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Beyond GMOs.
Biotechnology
in the agri-food sector



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in the agri-food sector* (July 2011)

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Dear Reader,
in order to respond to the economic, social and environmental issues that are looming on the horizon, the agriculture/food sector requires innovation. Climate change, the progressive reduction of arable land, the water emergency, population growth (resulting in the need to ensure access to food to a growing number of people) and the quality of food: these are all problems that require a new approach and new tools.

Processes of innovation are inherently multidimensional, the result of the combination of many factors, and are adapted differently in different geographical contexts. Among the different options available, the possibility of improving plant varieties through the adoption of biotechnology represents only one of the areas of great interest.

In order to understand what the contribution of biotechnology to the sustainability of the food system could be, the broad base of knowledge and all the tools made available by modern science and technology need to be taken into account. Knowledge that, as mentioned in the document's title, are beyond that of genetically modified organisms.

This is extremely important because it seems difficult to imagine that GMOs, designed and developed for an intensive, single-crop production model (dependent on chemical herbicides and fertilizers), could be a sustainable response to the complex challenges of the future in individual geographical areas. If in the past, work has mainly been conducted on the development of new seed varieties that can be used globally, the future will hold, instead, a looming need to identify specific varieties that are suited to individual geographical contexts.

For this reason, innovation should be more orientated toward forms of non-transgenic biotechnology, about which there is generally less talk and which we illustrate in this document.

The scientific knowledge that has been made available by modern genetics can greatly accelerate the production of new seed varieties which will be capable of giving adequate answers to the complex needs of the agri-food world.

Enjoy the read,
Guido Barilla

A man wearing a tan hat and a plaid shirt is kneeling in a field of tall grass and small pink flowers. He is using a yellow and black soil sampling tool to collect a sample from the ground. The background shows a clear blue sky and distant trees.

THE VISION OF THE BARILLA CENTER FOR FOOD & NUTRITION

TO OFFER A VARIETY OF HIGHLY SCIENTIFIC CONTRIBUTIONS AND BECOME A VALUABLE SERVICE TO THE INSTITUTIONS, THE SCIENTIFIC COMMUNITY, THE MEDIA AND CIVIL SOCIETY OVER TIME; A MEETING POINT FOR ANYONE WHO CARES ABOUT FOOD, THE ENVIRONMENT, SUSTAINABLE DEVELOPMENT AND ITS IMPLICATIONS ON PEOPLE'S LIVES.

THE FUTURE OF FOOD IS GROWING WITH US

THE BARILLA CENTER FOR FOOD & NUTRITION

The Barilla Center for Food & Nutrition (BCFN) is a center of multidisciplinary analysis and proposals which aims to explore the major issues related to food and nutrition on a global scale.

Created in 2009, BCFN intends to listen to the demands emerging from society today by gathering experience and qualified expertise on a worldwide level and promoting a continuous and open dialogue. The complexity of the phenomena under investigation has made it necessary to adopt a methodology that goes beyond the boundaries of different disciplines. These topics under study are broken down into four areas: *Sustainable Growth for Food*, *Food for Health*, *Food for All* and *Food for Culture*. The areas of analysis involve science, the environment, culture and the economy; within these areas, BCFN explores topics of interest, suggesting proposals to meet the food challenges of the future.



In the field of *Food for Sustainable Growth*, the Barilla Center for Food & Nutrition focuses on the issue of the optimization of natural resources within the framework of the food and agricultural sector. More specifically, the studies conducted so far have identified some critical issues and have evaluated the environmental impact of food production and consumption, putting forward a series of proposals and recommendations for individual and collective lifestyles which may have a positive effect on the environment and on natural resources.

In the field of *Food for Health*, Barilla Center for Food & Nutrition has decided to start its research work by analyzing the existing relationship between nutrition and health. It has studied in depth the recommendations provided by the most distinguished nutrition institutes in the world and the results of ad hoc panel discussions with some of the most accredited scientists at the international level. As a result, it has been able to provide civil society with a clear set of concrete proposals for more easily adopting a correct lifestyle and a healthy diet.



