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# GENETICALLY MODIFIED PLANTS: A NEED FOR INTERNATIONAL REGULATION

HENRIQUE FREIRE DE OLIVEIRA SOUZA\*

## I. INTRODUCTION

One of the most sensitive aspects of the technological evolution is linked with biotechnology. In this field human beings modify and create new forms of life and food. The field raises questions of ethics, questions of how to protect this “new” creation or version, questions of how commercially to explore this “new” creation or version, questions of how to protect consumers from potential or possible negative side effects of this “new” creation or version, and questions of how this “new” creation or version will affect the environment. Thus, biotechnology evokes both hope and fear.

Amongst all the possible issues related to biotechnology, the issue concerning genetically modified food (GMF) has special importance: while the “creators” of this kind of food are starting to exploit it commercially, resistance to genetically modified food has risen under the leadership of the European countries. This paper will be confined only to genetically modified plants (GMP), and their impacts on both the environment and the economy.

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In this paper, an overview will be provided of the issues involved in the context of GMP, including aspects of consumer and environmental protection, international trade, and intellectual property. Then, and using as a reference the ongoing discussion in Brazil concerning genetically modified soy, an analysis will be made of the questions relating to labeling and moratorium in the exploitation of these products. Finally, and after analyzing the situation mentioned above, and considering some of the general principles and concepts in international environmental law (specifically: state responsibility, the duty to assess environmental impacts, the obligation not to cause environmental harm, and the precautionary principle) a conclusion may be warranted. This conclusion is that an international regulation establishing not only a moratorium in the exploitation of GMP but also some minimum standards and an international label requirement should be introduced to counterbalance the economic power of the multinational companies acting in this field over developing or the less developed countries; second, more time should be provided for detailed studies on the environmental and health impacts of this kind of harvest; third, it will be necessary to protect the consumers; and finally, it must be in accord with general concepts and principles of international environmental law.

## II. DEVELOPMENT

### A. BIOTECHNOLOGY AND PLANTS

Four questions will be answered here: (a) why has this subject attracted so much attention? (b) What is the relationship between biotechnology and intellectual property rights? (c) What are the risks and benefits associated with this subject? (d) Balancing the benefits and risks, is GMP safe food?

#### 1. Historical Evolution (Including the Role of Intellectual Property)

Instead of preparing a detailed and chronological graphic of the evolution of biotechnology, it will be simpler to emphasize, as Sara Dunn explains, that “genetic manipulation to enhance favorable characteristics of agricultural product is not a new phenomenon. Pests and drought have always influenced genetic composition through the process of natural selection. Historically, producers have also influenced natural selection favoring crops that were bred to enhance desirable traits such as higher

yields or drought resistance.”<sup>1</sup> So, the question now is: why is this subject, this “old issue,” this “old practice” attracting so much attention nowadays? And the answer is that: times have changed, the technology now is unique and widespread, and man now is starting to understand and fear the basic rule of evolution: adapt or die.

As Ms. Dunn observes, biotechnology is currently “among the faster growing industries in the world, with no end to growth in sight.”<sup>2</sup> This means that the time for a new product to be released in the market today is shorter than before, and likewise that the time for consumers (farmers or the general population) to assess the product and its potential or real side effects is also short. Consequently, consumers are using and consuming the product without, most of the time, being properly informed or without having enough time to evaluate information concerning the health or environmental side effects of the product. The irony is that even though man is able to create “new lives,” he is not able, at this time, to explain the effective consequences of the interaction of this “new life” with another specific form of life in a specific case, or with the environment in general.

Not only is time short, and the number of new biotech products being released high, but technology nowadays is unique, and sometimes unreal and inexplicable to the majority of people. One could say that all technological process will always seem unique, unreal and inexplicable for the majority of people, and this is true. The problem here is that the technology in this field is becoming widespread, at least in terms of final products, and a good example is the fact that 60% to 70% of foods sold in the U.S.A contain substances developed through genetic engineering.<sup>3</sup> This happens in order to provide protection against insect disease, or develop resistance to some chemicals, or improve its intrinsic quality.<sup>4</sup> It means that two basic rights of consumers have been violated: the right to be informed, and the right to make choices.

The combination of “time and technology” would not be enough to attract all this attention without the existence of a growing trend of

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1. Sara M. Dunn, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145, 148-149 (1998).

2. *Id.*, at 150. Moreover, “between 1985 and 1990, biotechnology patent applications increased by fifteen percent annually in the United States and total products sales are expected to exceed \$50 billion by the year 2000.”

3. CNN.com, *U.S., Europe React Differently over Modified Foods* (last visited Sept. 2, 1999) <[cnn.Com/NATURE/9907/08/genetics.enn/](http://cnn.Com/NATURE/9907/08/genetics.enn/)>.

4. Dunn, *supra* note 1, at 149.

respect for the environment. This is a consequence of a great change — provoked by fear or education — in the way in which man sees his own relationship with the environment. If in the past this was a win-lose relationship, nowadays it is becoming a win-win relationship, and man today, unlike in the past, not only pays more attention to the environmental consequences of his acts, but also understands that the only way to survive is by keeping the environment good enough to support life. In this new kind of relationship agriculture has a special role, because, as John Barton says, agriculture “directly uses over a third of the earth’s land areas.”<sup>5</sup>

Another important point to be emphasized concerns how biotechnology and plants are related to intellectual property rights (IPR),<sup>6</sup> and the main issue here is: should a new form of life be protected by IPR? The fact is that using biotechnology, man has been re-creating nature through the creation of new forms of life (plants and animals), which has provoked a re-thinking of moral, ethical and legal values. In order to understand the actual situation, the following general comments are essential:

Although it is clear that the main purpose of IPR is, according to Margereth Barret “to ensure a rich, diverse and competitive marketplace,”<sup>7</sup> the definition, the scope,<sup>8</sup> the kind of protection<sup>9</sup> and the remedies associated with IPR vary enormously around the world. The problem is even worse when considering that protection, if granted, will have effect only in the territory of the state where protection is granted, independently of the fact that nowadays “thoughts” [and sometimes also goods] are not restricted by any geographical barrier: they can go

5. John H. Barton, *Biotechnology, the Environment, and Intellectual Agricultural Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, n.1 (1996).

6. There are three basic ways of protecting intellectual property rights: trademark, copyright and patent. A new way would be related with breeder's rights.

7. MARGRETH BARRET, *INTELLECTUAL PROPERTY - CASES AND MATERIALS*, St. Paul, MN: West Publishing Co, at 2 (1995).

8. GEORGE A. BERMAN ET AL., *CASES AND MATERIALS ON EUROPEAN COMMUNITY LAW*, St. Paul, MN: West Publishing, at 396 (1993). “The three traditional categories of such rights, recognized by almost all modern free-enterprise legal systems (but rejected, until recently, by Marxist and many mixed-economy legal systems) are patents, trademarks and copyrights.”

9. Hugh Cameron, *International Collaborative R&D Intellectual Property Rights in Facilitating International Technology Co-Operation Proceedings of the Seoul Conference, DSTI/STP/TIP (97) 14/FINAL*, Mar. 28, 1999, at 89 <[http://www.oecd.org/dsti/sti/s\\_t/intel/prod/seoul.htm](http://www.oecd.org/dsti/sti/s_t/intel/prod/seoul.htm)>. One example here is provided when comparing patenting systems; so, for example and among other dissimilarities: (1) the patent will be granted in the European Patent Office and Japan for the first to file, in the U.S. Patent Office for the first to invent; (2) there is no patent for discovery in the European Patent Office and Japan, but this kind of patent exists in the U.S. Patent Office; and, (3) there is no grace period in the European Patent Office; in Japan this period is six months and in the US it is twelve months.

everywhere (it is the phenomenon of globalization). In order to try to achieve a more effective standard of protection as well as extraterritorial protection, a number of international multilateral and bilateral agreements have been signed, including: (a) the Berne Convention for the Protection of Literary and Artistic Works (Paris Act, July 24, 1971);<sup>10</sup> (b) the Paris Convention for the Protection of Industrial Property signed on March 20, 1883, as revised and amended;<sup>11</sup> and (c) the Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade and Counterfeited Goods (TRIPs).<sup>12</sup> Moreover there is a tendency not only to harmonize the rules, but also to grant extraterritorial protection in terms of IPR; two examples are worth mentioning: one is the fact that the Members of NAFTA (North American Free Trade Agreement) are trying to unify or harmonize the protection of intellectual property among their Member States,<sup>13</sup> and another example is that the European Community is also trying to do the same, and nowadays in the European Community there is a unified (although limited) system protecting patents (European Patent Convention (EPC) of October 5, 1973, in force in 1977)<sup>14</sup> and trademarks (Council Regulation 40/94 of December 20, 1993).<sup>15</sup>

So, the basic idea when thinking of IPR rights and its relation both to economic development and the activity of research and development is, as Christian Dambrini indicates, that: "globalization of economies cannot be effective without a strong, affordable, enforceable intellectual property rights system to protect its results."<sup>16</sup> Therefore the challenge is

10. SELECTED INTELLECTUAL PROPERTY AND UNFAIR COMPETITION STATUTES, REGULATIONS & TREATIES, St. Paul, MN: West Publishing Company, at 390 (1997). It protects, among other things, the following works: Literary and artistic, derivative, and applied art and industrial designs.

11. *Id.*, at 805. This Convention was revised at Brussels on December 14, 1900, at Washington on June 2, 1911; The Hague on November 6, 1925; London on June 2, 1934; Lisbon on October 31, 1958; at Stockholm on July 14, 1967; and amended on October 2, 1979. The protection here is for patents, utility models, industrial designs, trademarks, services marks, trade names, indications of source or appellations of origin, and repression of unfair competition.

12. Dunn, *supra* note 1, at 161. "The GATT attempted to implement the first truly comprehensive intellectual property rights system. The TRIPS Accord includes plants IPRs in the form of patents, breeder's rights, or both, reflecting the northern view of ownership of plant genetics."

13. SELECTED INTELLECTUAL PROPERTY AND UNFAIR COMPETITION STATUTES, REGULATIONS & TREATIES, *supra* note 10 at 822. The matter is regulated in Chapter 17 of the North American Free Trade Agreement, part SIX: Intellectual Property Chapter Seventeen: Intellectual Property. It regulates protection of, among others: copyright, sound recordings, and encrypted programs- carrying satellite signals, trademarks and patents.

14. BERMAN ET AL., *supra* note 8, at 422.

15. 1994 O.J (L 11/1) (Jan 14, 1994).

16. Christian Dambrini, Globalization of Research and Development: A Business Viewpoint in Facilitating International Technology Co-Operation Proceedings of the Seoul Conference, DSTI/STP/TIP (97) 14/FINAL, Mar. 28, 1999, at 27. Available at <[http://www.oecd.org/dsti/sti/s\\_t/inte/prod/seoul.htm](http://www.oecd.org/dsti/sti/s_t/inte/prod/seoul.htm)>.

to ensure, as Joseph Villela concludes, that: “[a] all countries set high standards of intellectual property protection and enforcement in their national laws and effectively support and enforce the standards once the improved laws are in place; [b] all countries recognize the special intellectual property needs of industrial sectors whose inventions, because of regulatory requirements, reach the market place with considerable delay, after patent grant; and [c] that intellectual property protection is maintained and updated appropriately in today’s rapidly changing technological world.”<sup>17</sup>

In order to ensure the worldwide protection of IPR and to minimize the risks related to lack of protection or enforcement of IPR, all developed nations have been developing a strong defense of these rights, and one example is provided by the posture of the U.S.A. The U.S.A. has been developing a great crusade in favor of the international and effective protection of IPR since the mid-1980s, which can be easily explained *first* because of the impact of infringements of IPR on American external trade, and *second* because of the economic importance of the trade in intellectual property for American international trade (it represented \$33 billion in licensing fees and royalties in 1997).<sup>18</sup> Today, as indicated by Bénédicte Callan, it is on the top of the American agenda: “1. The full and timely implementation of TRIPs by all countries party to the WTO; 2. The extension of TRIPs-level protection to countries not yet signatories to the WTO; 3. Adoption standards and enforcement mechanisms has to go beyond those contained in TRIPs; [and] 4. The expansion of protection to new issues through WIPO [World Intellectual Property Organization] or other multilateral agreements.”<sup>19</sup>

Finally, not only developed nations have been considering the protection of intellectual property as one of the most important elements in the protection of technology, but private companies are also sharing the same view.

The IPR’s connected with research and development in the field of biotechnology are usually protected by patents and plant breeders’

17. Joseph F Villela, Intellectual Property Protection: a Business Viewpoint in Facilitating International Technology Co-Operation Proceedings of the Seoul Conference, DSTI/STP/TIP (97) 14/FINAL, Mar. 28, 1999, at 83. Available at <[http://www.oecd.org/dsti/sti/s\\_t/inte/prod/seoul.htm](http://www.oecd.org/dsti/sti/s_t/inte/prod/seoul.htm)>.

18. Bénédicte Callan, Intellectual Property Rights: Policies and Issues in the United States in Facilitating International Technology Co-Operation Proceedings of the Seoul Conference, DSTI/STP/TIP (97) 14/FINAL, Mar. 28, 1999, at 110. Available at <[http://www.oecd.org/dsti/sti/s\\_t/inte/prod/seoul.htm](http://www.oecd.org/dsti/sti/s_t/inte/prod/seoul.htm)>.

19. *Id.*, at 103.

rights.<sup>20</sup> A patent is intended to protect a new, useful, and non-obvious process or product made by man, and these requirements are basically the same all over the world. However, the grounds for this protection may be different, depending on the country; some countries (like the USA)<sup>21</sup> will apply a social and economic rationale in order to justify the protection of IPR, and others (like civil law countries, in general) will apply a natural-right theory. Independently of the theory applicable, the main issue will always be whether new forms of life can be considered a process and/or a product, thus leading to questions like whether man has a right over another life. Moreover, this discussion goes far as the protection of IPR occurs locally. Despite efforts to unify the protection, basically IPR is protected locally. This means that each local jurisdiction will grant protection according to its own law, and that protection can be granted by one country and refused by another. A good example of how the same patent can be seen in different countries is provided by the so-called "Harvard Mouse": even though the Patent Trademark Office (USA) in 1988 issued the first patent concerning an animal, a transgenic mouse known as the "Harvard Mouse," Canada refused to do so.<sup>22</sup>

Plant breeders' rights (PBR),<sup>23</sup> evolved by the International Union for the Protection of New Varieties of Plants (UPOV) Convention, are exclusive

20. FAO, *Intellectual Property Rights* (last visited Sept. 15, 1999) <[www.fao.org/docrep/v4845e/v4845e0b.htm](http://www.fao.org/docrep/v4845e/v4845e0b.htm)>.

21. BARRET, *supra* note 7, at 93. In the USA, the monopoly conceded by the patent has as its objective to promote the progress of knowledge: "Jefferson's philosophy . . . The patent monopoly was not designed to secure the inventor his natural right in his discoveries. Rather, it was a reward, and inducement, to bring forth new knowledge."

22. Carrie F. Walter, *Intellectual Property Law Review 1999*, 31 INTELL. PROP. L. REV. 195, 196 (1999). These different procedures adopted by countries suggest that "the debate about animal patenting is, indeed, unresolved and anything but clear cut." In the USA, besides the Harvard Mouse, there is also a patent granted to a bacterium capable of breaking down crude oil (*Diamond v. Chakrabarty*, 447 U.S. 303), and genetically engineered oysters (*Ex Part Allen*, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Interferences 1987)), for example.

