

論 文

# India's Biosafety Policy on Genetically Modified Crops: A perspective from food security

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## Abstract

Current estimates indicate that India will have a major impact on the cultivation of GM crops worldwide. In addition, it seems clear that for food security and economic imperatives, India would have strong incentives to become a major cultivator of GM crops. Yet, it is less certain whether India would take this path. What might be desirable for food security aspects and even declared reason for the government to address GM crops, gets lost in the ensuing biosafety debates. Thus, in India, questions over the accuracy and objectivity of scientific data, are connected to organic farming; to farmers rights; to participation in decision-making; to issues of food sovereignty and even human security (farmers suicides). To what extent all these aspects pertain to mainstreaming GM crops for food security is the central question of this article.

For this, the study undertakes two case studies: the commercial approval of Bt cotton (the only GM crops approved so far), and the moratorium on Bt brinjal (Bt brinjal was close of becoming the first GM food crop approved for cultivation).

The article is the incipient phase of a research which analyzes both domestic and international determinants of India's GM crops policies, in how the interactions among different stakeholders have shaped the current state of Indian GM crops policies. The present paper's objectives are to either confirm or identify the main stakeholders, identified from a document analysis, and to draw a sketch of the interactions between them. In addition, this article briefly draws some attention to what India's case would mean to an international regime of GM crops.

The analysis shows that the number and importance of stakeholders changes from Bt cotton Bt brinjal. In Bt brinjal, NGOs emerge as forefront players organizing a national level campaign, which in an unprecedented

move determined the subjection of Bt brinjal to public debates, finally concretized into an indefinite moratorium. Even if the actions of the Minister of Environment and Forests were decisive, he seems just a last minute actor. NGOs are stronger than ever in India, and unless the new Biotechnology Regulatory Authority of India (BRAI) will bring significant changes in the regulatory environment (an unlikely event), the NGOs will be probably able to block any near-future GM crops commercialization attempts, especially food GM crops.

Yet the Government and the industry will continue to pursue GM crops, fact revealed by the high number of GM crops under research currently in India and the accompanying large investments in public research institutes. However, the regulatory problems, especially in enforcement, unlikely to disappear through the creation of BRAI will be major setbacks for attempts to international harmonization of the regulations in GM crops. They will also create problems in the event of an increase in the international trade in transgenics.

## Introduction

It is currently recognized that agriculture has to meet the growing demand for food, fight poverty and malnutrition, while being environmentally sustainable (Graff, Roland-Holst, and Zilberman, 2005). Due to raising food prices and climatic changes (floods, droughts, saline soils), losing arable land to the production of biofuels and steady rise in world demographics, the policy makers in developing countries are increasingly considering genetically modified crops as an instrument to tackle food security (Meijer and Stewart, 2004; Panos Institute, 2005 James, 2008; OECD, 2009).

Yet, GM (genetically modified) crops are a highly contentious subject. Known interchangeably as transgenic crops, the GM crops are obtained by introducing new traits (resistance to diseases, poor soils, enhancing nutritional content, etc) into plants by using recombinant DNA technology. The sustainers of GM crops claim pest and disease resistance, fighting drought, cold, floods, poor or polluted soils, increased yields, high nutritional value (Singh, 2000), along with low dependency on fertilizers and greater market potential (DaSilva et al., 2002). On the other side, its opponents talk

about a failure to deliver the promises for the products already on the market, potential threats to biodiversity, environment, and human health, increasing the dependency of farmers to the biotech multinationals and maintaining an intensive agriculture (Levidow and Carr, 2007).

One of the main contentions among stakeholders toward GM crops policies (alongside trade, consumer choice and food security, intellectual property rights, and research and development) is biosafety (Paarlberg, 2001). An international harmonization mechanism for biosafety signed by 103 countries, although notably not by the United States, is the Cartagena Protocol on Biosafety. The protocol designates biosafety as “a range of measures, policies and procedures for minimizing potential risks that biotechnology may pose to the environment and human health” (CBD webpage).