In the field of *Food for All*, the Barilla Center for Food & Nutrition deals with the issue of food accessibility and malnutrition with the aim to reflect how to promote better governance of the food and agricultural sector on a global scale, in order to have a more equitable distribution of food and a better impact on social well-being, health and the environment.



In the *Food for Culture* area, the Barilla Center for Food & Nutrition aims the relationship between man and food. In particular, BCFN has traced the most significant stages in the evolution of the man-food relationship, refocusing on the fundamental role of the Mediterranean diet.



In line with this approach, the activities of BCFN are guided by the Advisory Board, a body composed of experts from different but complementary sectors, which makes proposals, analyzes and develops the themes, and then drafts concrete recommendations.

One or more advisors have been individuated for each specific area: Barbara Buchner (expert on energy, climate change and the environment) and John Reilly (economist and expert on environmental issues) for the area *Food for Sustainable Growth*; Mario Monti (economist) for the area *Food For All*; Umberto Veronesi (oncologist), Gabriele Riccardi (nutritionist) and Camillo Ricordi (immunologist) for the area *Food for Health* and Claude Fischler (sociologist) for the area *Food for Culture*.

In its first two years of its activity, BCFN created and divulged a number of scientific publications. Driven by institutional deadlines and priorities found on the international economic and political agendas, it has reinforced its role as a collector and connector between science and research, and policy decisions and other governmental actions. BCFN has also organized events which are open to civil society, including the *International Forum on Food & Nutrition*. This event is an important moment of confrontation with the greatest experts in the field and is now in its second edition. BCFN continues its path of analysis and sharing for a third year, making its content accessible to as many interlocutors as possible and acting as a reference point on issues of food and nutrition.

In 2010, with the first paper that BCFN devoted to GMOs, we posed the question of whether GMO agriculture was sustainable. It was, therefore, natural to dedicate the work done during this year to the analysis of biotechnology beyond that of GMOs. Thus, the developments of various agri-food biotechnology have been assessed not only from a technical point of view, but also in geopolitical terms, analyzing the role that this type of innovation is having in both emerging and developed countries.



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BEYOND GMOS.
BIOTECHNOLOGY IN
THE AGRI-FOOD SECTOR



EXECUTIVE SUMMARY

1. GREATER AWARENESS OF THE ENVIRONMENTAL IMPACT OF AGRICULTURE IS INCREASING INTEREST IN MORE SUSTAINABLE AGRO-FOOD MODELS.

Increased awareness of the environmental impact of farming, and the widespread concern about the scarcity of resources, today lead to a rethinking of the global food system, to make it more sustainable in different territorial contexts and in a long-term perspective.

Therefore, to meet future challenges, sustainable agriculture must produce food and, at the same time, promote biodiversity by encouraging the creation of synergies between the species (aimed at strengthening the profile of ecosystems' resilience and their self management), supporting the processes of soil protection from erosion, optimizing the consumption and use of water, and minimizing the use of agrochemicals, synthetic fertilizers and, possibly, fossil fuels. However, at the same time, it must also provide decent incomes for farmers and affordable prices for consumers.

2. SUSTAINABILITY IS CONSIDERED THE CRITERIUM FOR EVALUATING BIOTECHNOLOGIES AND THEIR ABILITY TO RESPOND TO THE CHALLENGES OF THE FUTURE.

The agriculture and food biotechnology sector is vast and includes a set of techniques and instruments used by researchers to understand and change the genetic makeup of organisms in order to select varieties of plants that are useful in the production or processing of food products.

There are two broad categories of intervention in the field of food biotechnology:

- *correctly defined GM techniques of the recombinant DNA*, known more familiarly as "genetic engineering," by means of which the genome of an organism is changed through transgenesis, by inserting a foreign gene (named a transgene) into the genome of a living organism that serves as host, in order to introduce one or more new features.
- *non-GM techniques*, whose contribution is to make information available to guide the processes of the analysis and selection of favorable genetic variants. Among these, of particular importance are: *MAS* (Marker-Assisted Selection), *mutagenesis*, *TILLING* (Targeting Induced Local Lesions in Genomes), and the *characterization of germplasm and tissue culture*.