The importance of the patent for biotechnology is well explained by Pauline Newman (in Pauline Newman, *Intellectual Property Law and the New Biology*, 36 JUDGES J. 46, no. 3 (1997). Available in WESTLAW) when commenting on the decision in the case *Diamond v. Chakrabarty*, *infra.*, she said: "This decision is credited with enabling the rapid growth of the biotechnology industry in the United States."

23. FAO, *Issues and Concerns in Biotechnology with Special Reference to Developing Countries* (last visited Sept. 15, 1999) <[www.fao.org/docrep/v4845e/v4845e03.htm](http://www.fao.org/docrep/v4845e/v4845e03.htm)>. Even though there is a protection, the UPOV Convention adopts the fundamental principle of unrestricted access to genetic resources.

Moreover, and according to Sara M. Dunn, *supra* note 1, at 160: "there are three qualifications that a new variety must meet to receive protection under UPOV: (1) the new plant variety has to be clearly distinguishable from other varieties by one or more characteristics; (2) the new plant variety must be sufficiently homogenous in its sexual reproduction or asexual reproduction or asexual propagation; and (3) the new variety has to be stable in its essential characteristics. The UPOV's protection is limited in three different ways. First, the UPOV does not patent the new varieties; it only protects the breeder's rights to marketed varieties. This means that



and temporary rights granted by the government to plant breeders, allowing them to exclude others from producing or commercializing material of a specific plant variety.<sup>24</sup> This right has been incorporated by local laws. An example here is the Brazilian Law 9456, de 25 de Abril de 1997, that regulates the IPR concerning a cultivar (a cultivated variety of a plant distinguished from other plants) — this law will be commented on later during the analysis of the Brazilian Case. Another example is the Plant Variety Protection Act (an American right, [hereinafter PVPA]) establishing that “farmers may save new varieties of PVPA protected seed and use it for planting crops but cannot sell it as seed unless they have obtained the permission of the owner of the variety.”<sup>25</sup>

Concerning first the limits of the monopoly associated with the patent (the most important IPR in terms of technology), and second the rights to exclude others from producing or commercializing, associated with plant breeders' rights, the basic rule is that: although there is a protection, this monopoly/protection granted to the creator is granted for a determined period of time, and the creator must not abuse his/her rights. So, in the case of GMP the main refrain to the creator's action would be first the law, which means that he/she must avoid abuse of rights and he/she must also comply with other legal regulations concerning production, distribution, commercialization, consumer protection, and environment protection. A second refrain would be popular pressure by consumers or the general population, including boycott or negative market. A good example of the effect of popular pressure is the position adopted by Monsanto concerning the so-called “terminator technology” (or, sterile seeds) pursuant to such pressure.<sup>26</sup>

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new varieties may still be used by other researchers for their own breeding purposes. Second, the UPOV incorporates the concept of “farmer's right.” Farmers can reserve seed at harvest to use in planting the next year's crop but can not sell this seed to other farmers. Third, UPOV protection does not extend to the components chemicals of the plant.”

24. FAO, *supra* note 20.

25. Neil D. Hamilton, *Plowing New Ground: Emerging Policy Issues in a Changing Agriculture*, 2 DRAKE J. AGRIC. L. 181, 189 (1997). The Act is written in this way because of the decision by the U.S. Supreme Court in the case *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179. In this case, the Supreme Court held that “farmers could not raise PVPA protected seed for the purpose of selling it to others.”

26. Barnaby J. Feder, *Monsanto Won't Market Sterile Seeds*, S.F. CHRON., Oct. 5, 1999, C2. “[S]eeking to remove itself from one of the most inflamed debates in biotechnology, the Monsanto Co. said yesterday that it would make no effort to market seeds that produce crop plants that are themselves infertile. In the same matter, Dr. Melvin Oliver, a Department of Agriculture researcher in Lubbock, Texas, consider that “This [the position adopted by Monsanto] may be the right decision for Monsanto but I think abandoning the technology is a mistake . . . seed sterility could be an important tool for making sure that other genetically engineered traits like herbicide resistance do not escape into wild plants.”

Despite these concerns IPR has the important effect of stimulating the development of new process and products allowing the growth of industry in general; moreover, this kind of protection is essential in matters relating to high technology, such as biotechnology.<sup>27</sup> But two questions remain: (a) Does this system protect less developed countries? and, (b) Does it promote general development or only create bases for the increase of technological or economic distance among countries? Although a clear answer does not exist, it is possible to infer from the view of less or least developed countries that this system works against less developed countries, allowing the increase of technological or economic distance among them and developed or developing countries, and perpetuating in this way their condition of dependency: "(M)ost developing countries, especially the least developed ones, have more need to absorb and diffuse as widely as possible the new technologies for their development. They try to avoid the overpricing and monopolization that could occur through imposition of strict IPR systems. Some even consider that the current international patent regime works to their disadvantage and that they receive nothing in return for protecting inventions produced in the developed countries."<sup>28</sup>

As a matter of fact, nowadays countries can be classified not only as industrial, agricultural or service-based countries, but also as IPR's-based countries. The amazing thing is that whoever retains the IPR, and if this right is protected worldwide (it is not occurring at this moment, even though there are efforts in this vein), will be able not only to receive royalties or to generate more new processes or products but also, and in a worst scenario, will be able to control the dissemination of technology and the production of services and goods in all the other countries.

All these facts make clear the strong relationship between IPR and biotechnology, and also the strong relationship between IPR/Biotechnology and the world economy.

## 2. Benefits, Risks and Safety

As stated earlier, biotechnology today evokes both hope and fear. But what are the benefits and risks of biotechnology?

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27. Walter, *supra* note 22 at, 195. A patent "stimulates the growth of industry, and the industry of biotechnology welcomes any patent protection it receives."

28. FAO, *supra* note 23.

The main benefits of biotechnology can be summarized in the following way: (a) it contributes to the human food supply and to the protection of biodiversity, allowing a more efficient use of land, and a more productive harvest;<sup>29</sup> (b) it improves the quality of food;<sup>30</sup> (c) it may contribute to reducing the use of agrochemicals<sup>31</sup> and pesticide;<sup>32</sup> and finally (d) it may be helpful for the maintenance of germplasm collections.<sup>33</sup>

On the other hand, the risks associated with this activity can be divided and summarized into three categories: (1) risks to the economy; (2) risks to the environment, and (3) risks to the health.

The main risks to the economy are well explained by Carrie Walter: "[S]mall farmers fear that a small number of large corporations will be able to corner the market on genetically engineered animals, thereby depriving the small family farms of their livelihood. Additionally, the farmers are concerned that the initial acquisition price of genetically altered animals, and the subsequent royalties, will increase rather than decrease the costs for farmers and consumers."<sup>34</sup>

The main risks to the environment are the following: (a) the first risks are indicated by FAO in the following way "The inclusion of novel genes for herbicide resistance in plants may increase the occurrence of weeds with resistance to certain agrochemicals, the [FAO] reported warned. The

29. Barton, *supra* note 5, at 99. "[T]echnology can contribute to the human food supply with less impact on biodiversity and world land use . . . [and] can provide better foods by reducing post-harvest crop loss to vermin and rodents and by improving nutritional quality."

30. Walter, *supra* note 22, at 219. "Biotechnology holds the key to . . . [improving] the quality of our food."

31. FAO, *Biotechnology Can Help Feed an Increasing World Population - Positive and Negative Aspects Need to Be Balanced*, Press Release 99/2 (last visited Sept. 15, 1999) <[www.fao.org/waicent/ois/press%Fne/presseng/1999/pren9902.htm](http://www.fao.org/waicent/ois/press%Fne/presseng/1999/pren9902.htm)>. "The application of pesticides and fungicides could be reduced through plants with genetic pest resistance. Plants with tolerance for conditions of salinity or high iron toxicity could help to improve agricultural production in marginal areas." So, "biotechnology-derived solutions built into the genotype of plants could reduce use of agrochemicals, thus promoting sustainable yields."

32. Michael A. Whittaker. *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215 (1998). Available in WESTLAW: "transgenic plants containing natural insecticides may reduce the need for chemical pest control, benefiting the environment (which is now exposed to a barrage of harmful chemicals used in modern farming), farmers (who must now deal with an array of potentially harmful pesticides), and consumers (who ingest foods contaminated with pesticides residues). [Moreover] transgenic plants with increased resistance to herbicides may make it possible to use less toxic herbicides and increase crop yield."

33. FAO Press Release 99/2, *supra* note 31. "[S]ome biotechnological techniques, like in vitro culture, are very helpful for maintenance of germplasm collections of species with low fertility and species that are hard to keep as seeds in field gene banks."

34. Walter, *supra* note 22, at 211.

inclusion of pest resistance in plants should be carefully evaluated for potential development of resistance in pests and possible side-effects on beneficial organisms.”;<sup>35</sup> (b) Michael Wittaker considers as a second risk the fact that “while crops may be engineered to contain natural insecticides, insects can adapt, becoming resistant much more quickly than expected . . . . The planting of crops containing herbicide resistance genes may, ironically, result in increased herbicide use, as farmers would be free to use herbicides to control weeds without fear of harming the crop plants themselves. Further, the crop plants may transfer these resistance genes to wild plants, potentially creating herbicide-resistant weeds that are a threat to the environment.”;<sup>36</sup> (c) The third risk is identified by John Barton, who says that: “the introduction of any new organism into an ecosystem might affect the dynamics of the ecosystem or the gene pool of wild relatives. These effects can happen whether the new organism is a new crop variety or a new microorganism introduced for disease control, and whether it is genetically-engineered, bred by traditional means, or simply from a different ecosystem.”;<sup>37</sup> (d) Finally, another risk is the loss of diversity<sup>38</sup> provoked by the widespread use of one — or a few — species of crops.

The main risk to health is allergy, and one example is found in the allergic side effects provoked by the addition of Brazil nut protein in a soybean.<sup>39</sup>

Finally, is it safe to use GMP as food? A clear, conclusive, and well accepted answer does not exist: first because there is no scientific consensus;<sup>40</sup> second, because the standards for evaluating the

35. FAO Press Release 99/2, *supra* note 31.

36. Whittaker, *supra* note 32, at 1220-1221.

37. Barton, *supra* note 5, at 99.

38. DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 934 (1998). “Biodiversity thus encompasses all of the variability among the building blocks of life (i.e., genetic diversity), different life forms (species diversity) and the interrelationship of life (ecosystem diversity). The concept of biodiversity does not discriminate between wild and domesticate animals and plants.” The same author, on page 940, says, “in recent decades the trend in industrialized agriculture has been to plant ever more extensive fields of ever fewer varieties of these crops. Not only does the expansion of “monocultures” displace traditional varieties, but the lack of diversity makes crops highly susceptible to insects and diseases.”

39. Whittaker, *supra* note 32, at 1221. “[T]ransgenic soybeans may be made more nutritious by the addition of Brazil nut protein, but to an individual allergic to Brazil nuts, consuming a food containing this protein may present a life-threatening situation.”

40. Professor Liam Donaldson and Sir Robert May, *Health Implications of Genetically Modified Foods*, Department of Health, May 1999 (last visited Sept. 20, 1999) <[www.doh.gov.uk/gmfood.htm](http://www.doh.gov.uk/gmfood.htm)>. The Department of Health in the United Kingdom, in a study prepared May 1999, concludes among other things that: “many of the issues raised by foods resulting from genetic modification are equally applicable to foods produced by conventional means . . . . There is no current evidence to suggest that the GM technologies used to produce food are

consequences of a GMP used as a food vary from country to country;<sup>41</sup> and finally, because social and cultural aspects also influence the answer.<sup>42</sup> The actual fact is that nowadays there is a lot of "unsafe" food lawfully in the market, and one example here is the product *Sweet'n Low*, a sugar substitute commercialized in the USA by Cumberland Packing Group. The label of this product provides the following warning: "[u]se of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals."

Thus in evaluating the risks/benefits of GMP it seems that the crucial element is the impact of GMP on the environment instead of its impact on individual health.

## B. GMP AND COMMERCE

Here four questions will be answered: who are the producers? What is the position of the USA and the European Union? What are intergovernmental organizations and NGOs doing? Should developing countries be producers?

### 1. Who Are the Producers?

Nowadays about 2.5 billion people have been eating GMP directly or indirectly, knowingly or not. Moreover, the number of consumers is expected to increase, just because: (a) multinationals have been investing billions and billions of dollars in new products,<sup>43</sup> and (b) each day more

inherently harmful. . . . [N]othing can be absolutely certain in a field of rapid scientific and technological development . . . ."

41. Dunn, *supra* note 1, at 154, 166. "Allergic reactions could occur in humans from inadvertent transferring of proteins during the genetic engineering process. The allergenic potential for GMOs is largely unknown, yet US government officials are joining the seed companies in claiming that these products are safe . . . [concerning] the evolution of resistant plants and insects from overuse of genetically modified seed . . . laboratory experiments and field trials have failed to produce [the insect European Corn Borer] EC Borer that are resistant to Bt corn, but growers as still advised to plant twenty-five percent of their acreage to non-Bt corn varieties . . . [concerning] the loss of biodiversity . . . biodiversity needs to be protected and preserved for its intrinsic value as well as its economics values . . . biotechnology will provide necessary tools for the twenty-first century."

*See generally* Barton, *supra* note 1 at 106. Bt means "Bacillus thuringiensis [a] genes or virus coat protein that confer resistance to respective categories of insects or viruses."

42. Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525 (1998). Available in LEXIS: This author provides a good analysis of the influence of culture in biotechnology issues.

43. O GLOBO ON – Vanice Cioccarri, *A nova Revolução Transgêncica da Agricultura* (last visited Aug. 30, 1999) <[www.oglobo.com.br/arquivo/ciencia/19990704/civi10.htm](http://www.oglobo.com.br/arquivo/ciencia/19990704/civi10.htm)>.

countries are allowing cultivation of GMP, in a market that will reach US\$ 500 billions/year in the next few years.<sup>44</sup>

The table below, translated from an article available in C&T Brasil,<sup>45</sup> shows which countries have already authorized the harvest of GMP:

Country	GMP commercialized / Beginning of Commercialization
Argentina	soy/1996, corn/1998, cotton/1998
Brazil	None **
Canada	corn/1998, cotton/1996, canola/1997, MELAO/1998, potato/1999, wheat/1999
EUA	MELAO/1994, soy/1994, tomato/1994, cotton/1994, potato/1994, canola/1995, corn/1995
Japan	soy/1996, canola/1996, potato/1996, corn/1996, cotton/1997, tomato/1997
EU	Tomato/1995, canola/1995, soy/1996, corn/1997, potato/1998, cotton/1998.

\*\* It had given authorization to Monsanto to commercialize soy, but this authorization was revoked by a judicial decision (See in this paper the topic "The Brazilian Case"). Moreover, it is clear that transgenic soybeans have been developed in Brazil and, at least in one case, this product, according to Michael Whittaker, provoked allergy.