However, on what is a risk and what is an acceptable level for it, is not always easy to reach a consensus. For GM crops the debates range from a total rejection (being a live product entirely new, man-made, insufficiently known, and therefore unpredictable) to considering GM crops as not essentially different from non-GM crops (they are just plants with novel traits, just as the hybrids of the Green Revolution). Coming to the assessment of risk for GM crops, its definitions pertaining to public policy include either a scientific base making a distinction between risk assessment (scientific issues) and risk management (extra-scientific issues) (Deane, 2001; Nunn, 2001) or a consideration, besides of “sound science,” of the discursive contexts of culturally perceived technology, the influence of institutions on scientific results, and the ecological and socio-economic factors (McAfee, 1999). Moreover, risks for GM crops are increasingly perceived as constructed from a wide array of socio-economic and even political factors (Johnston et al. 2008). In this context, the science of biosafety assessment cannot constitute an objective apolitical instrument for settling disputes. The science itself becomes politicized (Keeley, 2003).

To substantiate the politicization of biosafety policies and hence, the failure of science to be an objective apolitical instrument for settling disputes, the EU/US conflict is a good example. It is generally known that US and EU are the proponents of the two diametrically opposed approaches to GM policies: the “substantial equivalence” and respectively the “precautionary

principle.” The substantial equivalence is evaluating the safety of new GM products by looking for differences between GM products and their non-GM counterparts. For the precautionary principle, its most famous definition belongs to the 1992 Rio Declaration: “Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” (United Nations Environment Programme webpage). A precautionary approach to biosafety regulation includes assessments of novel GM products on a case-by-case basis, an expansion of the tests evaluating the differences between GMOs and their non-GM counterparts to detailed and longterm toxicological and allergenic studies, and even socio-economic considerations. The international conflict between the EU and US, each attempting to impose its own regulatory approach, was deemed a “GM Cold War” (Meijer and Stewart, 2004).

The developing countries are trapped between US conditions binding development assistance to biotech adoption and EU (for some developing countries a traditional market) refusal to accept their GM agricultural products. Yet, some developing countries are in a better position compared to others. The countries classified as type I (regulatory and research capability, GM crop export capacity and even GM development) are described to be favored compared to countries from type II (cannot develop GM crops) or type III ( no capacity, depends on other countries ) (Meijer and Stewart, 2004). Especially India and China (both type I) are depicted as less dependent to US or EU in what the commerce with transgenics is concerned, due to their “large internal market” and their major investments in science and technology (van den Belt and Keulartz, 2007). Some authors even claimed that the future of the GM crops depends on the two countries (Feffer, 2004).

India certainly seems to be living to that expectation. For India to address specifically biotechnology more than twenty years ago appears now a visionary decision concretized into an impressive biotechnology sector, with numerous accomplishments in healthcare and agriculture (Lohray, 2003; Thorsteinsdottir et al, 2004; Chaturvedi, 2005; Reddy, 2007). In agriculture, even if Bt (*Bacillus thuringiensis*) cotton is the only GM crop approved until now, the country has the largest biotech research program among developing countries, following an early designation of biotechnology as a strategic field

in 1986. In India, biotech benefits also from a complex regulatory system, one of the earliest even among developed countries (Johnston et al. 2008).

The future of GM crops in India looks encouraging as well. An OECD report on the emergence of the bioeconomy (the contribution of biotechnology to economic output, OECD, 2009, p.22) places India and China as key drivers of bioeconomy by 2030. The report predicts that by 2030 40% of the world workforce would be concentrated in these two countries. The increase in population as well as the increased incomes would lead to increased food requirements. The economic growth would increase demand for biofuels as well. For India, given the importance of agriculture for its economy (over 60% of the workforce engaged in agriculture), the ongoing major investments in research and development for GM crops and the extent of the field trials, as well as the impressive and increasing number of PhD holders in agricultural biotechnology, the report predicts that the country will become a major cultivator of GM crops (OECD, 2009).