Sustainability is the fundamental perspective for assessing the contribution of technological innovations and their ability to respond to the real needs, issues and challenges that the

global agricultural sector will be called upon to face in the future. In particular, besides the control of crop diseases and pests (the first to be developed), it is also interesting to identify techniques and approaches that allow us to cope with the growing scarcity of water, the reduction of soil fertility and the drop in the increase of agricultural productivity, without compromising on the improvement of food quality.

The development of sustainable agricultural models requires innovative processes. The imbalances that characterize the models in agricultural use, mainly due to structural elements, need new tools in order to be resolved adequately: in our opinion, multidimensional approaches are required, based on an optimal combination of biotechnology and non-GM farming techniques. The use of traditional techniques combined with the new knowledge of biotechnology permits a drastic reduction in the time needed to develop new plant varieties that are able to contribute in a meaningful way to the pursuit of sustainable agriculture at the level of costs. A similar approach would also be applicable in the context of developing countries.

3. ANALYSES OF AGRO-FOOD BIOTECHNOLOGIES - GMOS AND NON-GMOS - IN EMERGING AND DEVELOPED COUNTRIES.

To understand the role biotechnology plays in the agro-food sector in the various countries, an analysis was conducted of the level of penetration of GMO and non-GMO crops, the objectives of the research programs, the national regulations which have been adopted and the degree of public support. The results:

- *The European Union* looks with interest to biotechnology in its different sectors of activity. This is demonstrated by the policies encouraging a knowledge-based bioeconomy adopted over the last decade and, more generally, by a strategic plan which is strongly imprinted upon biotechnology. This attention is reflected both in official documents and in the amount of investments made available by the Framework Programmes of the different DGs of the European Commission. Also, the number of patent applications related to biotechnology presented at the EPO (European Patent Office) provides the picture of a dynamic reality in the various sectors of research. However, at the same time, Europe has made the decision – a decade ago by now – to refrain from making transgenic biotechnology (GMOs) one of the strategic drivers of the development of its agriculture, based on the principle of precaution and as a result of the reluctance expressed by European citizens (clearly shown in the Eurobarometer survey in 2010).
- *The United States*, one of the pioneer countries in developing agricultural and food biotechnology, has made a convincing choice, organizing an advanced biotechnology sector specialized, in particular, in the development of transgenic organisms (GMOs), based on the substantial scientific knowledge available at the level of the country's system and an agricultural sector that proved to be very receptive to the new GM seeds right from the start. The penetration rates of these plant varieties are, however, so high and the intensive monoculture model is so optimized, that the only way to enable further increases in yield or productivity is through experiments in the new biotechnology applications or of new species.
- *China*, spurred by favorable public policies, and thanks to a regulation that is still in progress, now occupies a position of leadership among the emerging countries and, more generally, in the world, in the sector of food biotechnology. The significant amount of investments in R&D (Research and Development) and the growth trend that has characterized its evolution in recent years, make China a center of excellence in the development of important technological applications (both non-GMOs and GMOs,