Even though not mentioned in the table above, China is one of the largest producers, together with Canada, Argentina and the USA, and among these producers the USA is the largest.<sup>46</sup> As a matter of fact, according to Charles Margulis, a genetic engineering campaigner for Greenpeace, it is estimated that "75 percent of all bio-engineered crops are grown in the U.S. [moreover, and according to Mothers for Natural Law] 60 to 70 percent of foods on U.S. grocery store shelves contain genetically engineered substances."<sup>47</sup>

44. *Id.* Moreover, in the same article, the position and the importance of GMF for the USA is summarized in the following way: "USA has been cultivating GMF since 1994, and last week, Stuart Eizenstat, from the US Treasury Department, said that almost 100% of the agricultural products exported by USA in the next five years will be genetically modified or products combined with them."

45. C&T Brasil, *Percepção Pública da Biotecnologia* (visited Sept. 9, 1999) <[www.mct.gov.br/ctnbiotec/percep.htm](http://www.mct.gov.br/ctnbiotec/percep.htm)>. CTNBio showed this table in an article supporting its decision in authorizing the exploitation of the Soy Roundup Ready by Monsanto in Brazil.

46. FAO Report, *Technical Meeting on Benefits and Risks of Transgenic Herbicide Resistant Crops*, Rome, Italy, 16-18 Nov. 1998 (last visited Oct. 27, 1999) <[www.fao.org/WAICENT/FAOINFO/AGRICULT/magazine/default.htm](http://www.fao.org/WAICENT/FAOINFO/AGRICULT/magazine/default.htm)>.

47. CNN.com, *supra* note 3.

## 2. The Commercial Battle: The Positions of the USA and the EU

The question is: Why the USA and the EU? The answer is simple: in 1997 the USA was the main importer of agricultural products (excluding fish) in the world, and in the same year seven out of the ten most important importers of agricultural products (also excluding fish) were members of the EU: France, Germany, Italy, Spain, the United Kingdom, Belgium, and the Netherlands.<sup>48</sup> So, if they are the most important importers, the perception that they have concerning biotechnology and its application to agriculture will have a great impact in terms of acceptance of this technology by other potential producer countries, and their views concerning the issue are completely different.

If it is clear that there is a high standard of protection of consumers' rights and consumers' health, it is also clear that they have a different way of approaching this matter, for example: (a) in the USA, GMP will be considered safe,<sup>49</sup> unless there is actual proof against this assumption, and if the GMP is safe, the food is also safe and there is no need for special label indicating that the food originated from GMP.<sup>50</sup> On the other hand, the position in EU is that the GMP and its products are

48. FAOSTAT Agriculture data, *Food Excl Fish Imp Val at Base Yr Price (1000\$)* (last visited Oct. 27, 1999) <apps.Fao.org/cgi-bin/nph-db.pl?subset=agriculture>.

49. Echols, *supra* note 42, at 537. "The fundamental concept underlying the regulatory scheme is that foods derived from new plant varieties are like any other foods and are safe."

50. Judith E. Beach, *No "Killer Tomatoes:" Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD DRUG L.J. 181, 182 (1998). Available in LEXIS: "most federal agencies and officials now take the position that there is no difference between genetically modified and traditional food crops, and therefore biotechnology foods requires no special labeling unless specific safety issues are raised. Indeed, the U.S. government objects to the European Union's (EU's) special labeling of genetically altered foods as unwarranted and scientifically irrational."

*See also* CNN.com, *supra* note 3. "To date, the U.S. Food and Drug Administration has not required testing of any GM foods, stating they are not aware of any information showing that GM foods differ from any other foods."

Moreover, the process of approval in the United States is well explained by Sara M. Dunn, *supra* note 1, at 152: "genetically enhanced crops such as Bt corn and Round ready soybeans require approval of the US Environmental Protection Agency (EPA), the FDA, and the USDA before they can be market. A company developing a genetically engineered plant must obtain a permit from the USDA to begin field testing. Field testing is necessary to determine whether the plant will perform in the natural environment in a manner similar to that of the laboratory trials. After field tests are complete, the company may apply for the plant to be exempted from further USDA regulations and approved for commercial use. After the USDA has approved the plant the FDA and the EPA become actively involved. The FDA ensures that all new food products are safe. The EPA reviews the product to determines whether unintended negative impacts on the environment or other organisms would result."

And finally, this process in the view of Philip S. Angell (Director, Corporate Communications MONSANTO Company) "is doing quite well." Moreover, he also said that: "It is because of that track record, and because our system remains flexible, that we should be wary of any proposal for radical change." Forum, *How Should We Regulate Biotechnology in Agriculture?*, 16 ENVTL. FORUM 48 NO. 2 (MAR./APR. 1999).

considered unsafe, unless there is clear proof against this assumption, and if the food is not safe “a priori” the consumer must be protected through a special label;<sup>51</sup> and (b) in the words of US Ambassador David Aaron, Under Secretary for International Trade U.S. Department of Commerce, in the USA the process is more science-based while in Europe this process is driven by political pressure, and it makes the process in Europe slow and non-transparent.<sup>52</sup> In the same way Dan Glickman, Secretary of Agriculture in the USA, emphasizes that “We [USA] base decisions on rigorous analysis and sound scientific principles.”<sup>53</sup>

Marsha Echols comments on these differences saying that: “while Europe supports traditional processes, often it struggles in developing a food safety policy toward new or “novel” products and technologies . . . the U.S. usually is more receptive to both . . . [another distinction] philosophically, the U.S regulatory approach permits a great deal of industry self-regulation, while Europeans usually adopt a more detailed regulatory scheme.”<sup>54</sup>

These approaches: (a) first reflect the way through which GMP and its products are analyzed for approval (or not) in both areas, as explained by Terence Stuart and David Johanson: “the United States has an established regulatory system for approval of genetically modified organisms (GMOs), which makes the process of introducing a genetically modified food or agricultural product into the market fairly

51. Terence P. Stuart and David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243 (1999). Available in LEXIS: “Under Article 16 a member state may “provisionally restrict” a GMO approved for sale under Directive 90/220/EEC if the state has “justifiable reasons” to believe that the product might adversely affect human health or the environment . . . . The Commission’s original proposal for the mandatory labeling legislation for the relevant GMO maize and soya provided that in cases in which it is uncertain as to whether a product contains these GMO products, the label should state ‘may contain GMOs.’ . . . Regulation No. 1139/98 requires that products containing DNA or protein resulting from genetic modification of the relevant GMO soya and maize be labeled as “genetically modified,” or produced through genetic modification . . . . The regulation does not provide for the “may contain” labeling option for products for which it is not possible to determine whether they contain the relevant GMOs.”

52. Prepared Statement of Ambassador David L. Aaron, Under Secretary for International Trade U.S. Department of Commerce, before the U.S. House of Representatives - Committee on International Relations, June 15, 1999 (last visited Nov. 2, 1999) <[www.ogc.doc.gov/ogc/legreg/testimon/106f/aaron0615.htm](http://www.ogc.doc.gov/ogc/legreg/testimon/106f/aaron0615.htm)>.

53. The United States Mission to the European Union, Glickman on Hormone Beef and Biotechnology. Remarks as Prepared for Delivery by Secretary of Agriculture Dan Glickman before the National Press Club on *New Crops, New Century, New Challenges: How will Scientists, Farmers, and Consumers Learn to Love Biotechnology and What Happens if they Don't?*, July 13, 1999 (last visited Nov. 2, 1999) <[www.useu.be/issues/glick0715.html](http://www.useu.be/issues/glick0715.html)>.

54. Echols, *supra* note 42, at 533.



predictable . . . [on the other hand] few Europeans appear satisfied with the European Union's laws in this area. Consequently, these laws are frequently changing and will likely continue changing in the foreseeable future. This legal uncertainty significantly impacts U.S. agricultural producers seeking access to the European market";<sup>55</sup> (b) second reflect a different level of technology applied in the agricultural process in both areas, as commented by Luiz Barret: "it is not amazing that Europeans, who practice an agriculture not competitive, and dependent on chemicals, be against biological solutions;"<sup>56</sup> and, finally, (c) they reflect the position of the consumers. Terence Stuart and David Johanson summarized the position thus: "while the introduction of genetically modified food products into the U.S. market has been challenged by consumers' groups on grounds of possible health risks, the use of biotechnology appears accepted by the American public . . . . In contrast, the sale and cultivation of GMO agricultural products in the European Union has been and continues to be heavily contested by consumers."<sup>57</sup> However, the acceptance by American people does not overrule the right of information: 85% of Americans considered the labeling of GMF very important, according to the United States Department of Agriculture, and 99% desire a clear identification in the label indicating that the product is a GMF.<sup>58</sup>

These facts show clearly that EU and USA have different positions concerning GMP, and also show that differences in culture, and differences in economic organization, are the main reasons for that. As a consequence of these differences, measures such as moratorium, ban, or label requirements have been taken by the EU or by some of its members, and the result of this action, as per the view of the USA, is first the impairment of the free trade concept, with violation of the rules set in out the GATT Agreement, and second direct damage to America's farmers harvesting this kind of crop.

But what are the roles of international organizations and NGOs on this issue?

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55. Stuart, *supra* note 51 at 246, 247.

56. Vannildo Mendes, *Brasil pode Restringir a Produção e o Consumo dos Alimentos Transgênicos*, O GLOBO ON (last visited Aug. 30, 1999) <[www.oglobo.com.br/ciencia/civid10.htm](http://www.oglobo.com.br/ciencia/civid10.htm)>. It was the opinion of Luiz Antonio Barret, the former president of CTNBio in Brazil. The original text in Portuguese is: "Não é surpreendente que os europeus, que praticam uma agricultura sem competitividade internacional, dependente de insumos químicos, sejam contrários a soluções biológicas."

57. Stuart, *supra* note 51, at 246.

58. IDEC, *O Risco dos Alimentos Geneticamente Modificados*, (last visited Sept. 9, 1999) <[www.uol.com.br/idec/campanhas/bio2\\_novo.htm](http://www.uol.com.br/idec/campanhas/bio2_novo.htm)>.

### 3. The Role of Intergovernmental Organizations (IOs) and NGOs

On October 12, 1999, the total population in the world reached six billion, six times the total population in 1804, and 60% of the total population expected by 2050.<sup>59</sup> This fact together with the evolution of technology, dissemination of information, development of international organizations acting in protecting the environment, and economic globalization,<sup>60</sup> has been increasing the importance of questions relating to environment and sustainability of life on the earth.

Moreover, this evolution of environmental concerns, and the forces relating to it, have provoked different reactions in society, and these different reactions may well be seen through the position concerning the GMP adopted by IOs and NGOs. The positions adopted by the Food and Agriculture Organization (FAO), by the Organization for Economic Cooperation and Development (OECD), and by Greenpeace, deserve attention and the reasons can be explained in this way: (a) FAO deserves comment first because its activity is connected with environmental conditions,<sup>61</sup> second because the matter of GMP is directly linked with this organization, third because this organization has been developing a close relationship with other organizations,<sup>62</sup> and finally, because its

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59. *And Baby Makes 6 Billion*, S.F. CHRON. (East Bay Edition), Oct. 10, 1999, at A1.

60. Lynton K. Caldwell, *Is World Law an Emerging Reality?* *Environmental Law in Transnational World*, 10 COLO. J. INT'L ENVTL. L. & POL'Y 227 (1999).

61. *Id.*, at 231. "The intergovernmental organizations that are concerned with environmental affairs are largely associated with the United Nations: the Specialized Agencies; the Food and Agriculture Organization; the World Health Organization; the World Meteorological Organization; the United Nations Educational Scientific and Cultural Organization; the World Bank; the United Nations Environmental Programme; the Commission on Sustainable Development; and bodies subsidiary to one or more of these agencies, such as the Global Environmental Facility. Regional intergovernmental organizations such as the Organization for Economic Cooperation and Development, the Organization of American States, the Organization of African Unity, and the European Union also have environmental agencies and/or agendas."

62. Some examples of this cooperation are found in FAO, *Biotechnology in Agriculture, Forestry and Fisheries: FAO Policies and Strategies*, (last visited Sept. 15, 1999) <[www.fao.org/sd/rtdirect/rtre0001.htm](http://www.fao.org/sd/rtdirect/rtre0001.htm)>: "FAO will continue to cooperate with United Nations Industries Development Organization (UNIDO), UNEP and WHO in the establishment of codes and guidelines for biotechnology-related environmental and health risk assessment. The UNIDO/UNEP/WHO/FAO Working Group on Biosafety brought out a Voluntary Code of Conduct for Release of Organisms into the Environment in 1991 . . . FAO has been collaborating with several UN and non-UN agencies/systems in a number of activities related to biotechnology. For instance, it takes part in the UNEP-initiated effort to establish a Convention on Biodiversity and in the Biotechnology Working Group formed in that effort. FAO was a member of the Working Group on Biotechnology which was created in preparation for the 1992 UN Conference on Environment and Development (UNCED), and will continue to work with other UN Agencies in implementing the Action Plan on Biotechnology contained in UNCED Agenda 21. The Organization has been working with UNIDO, UNEP and WHO in developing a Code of Conduct for Biosafety, and in developing food safety standards. It will continue to work closely with WIPO and GATT in evolving

status is not only local or regional, but international, as a specialized agency of the United Nations. (b) OECD deserves comment because OECD countries (only 29 members) produce two thirds of the world's goods and services,<sup>63</sup> and (c) Greenpeace deserves comment not only because it is one of the most well known and respected NGOs in the world, but also because it plays a key role in the Brazilian Case, which will be discussed in this paper.

FAO was founded in October 1945 having as one of its goals: to "raise levels of nutritive and standards of living, to improve agricultural productivity, and to better the conditions of rural populations."<sup>64</sup> The role developed by FAO for GMP can be summarized as follows: *First*, FAO acts as a special forum where matters relating to food and agriculture are discussed.<sup>65</sup> Two good examples of the results of these discussions are the preparation of the Report on the State of World's Plant Genetic Resources for Food and Agriculture (prepared for the International Technical Conference on Plant Genetic Resources — Leipzig, Germany (June 17-23, 1996), and the Reporter of the Commission on Genetic Resources for Food and Agriculture (prepared during the Eighth session in Rome, April 19-23, 1999), where FAO analyzed the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture adopted in the Leipzig Conference.<sup>66</sup> In these documents FAO recognizes among other things that:

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appropriate intellectual property protection systems suitable for both developed and developing countries . . . ."

63. OECD, *What is OECD*, (last visited Oct. 29, 1999) <[www.oecd.org/about/general/index.htm](http://www.oecd.org/about/general/index.htm)>. The members are: Australia, Canada, Finland, Greece, Ireland, Korea, The Netherlands, Poland, Sweden, United Kingdom, Austria, Czech Republic, France, Hungary, Italy, Luxembourg, New Zealand, Portugal, Switzerland, the United States, Belgium, Denmark, Germany, Iceland, Japan, Mexico, Norway, Spain, and Turkey.

64. FAO, *What it Is, What it Does*, (last visited Oct. 29, 1999) <[www.fao.org/UNFAO/WHATITIS.html](http://www.fao.org/UNFAO/WHATITIS.html)>.

65. *Id.* More than act as a forum for debate, FAO also "offers direct development assistance, collects, analyses and disseminates information, provides policy and planning advice to governments . . . ."

