required. Concerning the Swiss labeling requirement, see also Kohler and Maranta, supra note 43, at 1407-1411.

[46] *See* Martin Schrott, *Neue Bestimmungen zur GVO-Deklaration: Informierter Entscheid beim Lebensmittelkauf*, BIOTECH FORUM, Sept. 99.

[47] *See Deklarationslimite für gentechnisch veränderte Lebensmittel (GVO)*, BIOWORLD, August 12, 1999.

[48] *See supra*, note 45.

[49] *See* Schrott, *supra* note 46.

[50] *See* LMV, art. 22b(8), *supra* note 20.

Finally, labels proclaiming that a food product is "GMO free" are not permitted under Swiss regulations.[51] This feature of the labeling regime stems from the observation that it is not possible to guarantee that a product is 100% free of GMO contamination. The regulations prohibiting the use of "GMO free" labels and requiring that "produced without genetic engineering" labels be allowed only when a similar product on the Swiss market does contain GMOs, underline the legislation's motivation to prevent deceptive practices.

3. *Release of GMO Crops into the Environment*

Field releases of GMO crops are permitted only after authorization has been obtained.[52] Like the approval process used for GMO food products, authorization is granted only if there is certainty, based on actual sound scientific knowledge, that the release will not have any harmful effect on human health or the environment. Requests for a field release must be accompanied by a risk assessment and monitoring plans that analyze the possible negative environmental effects of the release.[53] In August 1999, the Swiss Agency for Environment, Forests and Landscape proposed the adoption of a ten-year moratorium on non-scientific releases of GMOs. However, this moratorium will most likely not be adopted and the regulations will probably continue to exist in their present form.

Using a precautionary approach,[54] the Swiss Agency for Environment, Forests and Landscape rejected two requests for scientific field tests in April 1999 because of the uncertainty of their impacts on human health and the environment.[55] Both requests involved the use of antibiotic resistance marker genes.[56] The first

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[51] *See* Schrott, *supra* note 46.

[52] *See* FrSV, arts. 7, 18-25, and annex 4, *supra* note 19.

[53] *See* FrSV, art. 9.1(c)-9.1(d), *supra* note 19.

[54] *See* USG, art. 1.2, *supra* note 19 (requiring the agency to adopt a precautionary approach).

[55] *See* Plüss-Staufer, *supra* note 35; Décision du 16 avril 1999 concernant la demande de la Station fédérale de recherches en production végétale de Changins fisant à obtenir l'autorisation d'effectuer une dissémination expérimental de pommes de terre génétiquement modifiées à Duillier/VD et Bullet/VD [hereinafter Changins]; Alison Abbott, *Swiss Reject GM Trial to Protect Organics*, NATURE, Apr. 29, 1999, at 736.

[56] *See* Changins, *supra* note 55, at B.2.2(d) (dealing with the field test of a antibiotic-resistant gene used in medicine); Plüss-Staufer, *supra* note 35, at B.2.2(e).

was denied when it was found that the site of one of the field tests was close to organic farms and that cross-pollination could potentially lead to the contamination of organic crops.[57] The denial of the other request was based on inadequate risk-assessment data.[58] The Ethics Committee, which was invited to comment on the first of the two requests, argued that the scientific benefits that could be gained through the field testing did not justify the risks it posed to the environment and the ecosystem as a whole.[59] The first decision is still under appeal.

4. *Liability Regime for GMO Crops*

At this time, Switzerland does not possess a distinct liability regime for GMOs. However, the Swiss government and Parliament pledged before the last constitutional referendum on genetic engineering to enact a stringent liability regime that takes into account the uncertainties involved with GMOs. A revision of the current liability structure for GMOs is therefore expected to appear in the upcoming months.

III
Switzerland and the International Context

While larger states may be in the position to develop a more autonomous approach, Switzerland has to consider fully the constraints of international law. Therefore, the goal of the Swiss regulatory approach is to adopt regulations that conform to international law. The two major obligations established by international law relevant for national GMO legislation are arguably the duty to protect the environment,[60] and especially to protect global biological diversity, on the one side,[61] and the obli-

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[57] *See* Abbott, *supra* note 55, at 736; Pluss-Staufer, *supra* note 35, at B.2.2(b).