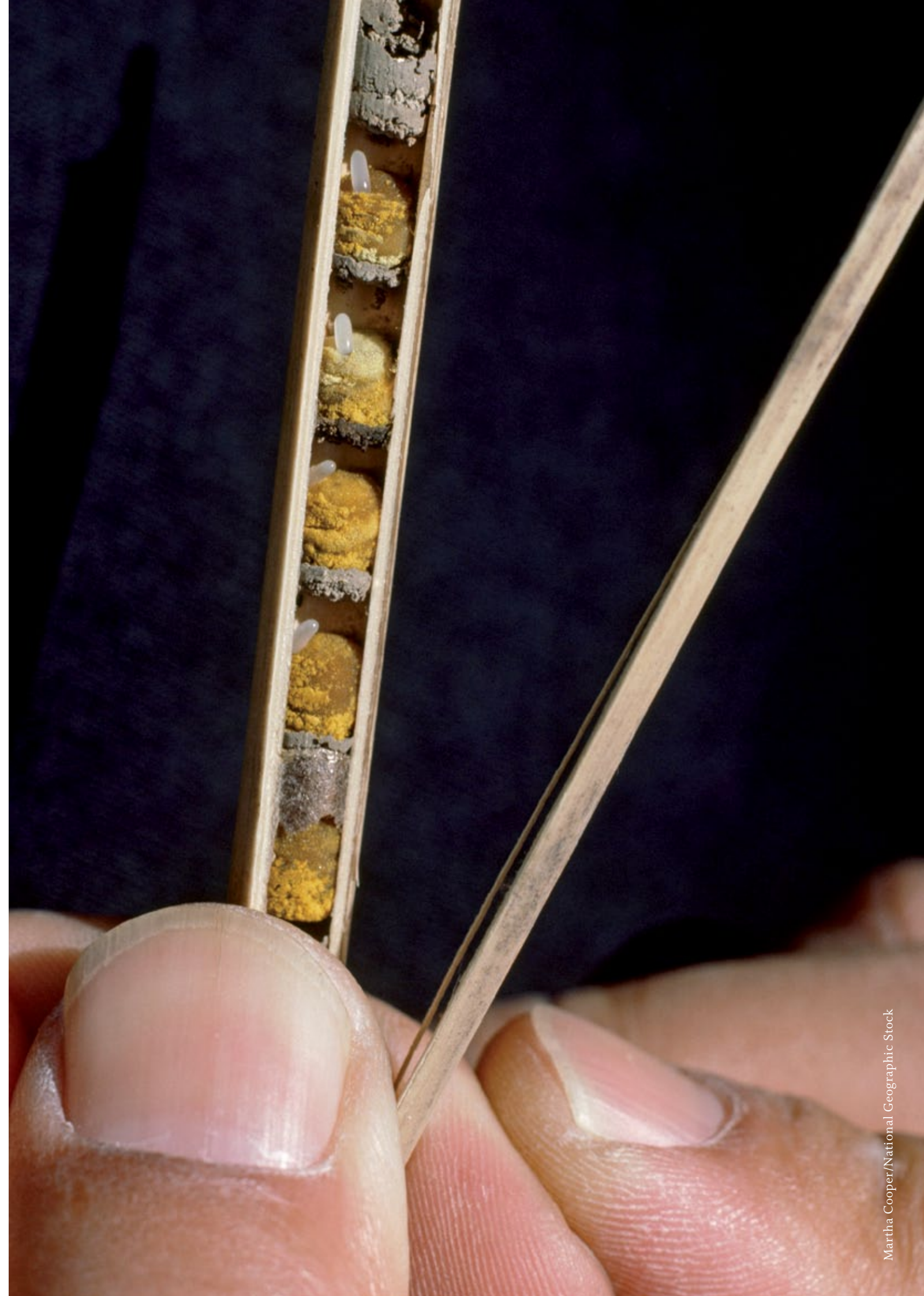
among which mutagenesis should be mentioned). However, none of the authorized GMO varieties have been introduced into the diet of the Chinese population.

- In *India*, the biotechnology sector in the food and agriculture field is one of the roads identified by past governments to encourage the development of the nation. The presence of highly qualified human resources, fair and transparent regulations for the protection of intellectual property rights, cutting-edge research infrastructures and growing investments by both public and private sectors are some of the elements that have facilitated this choice. However, ever since Bt cotton was introduced on the market, many controversies and disputes have arisen within the country, demonstrating that there is not a full sharing of some of these choices, and that this industry needs to make information more transparent.
- *Argentina* adopted GM crops right away, demonstrating an openness to biotechnology, but it now risks a loss of its competitive advantage over other countries producing biotech crops: the growing concerns of businesses, blaming excessive slowness of the processes of authorization and control, have led the country to begin a process of reflection, to try to understand if other technological applications (non-GM), less constrained by government regulations, can contribute positively to the sustainable growth of the agricultural sector.
- *Brazil* is one of the most significant examples worldwide regarding the field of agriculture and food research in the sector. The extent of its agricultural areas, its impressive level of biodiversity, the level of its agricultural production, the size and ubiquity of its R&D in the food sector, all help to place Brazil among the leading countries in this field. The great development of research and applications in biotechnology in Brazil has been possible thanks to its strong scientific tradition in the field of biotechnology, to the significant public funding allocated to basic research, and finally, to the presence of a regulatory framework that is generally favorable to biotechnology research and the dissemination of innovations derived from it.