66. FAO, *Report on the State of the World's Plant Genetic Resources for Food and Agriculture - Prepared for the International Technical Conference on Plant Genetic Resources*, Leipzig, Germany, June 17-23, 1996, at 6, 8, 13, 15 (last visited Sept. 16, 1999) <[web.lcppgr.fao.org/wrlmap\\_e.htm](http://web.lcppgr.fao.org/wrlmap_e.htm)>. "The conservation and sustainable utilization of plant genetic resources is key to improving agricultural productivity and sustainability thereby contributing to a national development, food security, and poverty alleviation . . . Historically, plant genetic resources have contributed to stability in agro-ecosystems and provided the crucial raw material for the rise of modern scientific plant breeding . . . Many plant genetic resources which may be vital to future agricultural development and food security are threatened today. Country Reports indicate that recent losses of diversity have been large, and that the process of "erosion" continues . . . The chief

(a) the sustainable use of plant genetic resources is essential for increasing agricultural productivity, and this fact can contribute not only to food security but also to natural development, allowing both the alleviation of poverty and starvation;<sup>67</sup>

(b) modern agriculture is the most important cause of loss of genetic diversity, and the loss of diversity increases the possibility of crop losses;<sup>68</sup> and

(c) much needs to be done, and done locally, moreover; in the long term the preparation of a Report on the State of Agricultural Diversity should be considered.<sup>69</sup>

*Second*, FAO works in order to establish food standards, including recommendations for food labeling, food additives, and pesticide residues. An example here is the so-called Codex Alimentarius, developed by the FAO together with the World Health Organization (WHO), establishing more than 200 standards.<sup>70</sup> In terms of labeling, FAO also recognizes that a label is a way for allowing a proper choice of

contemporary cause of the loss of genetic diversity has been the spread of modern agriculture. The largely unintended consequence of the introduction of new varieties of crops has been the replacement - and loss - of traditional, highly variable farmer varieties . . . The concomitant increase in uniformity may also lead to greater risk and uncertainty. The US National Academy of Sciences described genetic vulnerability as "the condition that results when a widely planted crop is uniformly susceptible to a pest, pathogen or environmental hazard as a result of its genetic constitution, thereby creating a potential for widespread crop losses."

67. *Id.*

68. *Id.*

69. FAO, *Report of the Commission on Genetic Resources for Food and Agriculture* (Eighth Session) Rome, April 19-23, 1999, at 3, 4 (last visited Sept. 16, 1999) <[www.fao.org/WAICENT/FAOINFO/AGRICULT/cgrfa/docs8.htm](http://www.fao.org/WAICENT/FAOINFO/AGRICULT/cgrfa/docs8.htm)>: FAO analyzed the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture, adopted in Leipzig, Germany, in June 1996, and concluded basically that: "while there had been significant progress, much remains to be done at local, national, and international levels . . . The Commission recognized the need to develop mechanisms for early warning on threats to plant genetic resources, and to increase capacities to promote the regeneration of plant genetic resources. . . It was suggested that, in the longer term, a Report on the State of Agricultural Biodiversity might be envisaged . . ."

70. FAO/WHO, *Codex Alimentarius*, (last visited Sept. 15, 1999) <[www.fao.org/news/1999/codex-e.htm](http://www.fao.org/news/1999/codex-e.htm)>. This Code is "a compilation of all Standards, Codes of Practices, Guidelines and Recommendations of the Codex Alimentarius Commission . . . The Codex adopts international recommended standards, guidelines and codes of practice after thorough consideration by the Codex member countries. The Codex Alimentarius contains more than 200 standards. There are general standards or recommendations for: food labeling; food additives; contaminants; methods of analysis and sampling; food hygiene; nutrition and foods for special dietary uses; food import and export inspection and certification systems; residues of veterinary drugs in foods; and pesticide residues in foods."

food by consumers.<sup>71</sup> Finally, FAO recognizes that even though biotechnology is a powerful instrument to increase the world's of food supply, it has positive and negative aspects that must be carefully considered,<sup>72</sup> and each country is responsible for making this decision.<sup>73</sup>

OECD came into being in September 1961, superseding the Organization for European Economic Cooperation (OEEC) created on April 16, 1948,<sup>74</sup> and its main objectives include: the development of sustainable economic growth and employment, the expansion of economic trade on a non-discriminatory basis, and the allowance of cooperation among its members.

Biotechnology is not a new subject in OECD. Since 1980 this matter has been discussed by OECD, and as a consequence of the discussion, in 1982 OECD published "Biotechnology: International Trends and Perspectives," containing a number of recommendations, including one stating that governments must have mechanisms regulating the safety of products of modern biotechnology. In 1986 another publication, "Recombinant DNA: Safety Considerations," also known as "1986 Blue Book," dealt specifically with genetic engineering.<sup>75</sup> In 1992 the first commercial approval took place (in the USA - a member of OECD), and in 1993 an Internal Co-ordination Group for Biotechnology was established in order to coordinate and facilitate cooperation among various directorates dealing with biotechnology, including the Environment Directorate, the Directorate for Science, Technology and Industry, and the Agriculture Directorate.<sup>76</sup>

71. FAO, *Understanding the Codex Alimentarius -- Codex and Consumers*, (last visited Sept. 15, 1999) <[www.fao.org/docrep/w9950e/w9114e05.htm](http://www.fao.org/docrep/w9950e/w9114e05.htm)>. The food labeling provides "the consumer with information about a food so that a wise choice of food can be made."

72. FAO (Press Release 99/2), *supra* note 31. "Biotechnology is a powerful tool to feed an increasing world population, but its 'positive and negative potential' should be carefully evaluated . . . All concerns must be clearly balanced, respecting ethical aspects but reflecting the actual and potential possibilities of increasing food supplies and alleviating hunger . . ."

73. FAO, *supra* note 62: "Each country has a responsibility to formulate its own policies, priorities, strategies and programmes for harnessing biotechnology, and to weigh expected benefits, not only against possible negative effects but also against the risk of not exploiting the technology . . . [and] on request, FAO can provide technical inputs to assist in planning, programming, priority setting and strategy formulation."

74. *About OECD - OECD Origins*, (last visited Oct. 29, 1999) <[www.oecd.org/about/origins/oeec.htm](http://www.oecd.org/about/origins/oeec.htm)>.

75. OECD OBSERVER, *The Core of the Matter*, Issue no. 216 (last visited Oct. 25, 1999) <[www.oecd.org/publications/observer/216/e-toc.htm](http://www.oecd.org/publications/observer/216/e-toc.htm)>. This publication, as stated in OECD Observer, "put forward key safety concepts for development and commercialization of GMOs [genetically modified organisms], including genetically modified plants for agricultural use."

76. OECD OBSERVER, *Biotechnology at the OECD*, Issue no. 216 (last visited Oct. 25, 1999) <[www.oecd.org/publications/observer/216/e-toc.htm](http://www.oecd.org/publications/observer/216/e-toc.htm)>. See also *OECD at Work - OECD Main*

OECD recognizes that the matters relating to biotechnology are growing in terms of public debate:<sup>77</sup> (a) first, OECD recognizes that the concept “substantial equivalence”<sup>78</sup> is a useful tool when dealing with food and biotechnology, even though it “cannot always be readily established;”<sup>79</sup> (b) second, in a consensus document (on rape-seed oil) OECD also recognizes that genetically modified organisms impact the environment, but this “impact can differ from one place to another — the actual assessment itself remains the responsibility of the national authorities themselves to carry out”;<sup>80</sup> (c) third, OECD recognizes that “liberalizing trade policy will expand the volume of agricultural trade and alter regional productions patterns, but it will most likely not produce significant environmental effects.”<sup>81</sup> (d) fourth, OECD member countries recognize the need to harmonize regulatory approaches in terms of products of biotechnology “in order to avoid unnecessary trade barriers”;<sup>82</sup> and (e) finally, Donald Johnston, Secretary-General, in an editorial for OECD Observer, recognizes first that “traditional agriculture practices are polluting. In contrast, cultivation using biotechnology can reduce pollution,” and second that biotechnology is essential for “making a transition to a sustainable world economy [and concludes by saying that] like it or not, it is irreversible.”<sup>83</sup>

Just because biotechnology is considered essential, OECD is intensifying its work on biotechnology and, at the request of the G-8 countries, has invited NGOs for consultation on November 20, 1999, in preparation for their next summit meeting in July 2000.<sup>84</sup>

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*Activities*, <[www.oecd.org/about/work/index.htm](http://www.oecd.org/about/work/index.htm)> for a summary of the activities of the following Directorates: Environment, Agriculture, and Science, Technology and Industry.

77. OECD OBSERVER, *supra* note 75.

78. Greenpeace, *Nature Article Condemns GE Food Regulation as “Pseudo-Science,”* (last visited Oct. 24, 1999) <[www.greenpeace.org/~geneng/](http://www.greenpeace.org/~geneng/)>: “The concept of substantial equivalence embodies the idea that existing organisms used as foods, or as sources of food can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new.”

79. OECD OBSERVER, *GM Food, Regulation and Consumer Trust*, Issue no. 216 (last visited Oct. 26, 1999) <[www.oecd.org/publications/observer/216/e-toc.htm](http://www.oecd.org/publications/observer/216/e-toc.htm)>.

80. OECD OBSERVER, *What is Harmonisation of Regulatory Oversight?*, Issue no. 216 (last visited Oct. 25, 1999) <[www.oecd.org/publications/observer/216/e-toc.htm](http://www.oecd.org/publications/observer/216/e-toc.htm)>.

81. *Agriculture and Environment - The Environmental Effects of Reforming Agricultural Policies*, (last visited Oct. 29, 1999) <[www.oecd.org/agr/News/cont-1.htm](http://www.oecd.org/agr/News/cont-1.htm)>.

82. Environment Directorate, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide, ENV/JM/MONO (99) 9, Paris 1999.

83. OECD OBSERVER, *A Defense of Modern Biotechnology*, by Donald J. Johnston, Issue no. 216 (last visited Oct. 25, 1999) <[www.oecd.org/publications/observer/216/e-toc.htm](http://www.oecd.org/publications/observer/216/e-toc.htm)>.

84. OECD Online: Biotechnology & Food Safety, NGO Consultation Meeting, (last visited Oct. 30, 1999) <[www.oecd.org/subject/biotech/ngoconsultation.htm](http://www.oecd.org/subject/biotech/ngoconsultation.htm)>.

But what is the role of NGOs?

With regards to NGOs, the best known and organized in this field is Greenpeace.<sup>85</sup> It has acted in a very organized way in order to ban GMP, especially in Europe (and now in Brazil) where the public is more receptive to this idea. It has basically two areas of action: *first*, to publicize some issue, informing the general public that the issue exists, and *second*, to put together individual voices in order to create an effective pressure group. And the pressure works.<sup>86</sup>

The position of Greenpeace can be summarized in the following way: (a) Greenpeace considers inappropriate the application of the principle of "substantial equivalence," usually adopted not only by OECD but also by other defenders of GMP;<sup>87</sup> and (b) Greenpeace considers that the application of the precautionary principle is appropriate.<sup>88</sup>

An issue today is that the works of some intergovernmental organizations are not transparent to NGOs (GATT, for instance), even though NGOs currently have an observer status in the Montreal Protocol, Basel Convention, and Framework Convention on Biological Diversity.<sup>89</sup> The fact is that, because of its influence, NGOs are more and more involved with IOs, and the invitation by OECD, mentioned above, is a good example. The only problem is that the involvement, if really close, may destroy the most important characteristics of NGOs: independence and credibility.

85. *How Greenpeace Works*, (last visited Oct. 29, 1999) <[www.greenpeace.org/report98/html/content/works.html](http://www.greenpeace.org/report98/html/content/works.html)>: "Greenpeace is a global environmental campaigning organization . . . [and] organize[s] public campaigns for the protection of oceans and ancient forests, for the phasing-out of fossil fuels and the promotion of renewable energies in order to stop climate change, for the elimination of toxic chemical, against the release of genetically modified organisms into nature and for nuclear disarmament and an to nuclear contamination."

86. CNN.Com, *Gerber Ends Use of GM Ingredients*, (last visited Sept. 2, 1999) <[cnn.com/NATURE/9908/04/gerber.enn](http://cnn.com/NATURE/9908/04/gerber.enn)>. This material provides some examples: (a) in July 1999 Gerber, "the United States' largest producer of baby food, has decided to stop using genetically modified corn, soy and other foods in their baby food products . . . [and the reason for that was probably an] action by Greenpeace . . . ;" (b) Another victory, "last summer, Greenpeace confronted Novartis about the presence of bio-engineered ingredients in their Galactina line of baby food sold in Switzerland. As a result, Novartis removed many products lines from the Swiss grocery stores and made a promise to remove genetically modified ingredients from the Galactina foods."

87. Greenpeace, *supra* note 78. Greenpeace received great help from the scientific journal NATURE which published on October 7, 1999 an article indicating that the concept of "substantial equivalence" "lacks a usable definition."

88. Greenpeace, *OUT OF THE MAIZE*, (last visited Oct. 29, 1999) in <[www.greenpeace.org/report98/html/content/geneng.html](http://www.greenpeace.org/report98/html/content/geneng.html)>.

89. Kevin C. Kennedy, *The Illegality of Unilateral Trade Measures to Resolve Trade-Environment Disputes*, 22 WM. & MARY ENVTL. L. POL'Y REV. 375, 423 (1998).

Considering the important role reserved for IOs and NGOs, the conflicting position between the USA and EU, and the fact that the USA and the EU are great consumers of agricultural products, the question now is: what position should a producer (in this case a developing or an undeveloped country) adopt? The Brazilian Case commented upon below will give some hints about how these questions can be answered.

#### 4. Should Developing or Undeveloped Countries be Producers? (The Brazilian Case)

The Brazilian Case shows clearly what kind of pressure a country will encounter, and what kind of decision a country will need to take. Brazil is presently among the most important economies in the world, and its agricultural sector is responsible for 14% of its GDP.<sup>90</sup> The main agricultural products exported by Brazil are coffee, soybeans, and sugar cane.<sup>91</sup> Soybeans are responsible for US\$5 billion in export, and it is exported basically to Japan (US\$1.5 billion), and to EU (US\$2.5 billion).<sup>92</sup> Traditionally, the main commercial partners of Brazil are the EU and U.S.A.<sup>93</sup>

Environmental matters in Brazil are considered constitutional matters, and can be regulated not only by local government, but also by the federal government. In fact, the Brazil Constitution provides among other things that: (a) "Article 23. The Union, the states, the Federal District, and the municipalities, in common, have the power: . . . VI — to protect the environment and to fight pollution in any of its forms; VII — to preserve the forests, fauna and flora;" (b) "Article 24. The Union, the states and the federal District have the power to legislate concurrently on: . . . VI — . . . preservation of nature . . . protection of the environment . . . ;" and (c) "Article 225. . . § 1 . . . it is incumbent upon the Government to: . . . II — . . . preserve the diversity and integrity of the genetic patrimony of the country and to control entities engaged in research and manipulation of genetic material; . . . IV — demand, in the manner prescribed by law, for the installation of works and activities which may potentially cause significant degradation of the environment, a prior environmental impact study, which shall be made public; V —

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90. CIA, *The World Factbook 1999 — Brazil* (last visited Oct. 25, 1999) <[www.odci.gov/cia/publications/factbook/br.html](http://www.odci.gov/cia/publications/factbook/br.html)>.