Yet, India has proven difficult to grasp before, displaying paradoxes at many levels. In agricultural biotechnology, an over 20 years interest and investment in research and development (the Department of Biotechnology was founded in 1986) brought only the approval of Bt cotton and the near but failed approval of Bt brinjal. In what the involvement of civil society is concerned, India has probably one of the strongest (1.5 million NGOs) and better informed civil society in the world (Bound, 2007). They organized a strong anti-GM movement fueled by what they claim the failure of the Bt cotton (developed by a joint venture Monsanto/Mahyco) even connected by some to waves of suicides of small farmers in India (Stone, 2002). Moreover, India has the best legislation in the developing world protecting the rights of farmers against multinational biotech corporations. The Plant Variety Protection and Farmers' Rights Act (2001) provides the right to sell seeds even protected ones (except branded ones); it protects farmers plant varieties; it assures the traceability of new plant varieties; it does not allow the terminator technology; and it gives protection against innocent infringement (Sahai, 2004). Meanwhile, the Indian authorities not only seem cautious about the approval of GM crops but keeping GM-free crops is still considered in some circles as a vital trade interest for India, the country remaining the only in the world able to certify GM-free soy (Sahai, 2004).

Vis-a-vis the EU/US regulatory conflict, India has an ambivalent position as well. On one side, it mentions the substantial equivalence (US approach) as a base for risk assessment in official regulatory documents, it sustains a scientifically-based risk assessment, and it is a member of the WTO since 2005 (which does not recognize the precautionary principle as a principle of the international law). On the other side, in the official documents it is emphasized that the substantial equivalence is just a starting point and the evaluations will be considered on a case-by-case basis. In the same time, Indian regulations are following mainly the OECD guidelines, allergenicity tests were included in 1998 Biotechnology Safety Guidelines, the Cartagena Protocol was ratified in 2003 and GM mandatory labeling was introduced in 2005 (all characterizing the precautionary principle-EU approach). Of course, this is the situation on paper, because in reality, the complex regulatory system encounters problems with enforcement as illustrated in the inability to prevent or stop the cultivation of the illegal Bt cotton in Gujarat (Jayaraman, 2004).

Under these considerations, it seems clear that India will have a major impact on the cultivation of GM crops worldwide. In addition, it seems clear that for food security and economic imperatives, India would have strong incentives to become a major cultivator of GM crops. Yet, it is less certain whether India would take this path. More specifically, what might be desirable for food security aspects and even declared reason for the government to address GM crops, gets lost in the ensuing biosafety debates.

As stated in the beginning of this paper, generally the concept of biosafety, based on the perception of risk, evolved from defining risk strictly as environmental and human health threats (Cartagena Protocol on Biosafety), to a broader understanding including socio-economic and even political factors (Johnston et al. 2008). As such, even though biosafety is strictly speaking the evaluation of environmental and health risks of the GM products, the overall risk assessment process in India has come to include also socio-economic concerns over the impact of GM products. It is almost impossible to talk only about biosafety without socio-economic concerns, especially because the science itself behind the biosafety is being questioned (due to its proximity to extra-scientific factors and to the uncertainty of knowledge of a novel science: biotechnology). Thus in India, questions over the

accuracy and objectivity of scientific data, as well as the access of the public to that data are connected to organic farming, as being better alternative to GM cultivation; to farmers rights being infringed by biotech multinationals who are attempting to gain control over the Indian seed market; to participation in decision-making versus a technocratic process; to issues of food sovereignty and even human security (farmers suicides). Yet to what extent all these aspects pertain to mainstreaming GM crops for food security is the central question of this article.

In making its predictions, the OECD report presented above (OECD, 2009) fails to consider the particularities of the Indian decision-making environment on GM crops policies, especially the dynamics of the interaction between different stakeholders that translate into different decisions concerning GM crops. Many scholars identified the political environment as determinant in explaining differences in GM policies for different countries (Jasanoff, 2005; Johnston et al, 2008; Gupta et al., 2008; Ramessar et al., 2009). Yet current analyses of the Indian decision-making environment on GM crops policies are missing. When covering the decisionmaking environment on GM crops policies the literature generally covers industrialized countries or China. This paper represents the incipient phase of a research intended to fill this gap.