4. CONCLUSIONS

In light of the analysis and discussions held, some concluding remarks can be formulated, which we will limit ourselves here to recalling as summary points:

- the need to evaluate the sustainability of biotechnological innovations proposed for agriculture emerges ever more clearly;
- despite being one of the factors in the development of sustainable agriculture, the development of new high-yield plant varieties must not be the only objective;
- GMOs are important for an intensive single-crop agricultural model;
- the entrance of emerging countries is beginning to change the structure of the biotechnology sector;
- the development of public-private research partnerships to reduce limitations in research;
- property rights are unduly limiting the ability to exploit knowledge in the field of biotechnology;
- non-GM technology that is able to accelerate the traditional processes of crossing and hybridization is being increasingly used;
- there has been interest in developing varieties that are resistant to drought or suitable for saline soils.



1. SUSTAINABILITY AND INNOVATION IN AGRICULTURE



1.1 PREMISE: SUSTAINABILITY AS A CRITICAL FACTOR FOR EVALUATING INNOVATION IN AGRICULTURE

SUSTAINABLE AGRICULTURE IS “THE PRODUCTION OF FOOD THAT MAKES THE BEST USE OF THE GOODS AND SERVICES OF NATURE, WITHOUT DAMAGING IT”

One of the key issues for any serious reflection on agriculture today is the concept of “sustainability.”

Sustainable agriculture can be described as “the production of food that makes the best use of the goods and services of nature, without damaging it.”¹ The FAO reminds us that in order to achieve this, many requirements must be fulfilled: to be sustainable, farming must contribute “to preserve the natural resources, assist in protecting the environment, be appropriate for the context of reference (from the point of view of the techniques used) and, finally, be socially and economically acceptable.”²

There are various models of sustainable agriculture,³ but they all share some common traits. In fact, to be sustainable, farming has to encourage biodiversity, promote the creation of synergies between the species (aimed at strengthening the profile of resilience of ecosystems and their self-regulation), support the processes of soil protection from erosion, optimize the consumption and use of water, and reduce the use of agrochemical products and synthetic fertilizers.

The reasons for the growing interest in more sustainable forms of agriculture, compared to the intensive models now prevalent in many parts of the world, primarily stem from an increased awareness of the environmental impact of agricultural activities. In addition, there is growing concern about the scarcity (not only in the future) of resources that have supported the phase of accelerated development of agriculture known as the *green revolution*, starting with oil.⁴

As we know, the last fifty years have been characterized by the rapid evolution in agriculture toward the use of technologies to increase the productivity of the factors employed and toward a general modernization of production techniques. Moreover, since the '60s and '70s, the simultaneous introduction of crop varieties with a high yield (the so-called HYV, *high-yielding varieties*), the practice of monoculture (single crops), widespread mechanization and the contribution of agrochemical products (the massive use of pesticides, herbicides, fungicides and synthetic fertilizers, developed through the use of nitrogen, phosphorus and potassium) have all contributed to an extraordinary increase in production volumes – in equal measure – especially with regard to wheat, rice and soy.

This model is a combination of intensive monoculture, agrochemicals and mechanization, which – together – allow farmers to exploit the potential economies of scale throughout the supply chain of activities, inaugurating a season of high productivity and low food prices.

However, even though excellent results were obtained in the past, the production paradigm that emerged from the green revolution is now inadequate for addressing the major challenges of the agriculture-food sector. As stated in the 2009 IAASTD report entitled *Agriculture at a Crossroads*, which has been used for more than four years by some 400 experts around

the world, the resulting increased productivity has been achieved with the intensive, and often irreversible, exploitation of the natural resources: soil erosion, water contamination, pollution of rivers and seas, de-forestation and loss of biodiversity.