91. THE WORLD ALMANAC AND BOOK OF FACTS 1999, World Almanac Books, New Jersey, 770 (1998).

92. O GLOBO ON, *supra* note 56.

93. THE WORLD ALMANAC AND BOOK OF FACTS 1999, *supra* note 89: "Imports (1996): \$53.3 bil; partners: EU 26%, U.S. 24%. Exports (1995) \$46.5 bil; partners: EU 28%, U.S. 17% . . . ."



control the production, sale and use of techniques, methods or substances which represent a risk to life, the quality of life and the environment; . . . VII — protect the fauna and the flora, with prohibition, in the manner prescribed by law, of all practices which represent a risk to their ecological functions, cause the extinction of species or subject animals to cruelty.”<sup>94</sup>

According to its Constitution and following international trends established by international Conventions, including the Convention on Biological Diversity,<sup>95</sup> Brazil has enacted two important laws relating to GMP: Law No. 8.974, de 05 de Janeiro de 1995, D.O. de 06/01/1995 [hereinafter Law 8974], and Law No. 9.456, de 25 de abril de 1997, D.O. de 28/04/1997 [hereinafter Law 9456], and these Laws in connection with the Law 6938, de 31 de agosto de 1981, DO de 02/09/98 [hereinafter Law 6938] establish the basic legal framework regulating this matter. Besides this basic legal framework, two others Laws should be mentioned here: the Law No. 7347, de 24 de julho de 1985, DO de 25/07/1985 [hereinafter Law 7347], and Law No. 8078, de 11 de setembro de 1990, DO de 12/09/1990 [hereinafter Law 8078]. But what are the objectives of each of these laws?

Law 6938 was enacted before the actual Brazilian Constitution, and through this Law the National Environmental Policy was established, electing CONAMA (Conselho Nacional de Meio Ambiente — National Council of Environment) as the Council responsible for passing rules and defining standards to be followed in terms of environmental quality control. Basically, the objective of this policy is to allow sustainable development, making compatible social and economic development with

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94. FEDERATIVE REPUBLIC OF BRAZIL CONSTITUTION — 1988, art. 225 § 1 (translated and revised by Istvan Vadja, Patricia de Queiroz Carvalho Zimbres and Vanira Tavares de Souza. Brasilia 1998) (II, IV, V, and VII).

95. Convention on Biological Diversity. Decreto No. 2519, de 16 de março de 1998, DO de 17/03/98.

Brazil also signed the following multilateral agreements related to the environment: Antarctic -Environment Protocol, Antarctic Treaty, Climate Change, Desertification, Endangered Species, Environmental Modification, Hazardous Wastes, Law of the Sea Marine Dumping, Nuclear Test Ban, Ozone Layer Protection, Ship Pollution, Tropical Timber 83, Tropical Timber 94, Wetlands, and Whaling. Brazil also signed some bilateral agreements concerning environmental matters, including: one with Uruguay (Decreto Legislativo No. 74, de 04 de maio de 1995, DO de 10/05/950) and another one with Mexico (Decreto No. 1575, de 31 de julho de 1995, DO de 01/08/1995)

Finally, the relationship between an international agreement and the Brazilian Constitution or a Brazilian Law can be summarized in the following way: an international agreement in Brazil is considered inferior to the Constitution, and on the same level as federal law. So, it can be modified both by the Constitution and by subsequent federal law; it can modify prior federal law, but it can never modify Constitutional provisions.

the preservation of environment, ecological equilibrium, and natural resources. Based on this Law, CONAMA passed two administrative acts: (a) Resolução No 001, de 23 de janeiro de 1986 [hereinafter RES001], which provides in its Article 2 that the authorization of activities able to provoke changes in the environment will be subject to a prior environmental impact study, including an environmental impact report; moreover, it also establishes, in Article 6, II, how the environmental impact study should be prepared; and (b) Resolução No 237, de 19 de dezembro de 1997 [hereinafter RES237] complementing and modifying RES001 in order to clearly impose, as a mandatory procedure, the need for prior licensing in case of the introduction of genetically modified species in the environment (Article 2 § 1, annex 1; and Article 3), moreover, this license would be dependent on both an environmental impact study and an environmental impact report.

Law 7347 regulates Civil Public Action (CPA). A CPA can be brought among other situations in case of damage caused to the environment or to consumers. According to this Law (Article 5, I and II), a CPA can be brought by Federal Union, by States, by Municipalities, by an autonomous government agency, by Public Prosecution, by Public Companies, by Foundations, by Mixed Capital Companies, or by Association. An Association will be considered legitimate if it is in existence for at least one year, and if its activities include the protection of the environment or consumers (e.g., in Brazil, IDEC<sup>96</sup> and Greenpeace<sup>97</sup> are nowadays legitimate organizations for bringing a CPA).

Law 8078 deals specifically with consumer protection, and among other rights, indicates as a basic right of consumers the right to be informed clearly and adequately about the specification, characteristics, composition, quality, price and risks of the products or services (Article 6, III, and Articles 9 and 31), and the right to choose (Article 6, II).

Law 8974 regulates Article 225, section I, II and V, of the Brazilian Constitution, and establishes rules to be observed when using genetic engineering in creating, manipulating, transporting, commercializing, consuming, liberating, and disposing of genetically modified organisms

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96. IDEC (Instituto de Defesa do Consumidor), Conheça o IDEC (last visited Oct. 27, 1999) <[www.uol.com.br/idec/oque.htm](http://www.uol.com.br/idec/oque.htm)>. IDEC is the most important non-profit consumer association in Brazil. It initiated its activities in 1987, and its goal is the protection and defense of consumers.

97. Greenpeace (Associação Civil Greenpeace) (last visited Oct. 27, 1999) <[www.greenpeace.org.br/vitorias/batalhas2.html](http://www.greenpeace.org.br/vitorias/batalhas2.html)>. Greenpeace is one of the most important environmental associations in the world, and it initiated its activities in Brazil in 1992.

in the environment. Basically, (a) this law regulates the environmental impact study and the environmental impact report; (b) this law allows the Executive Power to create a special commission (CTNBio) to be responsible, among other things, for establishing norms concerning the safety use of these techniques in Brazil, and determining if any specific use would be considered safe; (c) this law also establishes the competence of several federal agencies in dealing with this matter, stating, however, that all these agencies would observe the opinion of the CTNBio in the case.<sup>98</sup> On November 30, 1998, through an Executive Decree, Decreto Regulamentar No 1752, de 20 de dezembro de 1995, DO de 21/12/95 (hereinafter DR 1752), the Executive Power officially created the CTNBio, connected to the Executive Secretary of the Ministry of Science and Technology. Among other things, DR 1752 allows the President of CTNBio to decide when a prior environmental impact study or an environmental impact report would be necessary. The consequence of this innovation was to transform the constitutional requirement of prior environmental impact study (regulated by Article 225, section 1, IV of the Brazilian Constitution, and discussed earlier) into a discretionary requirement, in a procedure that is clearly unconstitutional.

Law 9456 regulates the intellectual property rights concerning a cultivated variety of a plant distinguished from other plants (also known as "cultivar"). The protection of intellectual property rights is done through a requirement in the SNPC (Serviço Nacional de Proteção aos Cultivares), an agency subordinated to the Ministry of Agriculture and Food Supply. According to this Law, the SNPC will grant an applicant, subject to the fulfillment of other legal requirements, a certificate ("Certificado de Proteção de Cultivar"), and this certificate would be not only proof that the applicant has intellectual property rights over the cultivar, but would also be proof that the applicant is the only one who

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98. Law No. 8974, de 05 de janeiro de 1995, D.O. de 28/04/97. Original text, in Portuguese, of the Caput and Law No. 8974, art. 7: "Regulamenta os incisos II e V do paragrafo 1 do art. 225 da Constituição Federal, estabelece normas para uso das técnicas de engenharia genética e liberação no meio ambiente de organismos geneticamente modificados, autoriza o Poder Executivo a criar, no âmbito da Presidência da República, a Comissão Técnica Nacional de Biossegurança, e dá outras providências. . . . Caberá, dentre outras atribuições, aos órgãos de fiscalização do Ministério da Saúde, do Ministério da Agricultura, do Abastecimento e da Reforma Agrária, e do Ministério do Meio Ambiente e da Amazonia Legal, dentro do campo de suas competências. Observado o parecer técnico conclusivo da CTNBio e os mecanismos estabelecidos na regulamentação desta Lei: . . . ." This Law (in article 14) also provides that those who causes damages to the environment and third parties will be responsible for repairing the damages or for paying compensation.

can produce, offer to sell, offer to commercially deal with, or authorize to produce/sell/commercially deal with the cultivar.<sup>99</sup>

The complexity of the matter, the ambiguity of the legislation concerning GMP, the power granted to the CTNBio, the posture assumed by CTNBio in solving the questions related to GMP (indicating the adoption of the “American posture” instead of the “European posture,” with a tendency to disregard the need for a prior environmental impact study), and finally, the failure of CTNBio to enact proper and specific legislation, created a perfect environment for legal disputes to arise. The first important dispute arose in 1997, and the second arose in 1998.

The first dispute arose in December 1997, when the Brazilian Vegetable Oil Producers Association, based on authorization from the CTNBio, imported US genetically modified soy. This shipment arrived in the port of San Francisco do Sul — in Santa Catarina, a state located in the South of Brazil. Activists from Greenpeace prevented the unloading,<sup>100</sup> and as a consequence ten activists were arrested by the Federal Police in Brazil the next day.<sup>101</sup> Following this action, Greenpeace brought a CPA (Process No. 1997.34.00.036170-4) against the Federal Union in the sixth Federal District Court, questioning the authorization granted by CTNBio and the importation of soy genetically engineered. Later, the Brazilian Vegetable Oil Producers Association and Monsanto do Brasil Ltda joined the action as defendants.<sup>102</sup>

The second dispute had its origin on June 15, 1998, when Monsanto initiated the process for the commercial exploitation in Brazil of the soy Roundup Ready (soy modified genetically for being tolerant to the pesticide glyphosate), applying for authorization from CTNBio.<sup>103</sup> On

99. Law No. 9456, de 25 de abril de 1997, D.O. de 28/04/97, arts. 2, 4 and 9.

100. *Greenpeace Hazard Patrol Blocks U.S. Genetic Soya Landing in Brazil*, (last visited Oct. 24, 1999) <[www.greenpeace.org/~geneng/](http://www.greenpeace.org/~geneng/)>.

101. *Greenpeace Activists Arrested by the Brazilian Federal Police*, (last visited Oct. 24, 1999) <[www.greenpeace.org/~geneng/](http://www.greenpeace.org/~geneng/)>.

102. *Seção Judiciária do Distrito Federal - Resultado de Pesquisa*, Process 1997.34.00.036170-4 (6<sup>th</sup> Federal District Court) (last visited Oct. 24, 1999) <[www.trf1.gov.br](http://www.trf1.gov.br)>. The action was brought on December 16, 1997 and there is no final decision in this case. However, an injunction was granted in July 1998 determining that CTNBio must instruct the importers about the obligation of labeling all foods in which the soy genetically engineered is used, and this decision was made based on the Law 8078. *Greenpeace Protesta Contra Plantio de Soja Transgêncica no Brasil*, (last visited Oct. 24, 1999) <[www.greenpeace.org.br](http://www.greenpeace.org.br)>.

103. *Greenpeace Lança Campanha Pública pela Transformação do Rio Grande do Sul em Estado Livre de Transgênicos*, (last visited Oct. 7, 1999) <[www.greenpeace.org.biblioteca/imprensa/tche.html](http://www.greenpeace.org.biblioteca/imprensa/tche.html)>. Why did Monsanto choose Brazil? Brazil as the main producer of soy in the world retain a strategic position: it would be more difficult for

December 30, 1998, CTNBio, through an internal act (Instrução Normativa No. 18, D.O. No. 250-E, de 30 de dezembro de 1998) [hereinafter IN 18], authorized the commercial exploitation by Monsanto do Brasil Ltda (the Brazilian subsidiary of U.S. Monsanto Co)<sup>104</sup> of the Soy Roundup Ready.<sup>105</sup> Following that, Monsanto applied and obtained, in accordance with Law 9456 (discussed earlier), the certificate (Certificado de Proteção de Cultivar) from the SNPC (Serviço Nacional de Proteção ao Cultivar), protecting in this way its intellectual property rights on the following GMP: M-SOY 6363 RR, M-SOY 7777RR, M-SOY 8080 RR, M-SOY 7979 RR and M-SOY 8888RR.

Following this administrative decision, on November 5, 1998, IDEC brought a preparatory action (Process No. 1998.34.00.027681-8) against the Federal Union in the Eleventh Federal District Court in São Paulo, intending to obtain an injunction in order to bar any exploitation of the Soy Roundup Ready until a proper regulation governing the matter was enacted, and until a proper environmental impact study was prepared. The action was based on the following arguments: (a) CTNBio did not regulate the matter, as determined by DR 1752; (b) CTNBio did not ask for a prior environmental impact study; and (c) in case of commercialization of GMP, even though labeling should have been mandatory, there was no regulation determining how it would be done.<sup>106</sup> A provisory injunction was granted and IDEC brought the main action (a CPA). Later, this case was removed to the Sixth Federal District Court, because of its similarity to the prior action brought by Greenpeace.<sup>107</sup> IBAMA<sup>108</sup> joined the action as an author, Greenpeace joined the action as an assistant of the authors, and Monsanto do Brasil S/A and Monsoy Ltda joined the action as defendants. Finally, on August 10, 1999, the Sixth Federal District Court (federal judge Antonio Souza Prudente) decided the case in favor of IDEC, confirming the provisory injunction granted, and transforming this provisory injunction into a definitive order, holding in summary that commercial exploitation of the

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Monsanto's soy harvested in the United States and Argentina to be commercialized in Europe if Brazil were harvesting plants not genetically modified.

104. THE WALL STREET JOURNAL INTERACTIVE EDITION, *Brazil's Monsanto Says Biotech Soy Intervention Overruled*, Dow Jones Newswires, March 26, 1999 (last visited Oct. 6, 1999) <data.Free.de/gen.free.de/genet/1999/Mar/msg00095.html>.

105. Instrução Normativa No. 18, (last visited Sept. 9, 1999) <www.mct.gov.br/ctnbiotec/InstNormativas/Instnormat18.htm>.

106. IDEC, *supra* note 58.

107. Seção Judiciária do Distrito Federal, *Resultado de Pesquisa*, Process 1998.34.00.02768-1 (6<sup>th</sup> Federal District Court) (last visited Oct. 24, 1999) <www.trf1.gov.br>.

108. IBAMA (Instituto Brasileiro do Meio Ambiente) is a federal agency created by the law 7735, de 22 de fevereiro de 1989. Available in < www.ibama.Gov.br/organiza.htm> and last visited on Oct. 27, 1999.

genetically modified soy "Roundup Ready" in Brazil by Monsanto must be subject to prior enactment of a proper and specific regulation concerning biosafety and labeling, and to the presentation of a prior environmental impact study.<sup>109</sup>

Both judicial questions are not yet resolved, and in sum: (a) the action brought by Greenpeace (CPA) and the actions brought by IDEC (preparatory action and CPA) are together in the same court (Sixth Federal District Court); (b) in the action brought by Greenpeace, a preliminary injunction was granted and this injunction is not yet confirmed; (c) in the action brought by IDEC, a preliminary injunction was granted and confirmed the preparatory action decided in favor of IDEC; and finally (d) concerning the main actions (CPAs) there is no decision as yet.