Based on the above-mentioned background revolving around the debates on GM Crops both in the domestic and global contexts, this research, as a whole, analyzes both domestic and international determinants of India's GM crops policies, in how the interactions among different stakeholders have shaped the current state of Indian GM crops policies. In addition, it explores what are the implications of this political decision-making process for the future of GM crops in India and its food security strategy. This article briefly draws some attention to what India's case would mean to an international regime of GM crops. Specifically, it examines whether India will expand the cultivation of GM crops beyond Bt cotton to other GM food crops. A crucial moment in shaping GM crops policies is the commercial approval of a particular GM plant and the ensuing biosafety controversies. Thus, these are the moments of focus for this analysis. For this, the study undertakes two case studies, selected due to their relevance: the commercial approval of Bt cotton (the only GM crops approved so far), and the moratorium on Bt brinjal

(Bt brinjal was very close of becoming the first GM food crop approved for cultivation).

The present paper, as mentioned, is the incipient phase of the research. In it the objectives are to either confirm or identify the main stakeholders, identified from a document analysis, and to draw a sketch of the interactions between them. Basically, the research in this paper focused on three main topics: identifying stakeholders, interactions between them, and the future of GM crops in India. Toward these ends interviews were conducted with representatives from a few Indian stakeholders groups. To determine the interactions between them the interviewees were asked to make an evaluation of the general processes of the moratorium on Bt brinjal and of the approval of the Bt cotton (the two cases studies), in who and/or what had most impact on the course of events. The interviewees had thus the possibility to talk about their own involvement and of the other stakeholders, as well as make qualitative evaluations of them. Further, to determine the international stakeholders that are involved in the Indian policies on GM, they were asked to position India vis-a-vis the EU/US regulatory conflict and vis-a-vis the developing countries. In addition, since in India farmers are a particularly sensitive issue, with many of the stakeholders claiming that they speak for the benefit of farmers, a question was reserved on how stakeholders perceive farmers. At last, the respondents were asked for their view on the future of the GM crops in India.

## 1. Background of the two cases in India

In 2001 in Gujarat Mahyco-Monsanto Biotech (MMB) discovered the commercial cultivation of Bt cotton, a GM crop, a technology for which MMB had a patent on and was still waiting approval from the Genetic Engineering Advisory Committee (GEAC). NavBharat, the company that sold the Bt seeds as a hybrid resistant to bollworm, obtained them by crossing Bt gene containing cotton with local cotton varieties. The seeds obtained by NavBharat were sold to farmers in Gujarat since 1998 without mentioning that they are transgenic seeds and without performing a biosafety assessment for GM crops, therefore violating the Environmental Protection Act. GEAC ordered uprooting and burning the standing illegal crops, issuing warnings in



regional newspapers, destroying the remaining seeds and lint from farmers, and sanitizing the fields (Herring, 2007). Farmers refused, however, and were even sustained by the state government (van den Belt and Keulartz, 2007). Furthermore, the farmers were protected by the Plant Variety Protection and Farmers' Rights Act passed in 2001 which protects farmers from innocent infringement. Continuous improvements of the illegal variety by farmers and postgraduate students of Gujarat Agricultural University have been reported after that (Gupta and Chandak, 2005).

Bt cotton was approved for commercialization in 2002. Five more events (Bt cotton type modifications) were approved in India since then and they were incorporated in 522 hybrids (Choudhary and Gaur, 2010). Bt cotton is generally considered a success story in India, excepting some voices claiming its economic failure leading farmers to commit suicides (Shiva and Jalees, 2006). Yet the current situation of the "illegal" cotton in Gujarat remains controversial. Some claim that Gujarat is the largest manufacturer of illegal Bt cotton seeds in the country (Business Standard, April 2008). Others claim that the cultivation of the illegal cotton died off and that right now, at best there are just cases of spurious seeds (James, 2008).