Furthermore, new problems are arising (which, by definition, require new answers),⁵ mainly due to population growth in developing countries and the effects of climate change on agriculture.

Moreover, as we shall see in more detail below (Section 1.2), the rate of growth in agricultural productivity has dwindled significantly, to almost zero. This means that the development that had been achieved in the first thirty years following the introduction of the intensive monoculture paradigm has lost its momentum.

Therefore, we must thoroughly re-evaluate the existing models and logic, not only to see if it will result in a gap between the supply of and the demand for food, but above all, to understand how to make food products accessible and distributed more fairly.

It is our belief that the intensive single-crop paradigm is less and less sustainable and that it is, therefore, time to completely rethink the agricultural system using all available options, and not just those that are typically technological, so as to make it truly compatible with the different local contexts in a long-term perspective.

What interests us here is to highlight how sustainability should be considered the critical factor for evaluating every possible innovation with regard to agriculture.

For this reason, the first document published by the BCFN on the use of biotechnology (specifically, genetically modified organisms) was entitled *Is GMO agriculture sustainable?*: it proposes a multidimensional and dynamic interpretation of sustainability.⁶

SUSTAINABILITY SHOULD BE CONSIDERED THE CRITICAL FACTOR FOR EVALUATING EVERY POSSIBLE INNOVATION WITH REGARD TO AGRICULTURE



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1.2 WHY DOES SUSTAINABLE AGRICULTURE REQUIRE INNOVATION PROCESSES?

ACCORDING TO RECENT FAO ESTIMATES, MORE THAN ONE BILLION PEOPLE IN DEVELOPING COUNTRIES SUFFER FROM HUNGER AND JUST AS MANY ARE OVERWEIGHT IN DEVELOPED COUNTRIES

Despite the fact that the quantity of food products is now more than enough to feed the entire world's population, according to recent FAO estimates, more than a billion people in developing countries suffer from hunger and just as many are overweight in developed countries.

Moreover, not even the future prospects of access to food are reassuring. In fact, if you consider that in 2050 there will be 2.2 billion people to feed, the current situation – in the absence of incisive corrective actions coordinated at the international level – can only get worse.

It is not only a matter of an effect linked to the functioning of the markets, since the reasons for the imbalances are structural and regard both the demand for and the supply of agricultural products. Among the demand factors, first of all, is the significant increase in population and economic growth of countries like China and India, where the demand for food is increasing.

Given these dynamics of such rapid growth, the supply of food is struggling to keep up, in part because the phenomena of climate change, the production of biofuels and soil erosion – reducing the cultivated areas worldwide – are helping to make the whole picture even more uncertain.

In addition, the wastage of goods throughout the entire food chain, from farm to table, continues to be relevant.⁷

WE MUST UNDERSTAND HOW TO INTERVENE TO REDUCE THE PERCENTAGE OF CALORIES AND TO ENSURE EQUITABLE DISTRIBUTION AMONG THOSE WHO HAVE AND CONSUME TOO MUCH FOOD AND THOSE WHO HAVE TOO LITTLE TO BE ABLE TO SURVIVE

Added to all this is the data on agricultural productivity, which grew by more than 3% between 1960 and 1980, and which has plummeted to an increase rate of only 0.7% in the last two decades. Nevertheless, it would be wrong to think that the only solution for allowing the supply of food to meet the demand is an increase in productivity. The real commitment must be focused on understanding how to intervene, on the one hand, to reduce the percentage of calories, now over 50%, which is not available for human consumption and, on the other, to ensure an equitable distribution among those who have and consume too much food (even to the point of becoming ill) and those who have too little to be able to survive.

There is no doubt that productivity, too, has its weight and, if we consider sustainability as a prerequisite, this can be enhanced in several ways, namely by reducing the phenomena of post-harvest volume losses, transferring innovation to the most backward countries, building infrastructures in the poorest countries, investing in training, and spreading mechanization.