Three basic consequences arose from this judicial discussion: first, the SNPC obeyed the judicial decision in the case, suspending the effects of the registration by Monsanto of the following GMP: M-SOY 6363 RR, M-SOY 7777RR, M-SOY 8080 RR, M-SOY 7979 RR and M-SOY 8888RR.<sup>110</sup>

Second, this decision provoked a great debate in Brazil involving different areas of the government concerning not only GMP, but also related legislation, and the manner in which CTNBio conducted the process that led to importation of soy and the approval of the products by Monsanto;<sup>111</sup> so, and for example: (a) EMBRAPA, the leader in soy research in Brazil and linked to the Ministry of Agriculture and Food Supply,<sup>112</sup> was favorable to GMP;<sup>113</sup> (b) on the other hand, one specialist from FIOCRUZ,<sup>114</sup> Silvio Valle, said that "the ideal would be that Brazil

109. *Cópia da Sentença nos Autos da Ação Cautelar Inominada*, No. 1998.34.00.027681-8 (last visited Oct. 25, 1999) <[www.greenpeace.org.br/Biblioteca/relatorios/judicial.doc](http://www.greenpeace.org.br/Biblioteca/relatorios/judicial.doc)> visited on October 25, 1999. This decision is not final. In fact, Brazil presented an appeal on September 03, 1999, and this appeal has not yet been decided.

110. *Ministerio da Agricultura e do Abastecimento*, SNPC - Serviço Nacional de Proteção de Cultivares - Notícias - 23 de Agosto de 1999 (last visited Sept. 9, 1999) <[www.agricultura.gov.br/snpc/not1000.htm](http://www.agricultura.gov.br/snpc/not1000.htm)>.

111. O GLOBO ON, *supra* note 56. The original text in portuguese is: "O mais novo adversario da pressa nas decisões da CTNBio é o Ministro da Agricultura . . . ."

112. EMBRAPA "is a public company, linked to the Ministry of Agriculture and Food Supply, with private company characteristics. It researches products that form part of the Brazilian table: from bread to meat, from milk to beans." Available at <[www.embrapa.br/english/embrapa.htm](http://www.embrapa.br/english/embrapa.htm)> last visited on October 9, 1999.

113. O GLOBO ON, *supra* note 43

114. FIOCRUZ: "Oswald Cruz Foundation - FIOCRUZ, linked to the Brazilian Ministry of Health, develops actions in the area of science and technology in health . . . ." Available at <[www.fiocruz.br/ingles/index.html](http://www.fiocruz.br/ingles/index.html)> last visited on Oct 9, 1999.

create zones [based on ecological study] in order to allow the harvest of both soy [GMP and natural], being able to supply both markets;"<sup>115</sup> (c) following this idea, the most important agricultural states in Brazil affirmed that they will not allow the harvest of GMP in their territories;<sup>116</sup> (d) the new president of SBPC (Brazilian Society for Development of Science), Glaci Zancan recognizes that the technology of GMP is something that will be adopted now or later, although "there are a lot doubts that need to be clarified through research done in Brazil because plants react in different ways according to the environment."<sup>117</sup> As an immediate consequence of these discussions, on August 31, 1999 the new President of CTNBio indicated,<sup>118</sup> that the policy of CTNBio has not changed, and it has maintained its position in the matter in three ways: (a) making available its website articles and scientific studies in favor of the use of GMP;<sup>119</sup> (b) publishing a book on the subject;<sup>120</sup> and finally, organizing conferences about the subject.

Finally, issues concerning GMP were publicized in Brazil allowing the common people to be involved and informed about the matter. However, the involvement of the population is still low, and a recent survey supported by the newspaper "O GLOBO" concerning GMF showed that: 44% believe that GMF is not healthy, 38% had no opinion about the subject, and 18% considered GMF not harmful to health.<sup>121</sup>

115. O GLOBO ON, *supra* n 43. The original text in Portuguese is: "O especialista em biossegurança Silvio Valle, da Fiocruz, diz que o ideal seria que o Brasil fizesse um zoneamento ecológico para poder plantar soja transgenica e natural, atendendo assim a todos os mercados."

116. *Id.*

117. *Id.* The original text in Portuguese is: "Ainda há muitas duvidas que precisam ser esclarecidas com pesquisas. Mas pesquisas realizadas no Brasil porque as plantas reagem de formas diferentes de acordo com o meio ambiente."

118. Noticias do MCT - *Nomeada nova presidenta da CTNBio*, (last visited Sept. 9, 1999) <[www.mct.gov.br/sobre/noticias/31\\_08.htm](http://www.mct.gov.br/sobre/noticias/31_08.htm)>.

119. C&T Brasil, *Papers e Artigos*, (last visited Sept. 9, 1999) <[www.mct.gov.br/ctnbiotec/artigos.htm](http://www.mct.gov.br/ctnbiotec/artigos.htm)>. Here five articles are mentioned: including one article published by the new CTNBio's President; two articles published in THE FINANCIAL TIMES; one scientific study by the Royal Society in England; and the position of the head of the Ministry of Science and Technology when talking to Federal Deputies. All this material shows that the discussion about this subject has not been done in a rational manner; that the development of GMP is morally acceptable and essential for fighting poverty; that there is no safe food, and that the most important thing is having basic standards and requirements; that nowadays something around 80 to 90% of all soy oil is made using GMP; that the most important thing in this debate is the consent by the consumer, who has the right to choose.

120. C&T Brasil, *Publicações, Transgênicos*, (last visited Sep. 19, 1999) <[www.mct.gov.br/publi/transg.htm](http://www.mct.gov.br/publi/transg.htm)>. CTNBio indicates that although the book was sold out (more than 4,000 books were sold), it is still possible to have an online version of the book. The CTNBio indicates this matter now is "a bola da vez," an expression meaning basically that now everybody wants to talk about this, until another more important subject appears.

121. O GLOBO ON (last visited Sept. 20, 1999) <[www.oglobo.com.br](http://www.oglobo.com.br)>.

So, what are the lessons to be drawn from this case? In sum, the Brazilian Case showed five things: (a) in times of globalization, sometimes a country is only a strategic detail for a multinational company;<sup>122</sup> (b) the existence of legislation is almost meaningless if it is unclear or not consolidated, allowing the introduction of GMP without any prior local risk assessment of the impact of this new culture on the environment; (c) any possible decision against GMP taken by the country (label, moratorium, ban, stringent legislation based on health or environmental concerns) will be considered a restriction on free commerce, with possible consequences in terms of the GATT Agreement; (d) any decision in favor of GMP may create additional difficulties for the producer to sell his produce; and (e) there are good arguments on both sides, making the matters related to GMP highly polemic and undefined.

Then, should a developing or undeveloped country be a producer? Even though there is no standard answer to this question, the most appropriate answer seems to be: “No, at least not now!” The main support for this answer, considering all the uncertainties relating to the subject, is the precautionary principle<sup>123</sup> and the obligation of each state not to cause any environmental harm.

Now it is time to analyze international regulation on the subject, including the effects of the GATT Agreement.

### C. GMP AND INTERNATIONAL REGULATION

There is no specific international legislation concerning trade in GMP, despite all the discussions generated by this subject. The question is “why?” The reason is really simple; the most important economies are on completely different sides, and the efforts made by the Biosafety Working Group (including representatives of over 100 States) in negotiating a draft Protocol to the Convention on Biological Diversity is a good example of that. Since 1996, this Group, as explained by Paul Hagen “has attempted to negotiate a draft Protocol to the Convention on Biological Diversity . . . addressing risks relating to trade in genetically

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122. *Greenpeace Lança Campanha Publica pela Transformação do Rio Grande do Sul em Estado Livre de Transgênicos*, *supra* note 103.

123. Hunter, *supra* note 38: “the precautionary principle switches the burden of scientific proof necessary for triggering policy responses from those who support prohibiting or reducing a potentially offending activity to those who want to continue.”



modified organisms . . . the Cartagena Protocol on Biosafety,"<sup>124</sup> without final success.

The last round of the negotiations of this Protocol occurred in Austria in September 1999. In this round the parties did not reach an agreement on how to stipulate norms concerning the transport, handling, and use of GMP in a commercial way, and again the main reason for the failure was the resistance of the so-called Miami Group (EUA, Canada, Australia, Argentina, Chile, and Uruguay).<sup>125</sup> However, this round was not completely fruitless because: (a) a new meeting was scheduled for January 2000; and (b) the discussion concerning grains for food and feed is still open. Moreover, in a notice released by Greenpeace it was first made clear that "a significant development in Vienna was the firm resolve by the developing world to insist on their right to reject imports of GE commodities," and second that "genetic engineering is a new and untested technology which could have irreversible effects on the environment and requires a binding international agreement to give

124. PAUL E. HAGEN ET AL., *THE PROPOSED BIOSAFETY PROTOCOL TO THE CONVENTION ON BIOLOGICAL DIVERSITY*, at 143 (1999). Available in WESTLAW (SD66 ALI-ABA 139). The meeting happened in Cartagena in February 1999 (the Sixth Session). "The Biosafety Protocol negotiations represent the first attempt by governments of the world to agree upon a binding regime to address risks associated with biotechnology in a manner conducive to its productive development and use."

Moreover, "the Biodiversity Convention's *raison d'être* is habitat conservation and the equitable distribution of intellectual property rights flowing from biotechnology." Kevin C. Kennedy, *The Illegality of Unilateral Trade Measures to Resolve Trade-Environment Disputes*, 22 WM. & MARY ENVTL. L. POL'Y REV. 375, 389 (1998).

125. WTO – US and Canada Continue to Obstruct Progress: Biosafety Talks Tiptoe Forward but Close Without Result, 20 September 1999, (last visited Oct. 10, 1999) <[www.wto.org/wto/new/press140.htm](http://www.wto.org/wto/new/press140.htm)>: Vienna -- The UN sponsored talks to set international rules on genetically engineered organisms (GMOs) closed in Vienna late Sunday night after taking some small steps forward. "The political commitment to the Protocol by all countries was reinforced, which is vital," said Louise Gale, the head of the Greenpeace delegation in Vienna. "Given the collapse of the negotiations in Cartagena, the decision to finally agree and sign the Biosafety Protocol in January 2000 is promising. But major issues such as how the Protocol will deal with grains meant for food and feed (i.e. commodities) are still open to question," said Gale. The major grain exporting countries, the US, Canada, Argentina, Australia, Chile and Uruguay have resisted including commodities in the Protocol throughout the negotiations. A significant development in Vienna was the firm resolve by the developing world to insist on their right to reject imports of GE commodities. The Ethiopian delegate, Dr. Egziabher, crystallized their concern on Sunday when he said, "For us the right to say no is a matter of our survival." Grain exporters would prefer to have all GMO decisions treated as trade disputes by the World Trade Organization (WTO). "The great majority of the countries in Vienna rejected the demands made by a small minority of six countries," said Gale. "Genetic engineering is a new and untested technology which could have irreversible effects on the environment and requires a binding international agreement to give countries the right to protect their biodiversity. It is clear that the WTO is the wrong forum for GMOs."

Moreover, according to Greenpeace (Austria Protocol, *Greenpeace faz Protesto em Abertura de Reuniao da ONU sobre Biossegurança*, (last visited Oct. 7, 1999) <[www.greenpeace.org.br/biblioteca/imprensa/austriaprotocol.html](http://www.greenpeace.org.br/biblioteca/imprensa/austriaprotocol.html)>): "The Miami group consists of 6 major agricultural exporting countries."

countries the right to protect their biodiversity [and] it is clear that the WTO is the wrong forum for GMOs.”<sup>126</sup>

In addition to the States having such different positions, Greenpeace added more elements to this discussion, demanding among other things that: “(a) The precautionary principle must be the overriding objective and basis for all decision-making under the Biosafety Protocol. Countries must be given international rights to ban or restrict the import and use of GMOs [genetically modified organisms, and here plants are included] and products thereof as precautionary measures. (b) Countries must be provided international rights to give their advance informed agreement for all GMOs and products thereof prior to all transboundary movements. (c) The Biosafety Protocol must contain an international regime for liability and redress. (d) Countries must have the right under the Biosafety Protocol to require labeling and traceability of GMOs and products thereof for biosafety purposes. (e) The Biosafety Protocol must not be subordinate to other international agreements such as the World Trade Organization rules. (f) The Biosafety Protocol must prevent all releases of living modified organisms or products thereof into centres of genetic diversity and centres of origin. [and] (g) Trade with non-Parties to the Biosafety Protocol can only be permitted if it is on more environmentally stringent terms than those set out in the Protocol.”<sup>127</sup>

Despite all these difficulties, the final round of negotiations will happen in Montreal from January 20-28, 2000.<sup>128</sup> However, the Protocol, if signed, may have its efficacy affected by the fact that, the United States is not a party to the Convention on Biological Diversity and therefore cannot be party to the Protocol until it ratifies the Convention.<sup>129</sup>

126. *Id.* “The political commitment to the Protocol by all countries was reinforced, which is vital,” said Louise Gale, the head of the Greenpeace delegation in Vienna. “Given the collapse of the negotiations in Cartagena, the decision to finally agree and sign the Biosafety Protocol in January 2000 is promising. But major issues such as how the Protocol will deal with grains meant for food and feed (i.e. commodities) are still open to question,” said Gale. The major grain exporting countries, the US, Canada, Argentina, Australia, Chile and Uruguay have resisted including commodities in the Protocol throughout the negotiations.”

127. *X Negotiations for a Biosafety Protocol Proceed - Greenpeace Urges Government to Adopt Strong Standard*, Vienna, Sept. 15, 1999 (last visited Oct. 9, 1999) <[www.greenpeace.org/~geneng/](http://www.greenpeace.org/~geneng/)>.

128. *X Final Day of the Informal Negotiations for Biosafety Protocol in Vienna*, 19 Sept. 1999 (last visited Oct. 9, 1999) <[www.Greenpeace.org/~geneng/](http://www.Greenpeace.org/~geneng/)>.

129. Hagen, *supra* note 124 at 163: “the United States, the world leader in Biotechnology is not a party to the [Convention on Biological Diversity] (CBD) and, therefore, cannot become a Party to the Protocol (unless it first ratifies the CBD), makes the dynamic all the more complex and volatile. . . [moreover] it is not clear whether such an agreement could survive a challenge at the WTO should it significantly impair the trading rights of the United States as a non-party.”

In the absence of an international agreement specifically regulating the issue, what can the states do? Each State according to its own level of technology and respecting consumers' rights has been adopting its own solution. Basically, the countries have been adopting the following ways of protection: (a) ban or unilateral "de facto" moratorium; (b) internal legislation regulating approval and commercialization, imposing basic standards and/or mandatory labeling; and/or (c) external action asking for international regulation or an international moratorium on these products based on the need to protect not only the health of the population but also of the environment.

Only the first two ways of protection will be commented on here, because these two ways create a natural barrier impeding, or making more difficult, the free international commerce of these products, and as a consequence discussions may arise concerning the legality of such action in terms of the WTO/GATT Agreement.

#### 1. Ban or Unilateral "De Facto" Moratorium

Ban, moratorium, and "de facto" moratorium are different concepts even though they have an equal effect of disrupting the free trade of goods. The consequences concerning the GATT/WTO will be commented on later, and here I will be assessing only how they differ from each other, with some examples.