In the second case study, the Bt brinjal was considered for development by ProAgro in 2000 (The Hindu, September 2000) and by others after that, most notably by Mahyco-Monsanto, who by 2006 filled for approval for field trials. GEAC published the plant's biosafety assessments on their website, and waited for public comments within 15 days after which it would consider it for large scale trials, before commercial approval. The reactions against it, however, pointed toward the insufficiency of the data and questioning its objectivity since no independent evaluation was performed (The Financial Express, June 2006). It followed a court trial in September and a Supreme Court decision on a temporary ban on all GM field trials until an independent body of scientists can assess GM crops, not base the process on a particular company data (The Hindu Business, September 2007). The next step in the controversy over the disclosure of bio-safety data on GM food crops was in 2007 when the Central Information Commission (CIC) directed Mahyco-Monsanto to make the data for Bt brinjal public, establishing a precedent of disclosure of biosafety data before commercialization (The Financial Express, November 2007). In 2009 GEAC again states the safety of the Bt brinjal and

approves it for commercialization yet declining its final word in the matter and subjecting the final decision to the Government. In February 2010, at the end of the first anti GM national campaign, the Ministry of the Environment institutes an indefinite moratorium on the plant developed by Mahyco-Monsanto (The Economist, February 2010; India Together, February 2010).

## 2. Research Methodology and the Process of Data Collection

The main research, of which the present paper is the initial phase, analyses the main stakeholders and the interactions between them to determine which stakeholders translate their GM policy preferences into governmental policy and the mechanism through which they accomplish it, as well as the implications of this process on the future of GM crops in India. For this analysis, stakeholders are considered the actors or group of actors able to influence the governmental policy.

Several questions guide the research. What is the situation of GM crops in Indian agriculture? What is the place of GM crops in Indian food security strategy? How do different stakeholders see the place of GM crops in Indian agriculture? What is their perception on the future of GM crops in India? How are GM crops approved for commercialization in India? Do other groups outside of government have access to decision-making? To what extent?

The research will build on the study of documents, primary (governmental white papers, press releases, task forces reports, governmental committees reports, guidelines and regulations) and secondary (published reports and academic papers), as well as interviews with representatives from the main stakeholders.

The present paper constitutes the incipient phase of the research. In it interviews are conducted to either confirm or identify the main stakeholders and to draw a sketch of the interactions between them. The interviews focus on three main topics pertaining to the wider research: identifying the stakeholders, interactions between them, and the future of GM crops. As such, the paper draws mainly on 11 semi-structured interviews conducted in Delhi in August 2010. In a first phase, representatives of major groups involved are identified through an analysis of academic articles, Indian English media articles, and the Annexures to the Moratorium on Bt brinjal,

posted on the Ministry of Environment and Forests website. These Annexures contain selected documents submitted by various interest groups regarding the approval of Bt brinjal. These selected representatives were interviewed and some further provided a “snowball” or “chain-referral” sampling (Weiss, 1994). Each interviewee was asked a similar set of questions, but allowed to elaborate on certain subjects as long as they pertained to the research.

To ease the process of the analysis, to each of the respondents a number was assigned. In addition, to indicate the importance of the information received from the interviewees, Table 1 below provides some details on their background and thus, their position in the GM debate.

Number	Background of respondent
1	National Coordinator, ISAAA (International Service for the Acquisition of Agri-Biotech Applications) South Asia Office; an international non-profit organization funded by the biotech industry
2	One of the two organizers of the anti-Bt brinjal Greenpeace campaign
3	Director and founder of Navdanya (Indian NGO), Director of the Research Foundation on Science, Technology, and Ecology, a leader in the International Forum on Globalization; won the Alternative Nobel Peace Prize (the Right Livelihood Award). In 2010, she was awarded the Sydney Peace Prize
4	Director of Gene Campaign (Indian NGO), chaired the Planning Commission Task Force on Biodiversity and Genetically Engineered Organisms, for the Eleventh Plan. She is a member of the National Biodiversity Board and serves on the Research Advisory Committees of national scientific institutions, the Expert Committee on Biotechnology Policy and the Bioethics Committee of the Indian Council of Medical Research
5	Scientist working on the development of GM plants in Delhi
6	Scientist working on the development of GM plants in Delhi
7	Scientist working on the development of GM plants and are in positions to have access to governmental decisionmaking bodies
8	Scientist working on the development of GM plants and are in positions to have access to governmental decisionmaking bodies
9	Exec. Assist. for CIFA (Consortium of Indian Farmers Associations)
10	State representative for CRS (Catholic Relief Services)
11	Professor, J. Nehru University, Center for Social Medicine, conducted colloquium on public acceptance of Bt brinjal, sent letters to Prime-Minister, Ministry of Environment, Ministry of Science and Technology

Table 1. Codification and Background of Respondents.