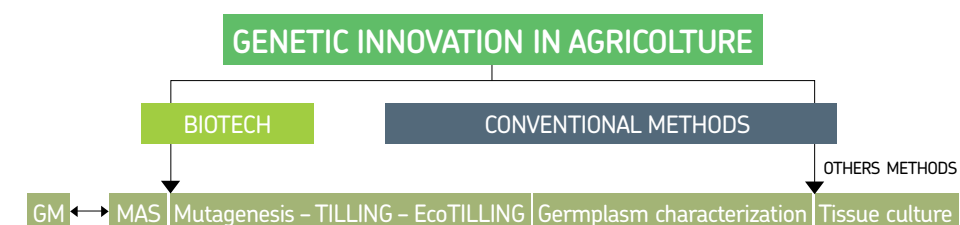
As for technological innovation for the improvement of plant varieties, non-GMO biotechnology is now one of the most promising fields.

1.3 THE *IS GMO AGRICULTURE SUSTAINABLE?* POSITION PAPER: THE FIRST STEP OF A BROADER PATH

As we will show in detail in this document, the biotechnology sector is vast and comprises various intervention techniques whose application to the agricultural sector is very useful in some cases. Wishing to simplify as much as possible, the different techniques can be classified in two main categories:

- the first, which sees genetic recombination as the main intervention technique and transgenic products as the main result of this approach, is based on *the genetic manipulation* of some plant species through the introduction of new genes into their genetic makeup, in order to produce plants with aspects of utility for the farmer (herbicide resistance, resistance to particular species of insects, drought tolerance, etc.). These are known as genetically modified organisms (GMOs);
- the second includes various other biotechnologies, which by their very nature are less invasive, whose contribution is aimed at *supporting*, making *the processes of crossing and hybridization* more effective and faster; these techniques have been known and used for over a century by farmers all over the world and mainly involve the analysis and selection of favorable genetic variations and the creation of new genetic variations.

TWO TECHNICAL CATEGORIES OF BIOTECHNOLOGICAL INTERVENTION: THE GENETIC MANIPULATION OF PLANT SPECIES AND THE CROSSING AND HYBRIDIZATION PROCESSES



Starting from this classification, last year we dealt with the issue of GMOs by publishing the position paper *Is GMO agriculture sustainable?*, to also take into account the media hype and the widespread interest and concerns accompanying the public debate on GMOs. Now, we are considering the issue of “other” biotechnologies with respect to GMOs.

This distinction, in practice, is of significant importance. From a strictly scientific point of view, the evaluation of a genetically modified product cannot be separated from the technical process that generated it, but the economic and social implications – and to an equal degree, *policy* – are far from negligible, as well. In fact:

- an activity is based on the *possibility of patenting* not only the product but also the individual genes, as well as techniques of genetic recombination (the current one, in this case, of GM products), which is particularly present in the sector of seeds. Citing a comment by Mario Monti,⁸ the perplexities of those who speak of GMEs – Genetically Modified

THE EVALUATION OF A GENETICALLY MODIFIED PRODUCT CANNOT BE SEPARATED FROM THE TECHNICAL PROCESS THAT GENERATED IT

Economies – do not appear to be entirely unfounded,⁹ rather than GMOs. The non-GMO biotechnologies, using techniques that have always been known and used in agriculture (but only when there is a greater degree of knowledge), lend themselves less to facilitating this oligopolistic process;

- however, the *scope of application* of the “other” biotechnologies is very broad by nature, even in comparison with the few traits of utility developed so far by the agricultural GMOs (herbicide resistance, resistance to insects and bacteria, and in some cases, foods integrated with specific nutrients). Thus, there is the potential for a widespread economic impact, but it has still not been fully exploited today;
- the data on the *diffusion of biotechnologies* is of uncertain interpretation: whereas, in the case of GMOs, there is a specific accounting (including economic) regarding the use of the products – precisely because of the complex system regarding the protection of intellectual property that governs them and the media attention surrounding them –, this is not the case of other biotechnologies. In fact, there is no product that, in this latter area, differs in its intrinsic characteristics or the nature of its production processes.

In summary, the problems and prospects of this sector differ significantly from those of GMOs and, thus, deserve to be dealt with on their own terms. After having highlighted – in the previous paper – the points of strength, interest and criticism of transgenic techniques, we have now chosen to conduct the same analysis of non-genetically modified biotechnologies.