A ban is a direct act prohibiting the commerce of some product in one country or among contracting parties to some international agreement (such as the EU). An example of a ban is the prohibition by EU (since 1985) of commercialization of beef produced with synthetic hormones.<sup>130</sup> Another example was when France, Luxembourg and Austria banned the cultivation of Bt corn.<sup>131</sup>

A moratorium, on the other hand, is an act determining that something will be done later. It will be unilateral when determined by only one party, and it will be "de facto" when, even though there is no formal act declaring the moratorium, a country or institution delays or postpones some action. An example here is the "delay" by EU in approving some

130. The United States Mission to the European Union, *USTR Press Release on WTO Arbitration in Hormone Beef Case*, (last visited Nov. 2, 1999) <[www.useu.be/issues/beef0713.html](http://www.useu.be/issues/beef0713.html)>.

131. Dunn, *supra* note 1 at 153-154: "France, Luxembourg and Austria, despite the approval by the European Commission, banned the cultivation of Bt corn, based on an "EC Directive that allows member states to ban GMOs to protect the environment or for health reasons."

GMO products from EUA.<sup>132</sup> The point is that when a moratorium lasts for a long time, it may have the same effect as a ban.

Another option for states is the adoption of a process of standardization and/or the institution of label requirements.

## 2. Basic Standards and Labeling

Basic standards and labeling are also different concepts, and both can be established by a local or international regulation. When a standard or a labeling requirement is established by an international agreement it has the effect of making the market more predictable having, then, the effect of facilitating commerce among countries.<sup>133</sup> The problem arises when a country unilaterally establishes standards or labels requirements, and when this happens there is a real probability of impairment of commerce.

Basic standards, simply indicates the minimum requirement for a product being commercialized in a specific geographical area, such as health standards for food or national standards for electrical appliances.<sup>134</sup> In terms of international basic standards on food, the Codex Alimentarius reigns absolute, being also recognized by the WTO/GATT as an international standard;<sup>135</sup> in terms of local or regional standards, an example is the proposal of EU to stipulate the maximum level of genetically modified material to be accepted into foods by accident.<sup>136</sup>

Labels, on the other hand, do not impose any internal requirement on the product. They only impose an external requirement in terms of information: some information about the product must be attached to the

132. The United States Mission to the European Union. Glickman on Hormone Beef and Biotechnology, *supra* note 53: "For 1998 44% of our [USA] soybeans and 36% of our [USA] corn are produced from genetically modified seeds. While only a few varieties of GMO products have been approved for sale and use in Europe, many more have been put on hold by a de facto European moratorium on new GMO products."

133. RICHARD SCHAFFER ET AL., INTERNATIONAL BUSINESS LAW AND ITS ENVIRONMENT, West Educational Publishing Company, 383 (4<sup>th</sup> ed. 1998): "The GATT 1994 Agreement on Technical Barriers to Trade . . . The Agreement recommends that countries develop and use internationally accepted standards where they exist. International standards will be presumed to be in compliance with GATT." The same author, on pages 383 and 385, mentions the International Organization for Standardization as the most important source of international standards, and delineates ISO 9000 as the most common international standard.

134. *Id.*, at 323.

135. *Understanding the Codex Alimentarius - Codex and the Future* (last visited Nov. 4, 1999) <[www.fao.org/docrep/w9114e/W9114e09.htm](http://www.fao.org/docrep/w9114e/W9114e09.htm)>. For more detailed explanation about this Code, see generally *supra* note 70.

136. The United States Mission to the European Union, *EU Committee Accepts two Labeling Proposals for Biotech Food* (last visited Nov. 2, 1999) <[www.useu.br/eugmo1026.html](http://www.useu.br/eugmo1026.html)>.

product. So, labeling has three basic functions: (a) it informs the consumer that some product is more or less dangerous to the consumer's health (making consumers more aware of the risks of the product),<sup>137</sup> or to the environment (e.g., the voluntary European Eco-Label);<sup>138</sup> (b) it protects consumers through a clear and honest exposure to the existing risks relating to the product; and (c) it allows consumers to make intentional choices, so if a similar product exists (in terms of characteristics, performance, taste, price and so on) it will enable the consumer to choose among them or opt for a substitute product.

Labeling is another area in which the USA and EU diverge: while EU has a mandatory scheme of labeling for foods containing genetically modified ingredients, and is intending to widen the scope of such labeling,<sup>139</sup> the USA does not require such labeling.<sup>140</sup>

But why do labels provoke so many fears among producers? There are two basic reasons: (a) first, if a label is mandatory, it would mean a loss of market, especially in a very educated consumer market (as in Europe, for example); and (b) second, labeling can be used as an instrument for making companies change procedures.<sup>141</sup> As a matter of fact, labeling is

137. Whittaker, *supra* note 32 at 1223: "labeling genetically engineered foods is required to alert consumers to the presence of such foods in their diet."

138. *The European Union Eco-Label*, (last visited Nov. 2, 1999) <europa.Eu.in/comm/dg11/ecolabel/index.htm>: "The European Eco-Label Scheme . . . is a major step forward in the co-ordination of actions to promote environmentally friendly consumption. It enables European consumers to easily identify officially approved green products across the European Union, Norway, Liechtenstein and Iceland. It allows manufactures to show and communicate to their customers that their products respect the environment."

139. The United States Mission to the European Union, *supra* note 53: "The European Commission is expected to adopt by the end of the year two measures concerning the labeling of bio-engineered food . . . the second measure concerns the labeling of foods containing additives and flavorings produced from genetically modified material. While existing laws already include safety requirements for additives and flavorings, the EU said the proposed regulation would ensure that these foods are labeled in the same way as foods containing other genetically modified ingredients."

140. *Id.* As Alan Larson, Assistant Secretary of State for Economic and Business Affairs, explains, the USA is "not convinced that it makes sense to engage in labeling when a product has no nutritional difference from other products or when it doesn't contain any type of allergens tat might cause people to have an allergic reaction . . . . We have no objection if a producer wishes to advertise a product and in labeling it or advertising it draws attention to characteristics that the producer thinks are important."

141. Atsuko Okubo, *Environmental Labeling Programs and the GATT/WTO Regime*, 11 GEO. INT'L ENVTL. L. REV. 599, 602 n.3 (1999). With respect to environmental labels, for example, Atsuko Okubo explains that: "because an environmental label is a market-oriented instrument, the underlying premise of a labeling program is that the strong environmental values of consumers can be used as a market force to leverage environmental improvement . . . . Labeling schemes will be successful if producers' response to the public pressure induced by the labeling schemes is significant enough to change their management procedures."

a powerful weapon for NGOs and other organized groups defending consumers and the environment.

Just because of that, labeling has slowly assumed a very important role in the commerce of GMOs, including GMP, and the following examples demonstrate it: (a) the Codex Alimentarium Commission, as stated by Judith Beach “has issued draft recommendations for changes to the labeling of foods obtained through biotechnology”;<sup>142</sup> (b) in the European Union, and according to a EU release “foods and food ingredients produced from GMOs have to be labeled according to Regulation (EC) No 258/97 (Novel Foods Regulations) and Regulation (EC) Number 1139/98 (labeling of two particular GM soya and maize products). This means that they have to be labeled when they contain protein or DNA resulting from genetic modification.”<sup>143</sup> Terence Stuart and David Johanson, however, emphasize that “the regulation does not provide for the “may contain” labeling option for products for which it is not possible to determine whether they contain the relevant GMOs”;<sup>144</sup> and (c) the matter of eco-labeling today has also been discussed in the WTO/GATT.<sup>145</sup>

The question now is: do these possible measures (ban, moratorium, de facto moratorium, basic standards and labeling) fit into the WTO/GATT scheme?

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142. Beach, *supra* note 50, at 188.

143. The United States Mission to the European Union, *supra* note 53.

144. Stuart, *supra* note 51, at 243.

145. *Eco-Labeling*, (last visited Oct. 10, 1999) <[www.wto.org/wto/envIRON/eco.htm](http://www.wto.org/wto/envIRON/eco.htm)>. “Eco-labeling programmes are important environmental policy instruments. Eco-labeling was discussed extensively in the GATT, and that laid the basis in the CTE for a detailed examination of the issues involved. The key requirement from the WTO’s point of view is that environmental measures that incorporate trade provisions or that affect trade significantly do not discriminate between home-produced goods and imports, nor between imports from or exports to different trading partners. Non-discrimination is the cornerstone of secure and predictable market access and undistorted competition: it guarantees consumer choice and it gives producers access to the full range of market opportunities. Subject to that requirement being met, WTO rules place essentially no constraints on the policy choices available to a country to protect its own environment against damage either from domestic production or from the consumption of domestically produced or imported products.

The CTE Report states that well-designed eco-labeling programmes can be effective instruments of environmental policy. It notes that in certain cases they have raised significant concerns about their possible trade effects. An important starting point for addressing some of those trade concerns is by ensuring adequate transparency in their preparation, adoption and application, including affording opportunities for participation in their preparation by interested parties from other countries. Further discussion is needed on how the use in eco-labeling programmes of criteria based on non-product-related processes and production methods should be treated under the rules of the WTO Agreement on Technical Barriers to Trade.”

## D. EFFECT OF THE RULES OF WTO/GATT

The basic problem to be solved here is whether a ban, a moratorium, a "de facto" moratorium, and the imposition of basic standards or a label constitutes a violation of any WTO/GATT provision. Two initial questions must be answered: (a) why is it important to know if there is a violation of any provision of WTO/GATT? And (b) what are the basic provisions of WTO/GATT?

Currently 135 countries are members of WTO/GATT.<sup>146</sup> The WTO/GATT scheme provides an effective way for solving conflicts in case of violation of any WTO/GATT provisions, and it is effective for four reasons: (1) Even though a member state can "block" or veto a panel decision, it does not happen very often, because, as explained by Richard Schaffer "they did not want to undermine a process for resolving disputes that they might want to use in the future. Furthermore, GATT/WTO panel decisions do carry the voice of world opinion and serve as an international conscience for determining which trade practices are acceptable and which are not";<sup>147</sup> (2) If a party does not "block" or veto, the party must comply with the decision, and if the party does not comply, the other party may negotiate for compensation (Art 22.2). If there is no agreement on compensation, the Dispute Settlement Body authorizes retaliation while pending full implementation (Art 22.2 and 22.6), and this retaliation will be done considering products from the same sector, or products from different sectors, or finally any other international agreement in existence (Art. 22.3);<sup>148</sup> (3) The WTO/GATT sets the basic rules concerning trade, and the violation of these rules may not only subject the violator to penalties under the WTO/GATT scheme but also may subject the violator to other unilateral economic sanctions, such as the retaliatory measures provided by U.S. Section 301 (including the Basic Section 301, the Special 301, the Telecommunications 301, and the Super 301);<sup>149</sup> (4) Finally, as explained by Atsuko Okubo, "in the event of a conflict between the WTO Agreement and any of the

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146. WHAT'S NEW, *Estonia to Become 135<sup>th</sup> Member of WTO*, Press Release (last visited Nov. 4, 1999) <[www.wto.org/wto/new/pressest.htm](http://www.wto.org/wto/new/pressest.htm)>. Moreover, 30 governments have applied to join the WTO, and their applications are still being considered. It is an impressive number considering that the United Nations nowadays has 185 members.

147. SCHAFFER, ET AL., *supra* note 133, at 331.

148. *Settling Disputes* (last visited Oct. 10, 1999) <[www.wto.org/wto/about/disoute.2.htm](http://www.wto.org/wto/about/disoute.2.htm)>.

149. SCHAFFER ET AL., *supra* note 133, at 398-401.

multilateral trade agreements annexed to it, the WTO Agreement prevails.”<sup>150</sup>

If it is important to comply with the rules of the WTO/GATT scheme, it is necessary to identify the basic rules which can be summarized as follows: (a) According to Michael Trebilcock, GATT/WTO “commits member countries . . . to enter into ‘reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discretionary treatment in international commerce’”;<sup>151</sup> (b) The WTO/GATT scheme is supported by three basic concepts:

- (1) the principle of non-discrimination, including the most favored nation principle (MFN);
- (2) the principle of national treatment; and
- (3) the elimination of quotas and any other non-tariff barriers.

However, the GATT/WTO scheme realizes that in some specific and special situations these concepts may be disregarded. According to Michael Trebilcock, this can happen when these barriers or quantitative restrictions are imposed in order to protect “domestic supply management or agricultural marketing . . . [or] if a country is facing serious balance of payment problems . . . ,”<sup>152</sup> moreover, they will be also allowed when, and now according to Atsuko Okubo, they are “necessary to protect human, animal or plant life or health” (Article XX(b)), or [they are related] “to the conservation of exhaustible natural sources if such measures are made effective in conjunction with restrictions on domestic production or consumption (Article XX (g)).”<sup>153</sup> Richard Schaffer summarizes these exceptions in the following way: the restriction will be legitimate when present in one of the following legitimate objectives: “national security, preventing fraud or deception of consumers, protecting public health or safety, or protecting the environment.”<sup>154</sup> (c) Even though some restrictions may be accepted, these restrictions may be considered as violations of the WTO/GATT scheme if they violate the principle of least-restrictive trade, The meaning of this principle has been

150. Okubo, *supra* note 141, at 603, 616.

151. MICHAEL J TREBILCOCK AND ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE*, Routledge: London, 25 (1995).

152. *Id.*, at.30.

153. Atsuko Okubo, *supra* note 141, at 603,618.

154. SCHAFFER ET AL., *supra* note 133, at 383.



explained by Richard Scheffer, who states that "a country in setting otherwise valid restriction on trade . . . shall make them no more restrictive than necessary to achieve the goals for which they were imposed."<sup>155</sup>

The final comment here is that a very interesting phenomenon has happened concerning WTO/GATT and the environment. WTO/GATT has been recognizing (very slowly) the importance of environmental considerations in worldwide trade, and this started in 1994 with the inclusion in the WTO/GATT scheme of four agreements on environmental issues: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement), Agreement on Agriculture, and the Agreement on Subsidies and Countervailing Measures (SCM Agreement).<sup>156</sup> Following this trend, nowadays WTO/GATT is considering environmental issues as an important element in international trade, and WTO/GATT has recently made it clear when released a press statement stating that: "a new WTO Secretariat report argues that international economic integration and growth reinforce the need for sound environmental policies at the national and international level. International cooperation is particularly important in addressing transboundary and global environmental challenges beyond the control of any individual nation. This would be true even if nations did not trade with one another."<sup>157</sup> Moreover, WTO/GATT is also considering that its

155. *Id.* at 383.

156. Kennedy, *supra* 89. "The SPS Agreement applies to all sanitary and phytosanitary measures that may, directly or indirectly, affect international trade . . . [and] expressly recognizes that Members have a legitimate right to protect human, animal, plant life and health, and to establish a level of protection for life and health that they deem appropriate . . . . The SPS Agreement requires Members to harmonize their SPS measures adopting international standards where such standard exist . . . . The most important[bodies developing such guidelines] are (1) the Codex Alimentarius Commission; (2) International Office of Epizootics . . . and (3) the Secretariat of International Plant Protection Convention (IPPC) [p.397-400]. The TBT Agreement does not establish or prescribe standards, technical regulations, or conformity assessment procedures. Rather, it establishes general procedural requirements to be observed when adopting or using such measures so they do not create unnecessary obstacles to trade . . . . Members are encouraged to base their technical regulations on international standards where they exists . . . [and] the leading international body involved in the drafting and promulgation of international technical standards is the International Standards Organization (ISO)[p. 408,412]. The SCM Agreement . . . authorizes transitional assistance to firms for pollution abatement expenditures . . . which makes environmental subsidies non-actionable, provided narrowly drawn criteria are met [p. 417] . . . . The Agreement on Agriculture . . . under the Agreement on Agriculture, developed-country Members agree to reduce their domestic agricultural subsidies twenty percent from 1986-88 base period levels by 2000 . . . expressly excluded are payments received under environmental programs [p.418]."