The respondents were asked to expose their views on who or what was determinant for the moratorium on Bt brinjal and for the approval of Bt

cotton; how do they position India in the regulatory conflict between EU and US; what is India's position toward the developing world; how do they view the Indian farmers vis-a-vis the GM crops, as a passive or as an active group; and finally, what is the future of GM crops in India.

The interviewees can undergo several classifications. On the acceptance of GM crops, there are some strongly opposing GM crops (2, 3), some strongly promoting them (1, 5, 6, 7, 8, 9), some stating that they are not acceptable in the current form, but do not discharge the possibility of becoming beneficial in the future (10, 4, 11). On their representativeness, they belong to some of the main stakeholders: industry (1), NGOs (2, 3, 4), scientists (5, 6, 7, 8), farmers (9). They also represent some minor ones: humanitarian relief agency (9), and social scientists (11). Key representatives from the government are missing but 7, 8 and 4 worked either as advisers for government, or were part of some governmental committees.

### 3. Analysis of the Cases

For every main topic, the findings are structured around the two case studies: Bt brinjal and Bt cotton. The topics are the identification of stakeholders, the interactions between them, and the future of GM crops. On the identification of stakeholders, in the Bt brinjal case, appear NGOs, farmers, scientists, biotech industry, and the government, also public opinion, political parties and external influences (EU and US). In the Bt cotton case are mentioned Mahyco/ Monsanto, the farmers and the central government as instrumental in the approval of the GM crops, with NGOs playing a minor, local role.

In addition, individuals appear as main figures in the decision-making on the moratorium on Bt brinjal (the Minister of Environment, eminent Indian scientist). When GEAC (Genetic Engineering Advisory Committee) renounced its right at being the authority with the last word in the commercial approval of GM crops (Bt brinjal in that case), it created a void of power, which the Minister of Environment filled in. The reasons for GEAC's action were either a mistake (4) or the result of the Minister's influence (1). In addition, although the Minister of Environment is recognized as the main force behind the moratorium, regardless of the modality through which he became entitled

to take that decision, the advice of an eminent Indian scientist was mentioned as weighting heavily in the Minister's decision (3, 7). There is no mentioning of individuals appearing as main figures in the Bt cotton case.

Moreover, the groups involved in the Bt brinjal case are not homogenous. In the Bt cotton case all the groups seem quite compact from interviewees' replies. For the Bt brinjal case, all the NGOs might have acted for instituting the moratorium, yet almost each acted from different reasons in different nuances. They cover from lack of transparency and participation in decisionmaking (2), questioning the objectivity and accuracy of Monsanto's scientific data (3), to a lack of expertise, enforcement and objectivity in the biosafety related decisions (4). Moreover, not all NGOs are rejecting a future beneficial role of GM technologies, or the use of current non-GM biotechnologies (4).

Among scientists (the majority) consider Bt brinjal safe, some (eminent Indian agricultural scientist and scientists connected to NGOs) reject it. For farmers, all the interviewees indicate them as a heterogenous group, with respondent 9 characterizing them as "highly divided."

For the interactions between stakeholders, the analysis focuses around the main aspects of the GM debates: the accuracy and objectivity of scientific data; organic farming, as being better alternative to GM cultivation; to farmers rights being infringed by biotech multinationals who are attempting to gain control over the Indian seed market; to participation in decision-making versus a technocratic process; external influences over the decision-making for GM crops regulation.

On an accuracy and objectivity of scientific data basis, the pro-GM side contests the results of the con-GM side and vice-versa, sometimes in too absolute terms to be believable. For example, one opinion states that the results of the NGO reports on the evaluation of the Bt cotton are "always biased" and that the scientists that agreed and advised on the moratorium on Bt brinjal had "no objective reason" for that (1). On the con-GM side there are claims that "Monsanto does public relations; does not do science" (3). Of course there are also more reasonable pro and con reactions, like the faith in the accuracy and objectivity of scientific data, because the same technology has been used over the world for many years without negative impacts (9), or the need for independent review of the scientific information, because the

current regulatory bodies are being influenced by industry (4).