[58] *See* Changins, *supra* note 55, at B.2.2(b) and B.2.2(c).

[59] *See* Plüss-Staufer, *supra* note 35, at B.2.1.

[60] *See generally*, Franz Xaver Perrez, Cooperative Sovereignty: From Independence to Interdependence in the structure of International Environmental Law 239-240 (Kluwer Law International, forthcoming 2000); Michael J. Glennon, *Has International Law Failed the Elephant?*, 84 Am. J. Int'l L. 1, 29 and note 238 (1990); Jörg Lücke, *Universelles Verfassungsrecht, Völkerrecht und Schutz der Umwelt*, 35 Archiv des Völkerrechts 1, 7, 10-13, 15.16 (1997).

[61] *See infra*, notes 63-65 and accompanying text. Meanwhile, the Biodiversity Convention has been supplemented with the Biosafety-Protocol dealing with

gation not to restrain unnecessarily international trade as established by the WTO-agreements, on the other side.[62]

The Convention on Biological Diversity obliges its members to contribute to the protection and conservation of biological diversity, sustainable use of its components, and a fair and equitable sharing of the benefits from the use of genetic resources.[63] The notion of biodiversity includes the diversity of genetic resources, organisms, species, and ecosystems.[64] The Convention explicitly states that the importing of non-native species which are a threat to biodiversity can be prohibited.[65] The Swiss regulatory regime meets the basic requirements established by the Convention in two ways. First, it allows deliberate releases of GMOs into the environment only upon actual sound scientific knowledge that they will have not have a harmful effect on the environment and the ecosystem. Second, the Convention mandates that proposals for field releases be accompanied by a risk assessment and plans for monitoring possible effects upon the environment.

The rules and principles established by the WTO agreements prohibit states from unnecessarily restraining international trade.[66] Specifically, states may not discriminate against imports and must treat them no less favorably than like products of national origin.[67] Moreover, the WTO requires that standards

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the risks living genetically modified organisms can pose to the global biodiversity.

[62] *See infra*, notes 66-71 and accompanying text.

[63] *See* Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818, arts. 1, 10. Since these three goals have equal status, the CBD encompasses environmental, economic, and developmental considerations.

[64] *See id.* at art. 2; JANET BELL & MICHEL PIMBERT, THE LIFE INDUSTRY: BIODIVERSITY, PEOPLE AND PROFITS 1-2 (Miges Baumann et al. eds., 1996); PHILIPPE SANDS, PRINCIPLES OF INTERNATIONAL OF INTERNATIONAL ENVIRONMENTAL LAW 368 (1995).

[65] *See* CBD art. 8h, *supra* note 63.

[66] According to GATT Art. XX, the states have the right, if necessary, to restrain international trade, if it is in pursuit of legitimate objectives. See *infra*, note 69 and accompanying text.

[67] *See* Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS (1994), at 7; 33 I.L.M. 1144, art. III [hereinafter WTO Agreement]; Agreement on Technical Barriers to Trade, April 15, 1994, Annex 1A, art. 2.1, RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS (1994), at 138, 1994 WL 761483, [hereinafter TBT Agreement]; Agreement on the Application of Sanitary and Phytosanitary Measures, April 15, 1994, WTO Agreement, Annex 1A, RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIA-

be transparent and generally follow relevant international standards unless doing so would prevent the fulfillment of legitimate objectives.[68] States are nevertheless entitled to adopt measures necessary to protect the life or health of humans, animals, or plants if such measures do not discriminate arbitrarily or unjustifiably between countries or constitute a disguised restriction of international trade.[69] Such measures to protect the environment and health must, however, be based on sound science.[70] Furthermore, states are free to select their own levels of risk and environmental protection.[71]

The Swiss requirement that the introduction of GMOs into the national food market and the release of GMOs into the environment be approached helps to guarantee that there will be, according to the actual sound scientific knowledge, no threat to health or the environment. As indicated above, the protection of human health and the environment is a legitimate objective for adopting trade restrictive measures.[72] Moreover, the Swiss approval procedure is transparent and ensures the confidentiality of information of commercial interest. And, it does not discriminate between products nor between states. The procedure is