157. Press Release, *Trade Liberalization Reinforces the Need for Environmental Cooperation*, 8 October 1999 (last visited Oct. 10, 1999) <[www.wto.org/wto/new/press140.htm](http://www.wto.org/wto/new/press140.htm)>. "The WTO Secretariat's Trade and Environment Report, to be released on 14 October 1999, addresses the economic and political economy dimensions of the interface between trade and environment. The report

cooperative model, "based on legal rights and obligations, could potentially serve as a model for a new global architecture of environmental cooperation."<sup>158</sup>

It is time now to analyze the measures of ban, moratorium, "de facto" moratorium, establishment of basic standards, and labeling in the light of the WTO/GATT scheme. Do they fit into the WTO/GATT scheme? The answer is that all these measures represent an impairment of free trade; so they are considered "*ab initio*" a violation of the WTO/GATT scheme.

A country, or any other international entity, in adopting any of these measures should do it based on one or more allowed exceptions; moreover, the country needs to make sure first that there was no other less restrictive measure to be adopted, and second that there was a real reason for adopting the measure. The burden of proof will be on the country adopting the measure, and in the case of a measure adopted in order to protect human, animal or plant life or health this measure must be based on "sufficient scientific evidence."<sup>159</sup> When adopting measures related to technical barriers to trade (e.g., basic standards and labels) the evaluation of the risks justifying the measure must be done based on "available scientific and technical information, related processing

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argues that there is no basis for the sweeping generalizations that are often heard in the public debate, arguing that trade is either good for the environment, or bad for the environment. The real world linkages are a little bit of both, or a shade of gray. 'Win-win' outcomes can be assured through well designed policies in both the trade and environmental fields."

This is a new position adopted by GATT. It is important to note that Kevin C. Kennedy, in 1998 wrote that: "GATT-WTO system [and NAFTA] are viewed as at best indifferent to legitimate environmental concerns and at worst hostile to them. [Moreover, it is also important to mention] "that GATT has few friends among environmentalists, who vilify GATT and have made it their bete noire. [and one reason for that] "was the 1991 GATT panel report in the Tuna/Dolphin dispute between Mexico and the United States." [another "conflict" between GATT and environmentalist, happened when] "1992 GATT Report on Trade and Environment was published, which concluded that trade restrictions used for environmental purposes are likely to be counterproductive because they reduce world prosperity." [However, at the end, the Author concludes that] In short, instead of viewing free trade and environmental protection as mutually reinforcing, environmentalists' working premise is that the GATT-WTO system is an obstacle to environmental protection. Short of a no-growth economic stance, this is a false premise. The GATT-WTO system and free trade are not environmental villains." See, Kevin C. Kennedy, *The Illegality of Unilateral Trade Measures to Resolve Trade-Environment Disputes*, 22 WM. & MARY ENVTL. L. POL'Y REV. 375-377, 394-505 (1998).

158. *Id.*

159. SCHAFFER ET AL., *supra* note 133, at 777. Article 2.2 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

technology or intended end-uses of products.”<sup>160</sup> Scientific evidence as such has played an essential role in the adoption of restrictive measures.

But how does it work in a practical sense? Two examples illustrate the application of these rules from WTO/GATT. The first example concerns labeling, and the issue is to consider if the label results “in discrimination against foreign producers and acts as a non-tariff barrier to trade.”<sup>161</sup> If it happens, and if it is not protected by any other possible exception, the labeling will be against the WTO/GATT rules. One instance is the Tuna/Dolphin case, where the GATT upheld the labeling provisions in the Marine Mammal Protection Act (an American act enacted in 1972) on the grounds that “they applied equally to all nations fishing for tuna and did not restrict the sale of tuna products.”<sup>162</sup>

The second example concerns a ban of a product, in this case beef produced by the USA. In 1985, the EU prohibited the importation of animals or their meat if they were treated with synthetic hormones for growth. On August 18, 1997, the WTO panel found that this ban was not based on “scientific evidence, a risk assessment, or relevant international standards, in contravention of the EU’s obligations under SPS

160. SCHAFFER ET AL., *supra* note 133, at 778. Article 2.2 of the Agreement on Technical Barriers to Trade.

161. Okubo, *supra* note 141, at 603, 610.

162. David Hunter et al, *supra* note 32. *The Tuna/Dolphin Case* (a dispute between Mexico and the USA) is an excellent example of how an extraterritorial application of a domestic law can drive the creation of binding international law. This case can be summarized in the following way: In the eastern tropical Pacific Ocean (ETP) yellowfin tuna tend to swim beneath certain species of dolphin. As a consequence, dolphins were a bycatch during the fishing for yellowfin tuna. The U.S fleet dominated the tuna fishing in the ETP and was responsible for more than 80% of the dolphins’ death. It led to the passage of the *Marine Mammal Protection Act (MMPA) in 1972*, imposing a reduction in the killing or incidental serious injury of marine mammals to insignificant levels approaching a zero mortality and serious injury rate. It was implemented through a General Permit and Observers placed on fishing vessels. This Act was Amended in 1981 (to define zero mortality); in 1984 (to impose trade restrictions banning importation of tuna into the US unless each nation exporting tuna adopted a dolphin protection comparable to the protection adopted by the US); and in 1988 (to impose trade restrictions on intermediary nations exporting tuna to the US). In 1990 Congress passed the *Dolphin Protection Consumer Information Act of 1990 (DPCIA)*, requiring that all tuna caught in the ETP and labeled “dolphin safe” must have been caught by a vessel too small to deploy its nets on dolphins, or have a certification from a qualified observer, or which did not harvest using a large-scale driftnet. Despite complaints that US actions violated GATT and illegitimately restricted activities by sovereign nations, today dolphin mortality from the tuna fishery in the ETP has been reduced to 1% of its previous level. Therefore, GATT: (a) found that the MMPA import ban constitutes both quantitative restriction and illegitimately regulated the method by which the tuna was caught (p.1029); (b) upheld labeling provisions because applied equally to all nations (p.1029); (c) found that a secondary embargo on intermediary markets also violated the GATT (p.1029). In response to this action by the US, the Inter-American Tropical Tuna Commission (IATTC) adopted the La Jolla Agreement (p.1030), a non-binding multilateral program designed to reduce dolphin mortality in the ETP over a seven-year period to levels approaching zero, while maintaining the present maximum tuna yield.

Agreement.”<sup>163</sup> This decision was confirmed by the Appellate Body, and then adopted by the Dispute Settlement Body. Because EU failed to observe this decision in time it was determined that the EU had to make a payment of \$116.8 million to the USA as compensation for damages.<sup>164</sup> On July 29, 1999 USA started to collect it through a special tariff.<sup>165</sup>

After seeing the situations in which a ban, a moratorium, a “de facto” moratorium, and the imposition of basic standards or a labeling will constitute violation of any WTO/GATT provisions; after seeing that the burden of proof is on the entity taking any one of these restrictive measures; and finally, after seeing that the proof in WTO/GATT is basically a scientific proof; it is now time to go to the conclusion and then pose the final question: is there a need for an international regulation?

### III. CONCLUSION

As seen in the earlier sections, there is no specific international regulation concerning GMP; moreover: (a) there is great pressure from multinational companies to commercialize new GMP; (b) there is great pressure from countries where GMP has been harvested to make GMP accepted worldwide; (c) usually developing or less developed countries do not have proper legislation concerning GMP, and when they have such legislation, they have less bargaining or economic power to enforce it; (d) the possible measures to be adopted by countries not willing to accept GMP (e.g. ban, moratorium, “de facto” moratorium, basic standard, label) are “prima facie” against the provisions of the WTO/GATT scheme; (e) there is no consensus regarding answers to the questions concerning the safety of GMP, in terms of environment or human health; and finally, (f) the provisions of the WTO/GATT scheme imposing the burden of scientific proof on the country establishing the restrictive measure concerning GMP are absolutely in conflict with the precautionary principle.

Considering the preceding facts, it is now time to attempt to answer the question: whether there is a need for an international regulation.

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163. The United States Mission to the European Union, *supra* note 132.

164. The United States Mission to the European Union, USTR Fact Sheet on Dispute with EU over Beef Hormones (last visited Oct. 2, 1999) <[www.useu.be/issues/hormone0713.html](http://www.useu.be/issues/hormone0713.html)>.

165. Final Product List in Beef Hormone Dispute (last visited Oct. 2, 1999) <[www.ustr.gov/releases/1999/07/99-60.html](http://www.ustr.gov/releases/1999/07/99-60.html)>.

The answer is in the affirmative. There is a clear need for an international regulation on GMP because: (a) the lack of clear legislation has been creating uncertainty in terms of safety and international trade; (b) the lack of clear legislation has been making it more difficult to perceive when a country is violating the principle of state responsibility, just because its obligations under international law are not clear (e.g., some actions or measures taken by an isolated state in order to protect its environment or the health of its population may violate some other international agreement); (c) the lack of clear legislation makes it more difficult for a country to observe its duty to assess environmental impacts, just because scientific findings are not absolutely conclusive in this matter, creating the possibility of discussion under WTO/GATT (e.g., the Monarch Butterfly Case<sup>166</sup>); (d) the lack of clear legislation on the other hand makes it more difficult to identify when a country is violating its obligation not to cause environmental harm; (e) the lack of specific international legislation has been causing the impairment of commerce, and one of the consequences here may be the limitation on research and development of new biotech products; and finally, (f) the lack of specific international regulation has been creating a tension between international trade law and international environmental law.

If there is a need for international regulation, the question now is: what kind of legislation? Should this legislation come as a chapter or appendix to any other international regulation already in existence (e.g., Biological Diversity, WTO/GATT) or should it constitute a new and independent agreement?

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166. Prepared Statement of Ambassador David L. Aaron Under Secretary for International Trade, U.S. Department of Commerce, June 15, 1999 (last visited Oct. 2, 1999) <[www.ogc.doc.gov/ogc/legreg/testmon/106f/aaron0615.htm](http://www.ogc.doc.gov/ogc/legreg/testmon/106f/aaron0615.htm)>. "Four varieties of U.S. developed "Bt", or pest-resistant corn, have been in the EU approval process for over two years. The Commission has not approved any biotech products in a year and it recently announced that it was postponing the approval of Pioneer's Bt corn application because of recent findings on the effects of GMO corn on the U.S. monarch butterfly population." These findings resulted from a study by Cornell University, and they are available at <[www.greenpeace.org/~geneng/reports/gmo/gmo011.htm](http://www.greenpeace.org/~geneng/reports/gmo/gmo011.htm)>.

Immediately after the publication of these findings, a "consortium of biotechnology and pesticide companies quickly provided funds for several studies to qualify the risk posed by the genetically engineered, pest-resistant species known as Bt corn [and the results, presented on November 2, 1999 in a scientific symposium in Chicago, USA, showed that] Genetically engineered corn plants appear to pose only a modest threat to monarch butterflies . . . ." See, *Gene-Spliced Corn no Big Threat to Butterflies, Studies Say*, S.F. CHRON. (East Bay Edition), Nov. 3, 1999, A11. So, the questions here are: will new studies have a different conclusion? Can a scientific study be considered a conclusive proof? If there is uncertainty in terms of science, why not apply the precautionary principle?

This legislation should be in the form of a multilateral agreement, and it should constitute an appendix to WTO/GATT. And the reasons are: (a) the consequences related to the trade on GMP are global; (b) WTO/GATT has 135 members, and among its members are preponderantly developed countries (this is not the case with the Convention on Biological Diversity, for example); and finally, (c) WTO/GATT has an effective process for solving disputes among parties.

Among other provisions, this new legislation should establish a moratorium on exploitation (allowing less developed or undeveloped countries to adjust their internal regulations), minimum standards (providing a minimum level of protection to be observed by all as a mandatory rule), and label requirements (guarantying the exercise of the right of choice by the consumers). Moreover, the most important recommended provision is the adoption by this new legislation of the precautionary principle in terms of GMP (in case of uncertainty concerning the consequences of GMP to the environment or to the health of a population, the commercialization could be suspended). The adoption of this principle would not be in conflict with the principle of "scientific evidence" currently in existence within the WTO/GATT scheme, and at the same time, it would be in accordance with general concepts and principles of international environmental law.

As a matter of fact, the precautionary principle and the principle of "scientific evidence" would be compatible if the burden of proof shifted. Thus, the new legislation in terms of GMP simply should (a) first, allow any country to take a restrictive measure (label, ban or moratorium, or minimal standard) based on the precautionary principle, and (b) second, allow any country suffering the economic consequences of this measure to challenge the same, and this country would be responsible for proving scientifically that the GMP is absolutely safe to the environment and to human beings, so the change would mean only a shift in the burden of proof.

These measures would also be in accordance with general concepts and principles of international environment law, especially the precautionary principle (discussed above), state responsibility (it would be clear which state would be responsible for taking the protective measures), the duty to assess environmental impacts, and the obligation not to cause environmental harm (in both these, the change in the burden of proof would allow for a better evaluation of the environmental impacts of GMP because of the need for strong proof against the presumption that

the GMP is unsafe, and it would allow the state to be in a better position to avoid environmental harm).

Moreover, these measures would also be in accordance with other international documents, especially documents protecting human rights and nature. These documents, in sum, provide that: (1) human rights must be respected,<sup>167</sup> inclusive of international economic relations,<sup>168</sup> and among these human rights is the right to life (including proper nutrition and health);<sup>169</sup> and (2) any activity which may have an adverse impact on nature shall be controlled."<sup>170</sup> The measures proposed would be in accordance with these documents simply because they would lead to the improvement of the quality and safety of food (thus improving the right to life), and they would also provide states with international redress for avoiding potential damage to the environment, thus allowing states to control activities that may have an impact on the environment.

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167. See also U.N. CHARTER (Chapter I - Purposes and Principles) arts. 1, 3. (Promoting and encouraging respect for human rights); UNIVERSAL DECLARATION OF HUMAN RIGHTS art. 3. (Everyone has the right to life . . .). Available in LOUIS HENKIN ET AL., BASIC DOCUMENTS SUPPLEMENT TO INTERNATIONAL - CASES AND MATERIALS, St. Paul, MN: West Publishing Company, (3d ed. 1993).

168. LOUIS HENKIN ET AL., BASIC DOCUMENTS SUPPLEMENT TO INTERNATIONAL - CASES AND MATERIALS, St. Paul, MN: West Publishing Company, at 513 (3d ed. 1993). International Economic Cooperation: Chapter I - Fundamentals of International Economic Relations "Economic . . . and others relations among states shall be governed, inter alia, by the following principles: . . . k) Respect for human rights and fundamental freedom."

169. See CHARTER OF THE ORGANIZATION OF AMERICAN STATES, Art. 33. "The members states . . . agree to devote their utmost efforts to accomplishing the following basic goals: . . . j) proper nutrition, especially through the acceleration of natural efforts to increase the production and availability of food;" UNIVERSAL DECLARATION OF HUMAN RIGHTS, art. 25(1). "Everyone has a right to a standard of living adequate for the health and well-being of himself and of his family, including food."

170. LOUIS HENKIN ET AL., *supra* note 168 at 705. "World Charter for Nature . . . II Functions . . . 11. Activities which might have impact on nature shall be controlled . . ."