For organic farming, the con-GM side designs them as being better alternatives to GM cultivation. There are certainly good reasons to believe so. The organic farming market is emerging as a profitable one (only in US the organic foods and drinks have grown from \$1 billion in 1990 to \$24.8 billion in 2009-OTA, 2010). In the same time, the reports on the performances of the GM crops in the developing world are mixed, as with the Bt cotton in India: some farmers had unquestioned benefits, other had harvests which could not justify the higher investment. The industry representatives seem to be aware of these reasons since, unlike with the accuracy and objectivity of scientific data, they do not position themselves on the opposite side in posting organic farming and GM cultivation as mutually exclusive. Instead, they are portrayed as non-competitors, each addressing different consumer shares (1).

Farmers rights being infringed by biotech multinationals who are attempting to gain control over the Indian seed market is an older controversy dating back to the Bt cotton case. The stakeholders were divided then between protecting farmers rights and those trying to simplify regulation and liberalize trade in transgenics. The main danger from these companies was in their intellectual property rights over the seeds and the terminator technology (it would not allow saving seeds and replanting, since the plants would bear sterile seeds). Protecting farmers from multinationals is still the purpose of some stakeholders (3). Yet at the time of the Bt brinjal controversy, Monsanto was in the impossibility of taking over the Indian seed market on the basis of intellectual property rights, since seeds cannot be patented in India. Moreover, due to the international battle against biotech companies and their research and patents on "trait technologies" (seeds that grow only if a certain herbicide or insecticide is employed, seeds that would not germinate in the first generation), Monsanto pledged to not commercialize the technology for which they had obtained a patent in 1998 (The Guardian, 1999). For other stakeholders, Monsanto and the biotech multinationals are not necessarily the only villains, with both Indian and international biotech industry promoting their interests in GM crops (4).

Another possibility for Monsanto and the multinationals to gain control over the seed market is through the establishment of a monopoly. This possibility is also questioned by the many variants (Bt cotton and other

crops currently under research) developed by Indian companies and public research institutions (5, 8). The debate has even pro-globalization proponents sustaining that multinationals are wrongly perceived, as they can bring many benefits in technology transfer and the public-private partnerships are being ignored (9).

For participation in decision-making versus a technocratic process, the majority of the respondents stated that the decision-making should be transparent and inclusive. The importance of experts does not disappear, however. Beyond the scientific expertise (1, 9), the necessity of experts in emerging inter-disciplinary fields like biosafety and their inclusion in regulatory bodies appear (4).

For external influences over the decision-making for GM crops regulation, EU and US appear in respondents' replies. Their influence is either on the approach to regulation, within the EU/US conflict, or directly in the Bt brinjal case. Therefore, EU appears as influencing the debate through NGOs funding (9) and through a cultural influence dating back to colonial times (1), while there are fears that the Minister of Environment might be replaced at US pressures (11), with an increasing US political influence over GM crops approvals in the future (4, 11). Yet there are respondents which do not perceive any EU/US influence over Indian approach to regulation (3, 5, 8), with respondent 5 saying that India is "unique."

There is an exception from this oversimplifying picture which still draws very definite lines between domestic and international divides, surprising when considering that the subject is such a globalized science and industry as biotechnology. Respondent 2 points out the fact that international/ domestic line in characterizing stakeholders is arbitrary, that many are in the same time global and local. This observation is more obvious for stakeholders immersed in transnational networks like scientists or NGOs, involved in solving local problems but drawing on international resources.

Finally for the future of GM crops in India, the majority of the respondents seem to agree that more time is needed. BRAI (Biotechnology Regulatory Authority of India), the autonomous regulatory body proposed to replace GEAC, is also a hope for better regulations in the future, but it might take some time to be set in function. The setting of BRAI, or NBRA (National Biotechnology Regulatory Authority) was recommended in 2004 by

the Task Force on Biodiversity & Genetically Modified Organisms (GMOS) for the Environment & Forests Eleventh Five Year Plan (2007-2012) to tackle the lack of standards and procedures for safety assessment and labeling, of coordination between governmental departments, of transparency and public communication, and a lack of specialized individuals for risk assessments of GMOs (ICMR, 2004; Planning Commission, 2006). A draft was made and subjected to public comments in 2008, but seems to have been put aside until the Bt brinjal controversy.