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TIONS: THE LEGAL TEXTS (1994), at 69, 1994 WL 761483, art 2.3 [hereinafter SPS Agreement]. *See also* ARTHUR E. APPLETON, ENVIRONMENTAL LABELLING PROGRAMMES: INTERNATIONAL TRADE LAW IMPLICATIONS 95-110 (1997); JOHN H. JACKSON, THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS 223-24 (2d ed. 1998). It is doubtful whether biotech-related regulatory actions would be covered by the SPS Agreement. Annex A, paragraph 1 of the SPS Agreement defines the objectives of SPS-regulation: the protection of humans, animals and plants from pests, diseases, disease-carrying or disease-causing organisms, additives, contaminants, toxins and the like. However, genetic modification can hardy be seen as "additives," "contaminants," or "toxins," moreover, products of biotechnology involve typically other risks than "diseases" and they might pose a threat not only to humans, animals and plants but also to ecosystems and the environment as a whole. But even if the SPS-Agreement does not apply, the general rules as established by the GATT and the rules of the TBT-Agreement would nevertheless still be applicable. *See*, *e.g.*, *Discussion Paper on Agricultural Biotechnology*, INSIDE U.S. TRADE, Sept. 24, 1999, at 21.

68 *See* TBT Agreement art. 2.4; SPS Agreement art. 2.3. *See also* JACKSON, *supra* note 67, at 224; APPLETON, *supra* note 67, at 118-20.

69 *See* GATT art. XX(b); TBT Agreement art. 2.2; SPS Agreement art. 2.1. *See also* DANEIL C. ESTY, GREENING THE GATT: TRADE, ENVIRONMENT AND THE FUTURE 46-52 (1994); Gabrielle Marceau, *A Call for Coherence in International Law*, 33 J. WORLD TRADE 87, 89ff. (1999).

70 *See* TBT Agreement art. 2.2; SPS Agreement art. 2.2.

71 *See* TBT Agreement Preamble para. 6; SPS Agreement Preamble para. 6.

72 *See supra* sources cited in note 67.

therefore fully compliant with the relevant WTO rules for such procedures.[73] Finally, Switzerland implements adequate international standards whenever possible. When such standards do not exist on the multinational level, Switzerland refers to regional standards. Only when no adequate international or regional standards exist at all is a national standard developed.

The Swiss labeling requirement also complies with WTO rules. While the goal of the approval requirement is protecting health and the environment, the motivation for the labeling requirement is to prevent deceptive practices. This objective has been explicitly mentioned as legitimizing the adoption of technical regulations such as labeling requirements.[74] Several elements of the Swiss labeling requirement underline that its objective is indeed to prevent deceptive practices. First, the one percent threshold is aimed at ascertaining that products that may have been unintentionally contaminated with minimal levels of GMOs must be labeled as "produced with GMOs." Indeed, consumers are deceived only if GMOs are purposefully added to a product, not when there is of incidental minimal contamination, which cannot be prevented. Second, products may be labeled as "produced without genetic engineering" only when a similar product that contains GMOs is admitted on the Swiss market.[75] Third, as it has become impossible to guarantee that products are totally free of GMOs, use of the "GMO-free" label has been abandoned in favor of the more accurate "produced without genetic engineering." As seen above, Swiss consumers are very sensitive about GM food products and a majority would oppose the sale of such products. In light of this, the labeling requirement is the least trade-restrictive measure, which on the one hand gives consumers the opportunity to make a choice according to their preferences, and on the other fully respects Swiss obligations to the WTO.