### Conclusions

The preliminary investigation constituting the subject of this paper is composed of interviews conducted to either confirm or identify the main stakeholders and to draw a sketch of the interactions between them. For stakeholders, their number and importance changes from Bt cotton case to the Bt brinjal one. In Bt brinjal, NGOs emerge as forefront players organizing a national level campaign, which in an unprecedented move determined the subjection of Bt brinjal to public debates, finally concretized into an indefinite moratorium. Even if the actions of the Minister of Environment and Forests were decisive, he seems more of a last minute actor. Even if they are led by different motives, the NGOs left aside their differences and worked in a common front whose efficiency increased thus considerably. In doing so, they drew also on international resources from the transnational networks in which they are integrated. A sure fact is that NGOs are stronger than ever in India, and unless the new NBRA/BRAI will bring significant changes in the regulatory environment, the NGOs will be probably able to block any future GM crops commercialization attempts, especially food GM crops. The power of NGOs in India is probably without precedent in the developing world, and they achieved major breakthroughs for farmers rights, conservation of biodiversity and traditional knowledge.

Another group highly integrated in transnational networks was the group of scientists, yet they were not able to utilize that asset. Perhaps one reason was that they did not dispose of the resources of the NGOs and their resonance to the public.

The external influences seem to be secondary and working through the



main actors rather than operating direct interventions. An indication to this is each party's accusation over the other's operating in the name of foreign interests without further elaboration or proof, which fit the usual strategy of tainting the adversary.

In the middle of this agitation the Government seems to be looking again for an opportunity to make everyone happy, like in the Bt cotton case. At that time, the illegal proliferation of Bt cotton satisfied the farmers, who could have the Bt technology at a much lower price, the industry who could finally have its product adopted for commercialization through this fait accompli, and some of the NGOs who could have perceived it as a victory against Monsanto. For the moment, this is accomplished by the setting of a new regulatory authority, NBRA/BRAI. Setting this authority has also the advantage that it can gain more time, which can bring new elements into the picture (severe pest attacks, increase in international crops prices, China's adoption of new GM crops).

Whether this new authority, once instituted, will increase the precautionary stance of the biosafety policies in India, it remains to be seen. On another hand, even if providing a more precautionary approach, the new regulatory autonomous authority might not represent a real chance for an increased precautionary stance. Considering the political and institutional environment in India, a truly autonomous, accountable, uncontroversial, transparent, and efficient regulatory authority seems impossible. There is a distance between the existence of a regulation and its efficiency, when the judicial system must act as the enforcer of rules and regulations, as it is presently the case in India. The regulatory system has rather a pragmatic approach, having precautionary provisions which are not enforced since it would require investments in infrastructure and increased expenditures. This pragmatism suits US and its substantial equivalence-based approach in that it proves the strains of a precautionary stance. It might also be the beginning of a third type of regulatory approach, the "Wild East": one where the rules and regulations comprise provisions of both EU and US approaches, but they are followed only when it is beneficial to do so.

The approval process has suffered a halt with the Bt brinjal moratorium, but it will not be a standstill. Due to the high number of GM crops under research currently in India and the accompanying large investments in

public research institutes, the Government will continue to pursue GM crops. Pressures will come also from the private companies, domestic or multinationals, which invested considerably in GM research. Moreover, the dream of the Green Revolution, of technological miracles delivering solutions to the standstill in agricultural production, still lingers in the minds of the policy-makers. Yet the regulatory problems, especially in enforcement, unlikely to disappear through the creation of NBRA will be major setbacks for attempts to international harmonization of the regulations in GM crops. They will also create problems in the event of an increase in the international trade in transgenics.

The pursuit of GM crops for food security is highly unlikely to happen in India any time soon. There is no advanced research on crops employed in food security policies, like cereals or pulses. After the controversies and the branding of the Basmati rice, the international partnership wanting to deliver the Golden Rice (vitamin A enhanced) will surely have no chance in India. In addition, there are no real scientific developments to prove necessary and beneficial in the eyes of the NGOs the pursuit of the GM crops to increase food security.

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