The Swiss labeling scheme is aimed at preventing deceptive practices, a goal explicitly recognized in the WTO Agreement on Technical Barriers to Trade (TBT) as a legitimate objective. However, the list of legitimate objectives mentioned in the TBT is not exhaustive. The objective to inform consumers about the physical characteristics, processes, and production methods of a

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[73] *See* TBT Agreement art. 5.
[74] *See* TBT Agreement art. 2.2.
[75] *See* LMV, art. 22b(8), *supra* note 20.

product may also be legitimate objectives.[76] Some authors have argued that international law contains a general principle of informed consent which requires that persons be made aware of possible genetic modification of products.[77] Thus, a labeling requirement for GMO food could also be justified as a means necessary for legitimate consumer information.[78]

Finally, it is interesting to note that a number of entities have enacted labeling requirements that closely resemble those in Switzerland. The E.U. and the Australia-New Zealand Food Standards Council have agreed to implement strict mandatory labeling of GMO food.[79] South Korea will also require GM foods to be labeled.[80] A bill requiring labeling of genetically engineered foods was introduced in the United States Congress in November 1999.[81] It seems that even the United States Food and Drug Administration (FDA) does not categorically reject the idea of labeling GM food. An FDA investigation has been launched on the issue of whether legislation requiring a compulsory labeling should be introduced.[82] Hence Swiss regulations, by differentiating between GMO and traditional food on the basis of sound science to further the protection of the environment and human health, to prevent deceptive practices, to provide consumers with information necessary for a transparent and effective market, and by being transparent and non-discriminatory

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[76] *See* TBT Agreement art. 2.2 ("Such legitimate objectives are, *inter alia*: . . .; the prevention of deceptive practices; . . . .").

[77] *See* Frank Bodendiek & Karl Nowrot, *Bioethik und Völkerrecht*, 37 ARCHIV DES VÖLKERRECHTS 175, 182-86 (1999) (while Bodendiek and Nowrot focus on biotechnology in the area of medicine, the principle of informed consent might be extended also to food products).

[78] However, a labeling requirement pursuing the objective of consumer information would probably have to adopt a zero percent threshold rather than a one percent threshold for GMOs.

[79] *See* Gwen Robinson, *Australia and New Zealand Move on Food Labelling*, FINANCIAL TIMES (LONDON), Aug. 4, 1999, at 6; *and* Donald G. McNeil, Jr., *Protests on New Genes and Seeds Grow More Passionate in Europe*, N.Y. TIMES, March 14, 2000, at A1. The E.U. has also adopted a one percent threshold: food products must be labeled only if one of their ingredients contains one percent or more GMOs. *See id.*

[80] *See Agriculture Markets Recovering, But Prices to Stay Low This Year: OECD*, AGENCE FRANCE PRESSE, April 26, 2000.

[81] *See* Ian Sheldon, *No Mandatory Labeling: Let the Market Decide Debate on Biotech Food*, THE PLAIN DEALER, May 31, 2000, at 9B.

[82] *See* Eva Herrmann, *Wann Kommt der Genmais mit Etikett?*, TAGES-ANZEIGER, Oct. 22, 1999, at 12.

between states, fully reflect the existing international obligations under the WTO.

Conclusion

Several lessons can be learned from the Swiss experience. First, it demonstrates that any constructive regulatory approach has to respond to important shifts in consumers' attitudes. Any democratic system must seriously consider such shifts and evolutions, which ultimately formulate the political framework for legislation and regulation.

Second, the Swiss experience shows that complex social, economic, environmental, and ethical issues raised by new technologies can be brought to the public's attention and informed democratic decisions can be made. During such a decision-making process, all major interests and concerns must be taken seriously. Through this process, a balanced result can be reached which isolates extreme positions, integrates seemingly conflicting interests, and establishes a constructive and prospective framework for genetic engineering. It seems that the broad, intense, and open debate in Switzerland has, in the long term, facilitated the making of basic decisions with regard to genetic engineering. As a consequence, Switzerland has assumed the role of a legislative leader in this field.

Finally, because the decision-making process in Switzerland had to integrate the same major concerns and interests which are also shaping the international discourse, it might serve as an interesting and useful example of, and perhaps even a model for, international solutions. It should be the goal of each democratic system to search for solutions which are not only supported by a majority, but which reflect the legitimate concerns of the minority. The Swiss solution, by bringing together the concerns of producer and consumer, of industry, science and ethics, and of trade and the environment, sought to pursue this goal. This approach may serve as a model or stimulant for the international community in their search for a fair, democratic, and effective approach to GM food which takes seriously and brings together all major concerns.