Further on in this chapter is the Executive Summary of the previous document, *Is GMO agriculture sustainable?* (presented to the public last December 1st, at the second edition of the “International Forum on Food and Nutrition,” organized by the Barilla Center for Food & Nutrition), and reading it may help in understanding the topics covered here. Then, refer to this document in its entirety for any further information.

1.4 INVESTIGATIVE METHODOLOGY AND APPROACHES

In the following pages, we propose to offer a sufficiently detailed introductory framework regarding the state of non-GMO food biotechnology in the world.

In this regard, it should be noted that, compared to the initial objectives of the study, we have found ourselves exploring a highly fragmented field of inquiry which is not always adequately mapped and quantified in terms of data on the diffusion and use of the various technologies. Nevertheless, it was decided not to renounce offering a first glimpse of this reality, aware that there will be other opportunities to address the issue again in the near future, given the importance and rapid evolution of scientific research on these topics.

The interview with Olivier De Schutter¹⁰ in the following pages clearly emphasizes the reasons for the urgency to expand the horizon of analysis of non-GM biotechnologies. For there is a tendency, both in terms of public opinion and policy making, to reduce the issue of biotechnology to only genetically modified organisms, whereas, although of no minor importance, they do not represent the whole field of biotechnology, which is much larger, richer and ever changing.

This document was produced by integrating different methods of collecting information and data relevant to the inquiry, namely:

- the collection of *about 15 interviews with opinion leaders*, scientists, entrepreneurs, members of public and private institutions and associations active in the field of biotechnology research and agriculture, in different geographical contexts (Europe, the United States, China, India, Brazil, Argentina);
- the *analysis and synthesis of the latest documents on the subject*, with a declination of a geographic nature, where necessary;
- supervision of the *methodology aspects by the Advisory Board¹¹* of the Barilla Center for Food & Nutrition, which directed the research work and contributed to commenting on the results obtained.

Appendix 1. Executive Summary of the position paper *Is GMO agriculture sustainable?*

The safety issue of genetically modified foods is one in which there is a greater alignment between the different positions in the field. The European licensing system for the marketing of genetically modified ingredients seems to have measures that are the most restrictive of those adopted by various countries; nevertheless, some aspects of their *risk assessment* can be further improved, for example, with the introduction of tests conducted by independent bodies.

THERE IS A TENDENCY TO REDUCE THE ISSUE OF BIOTECHNOLOGY TO ONLY GENETICALLY MODIFIED ORGANISMS, BUT THEY DO NOT REPRESENT THE WHOLE FIELD OF BIOTECHNOLOGY

ARE THERE HEALTH RISKS INVOLVED IN THE CONSUMPTION OF GENETICALLY MODIFIED FOODS ON THE MARKET TODAY?



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Interview with Olivier De Schutter, Special Rapporteur on the Right to Food (United Nations)



From the point of view of the right to food and human development, what do you think is the role of GMOs and other biotechnologies used in the field of food and agriculture?

This is a difficult question to answer because, although GMOs have been analyzed in terms of their impact on the health of individuals and the environment, they are still very controversial. I believe that much research must still be conducted on these issues. Unfortunately, this has not been facilitated because the research itself is carried out by the same people who hold the rights to the genetically modified organisms and, very often, they do not allow further research to be undertaken. It truly is a bad signal that is being sent to consumers and that, without a doubt, makes them less certain.

In particular, concerning the right to food, I think it is important to emphasize that the real issue is not just how GMOs have led to the increase of crops over the years, which is still a good question, but what the impact of GMOs has been on the incomes of poor farmers working in difficult environments, specifically in developing countries. First of all, the answer is that since 1996 – the year the commercialization of Genetically Modified crops began – they have been mainly used to develop four types of crops, two of which are useful for producing their own pesticides and the other two which are resistant to certain types of pesticides that can be used later in the crops produced. Furthermore, small farmers in developing countries have not benefited from these technologies because they have been designed primarily for the rich farmers in developed countries.

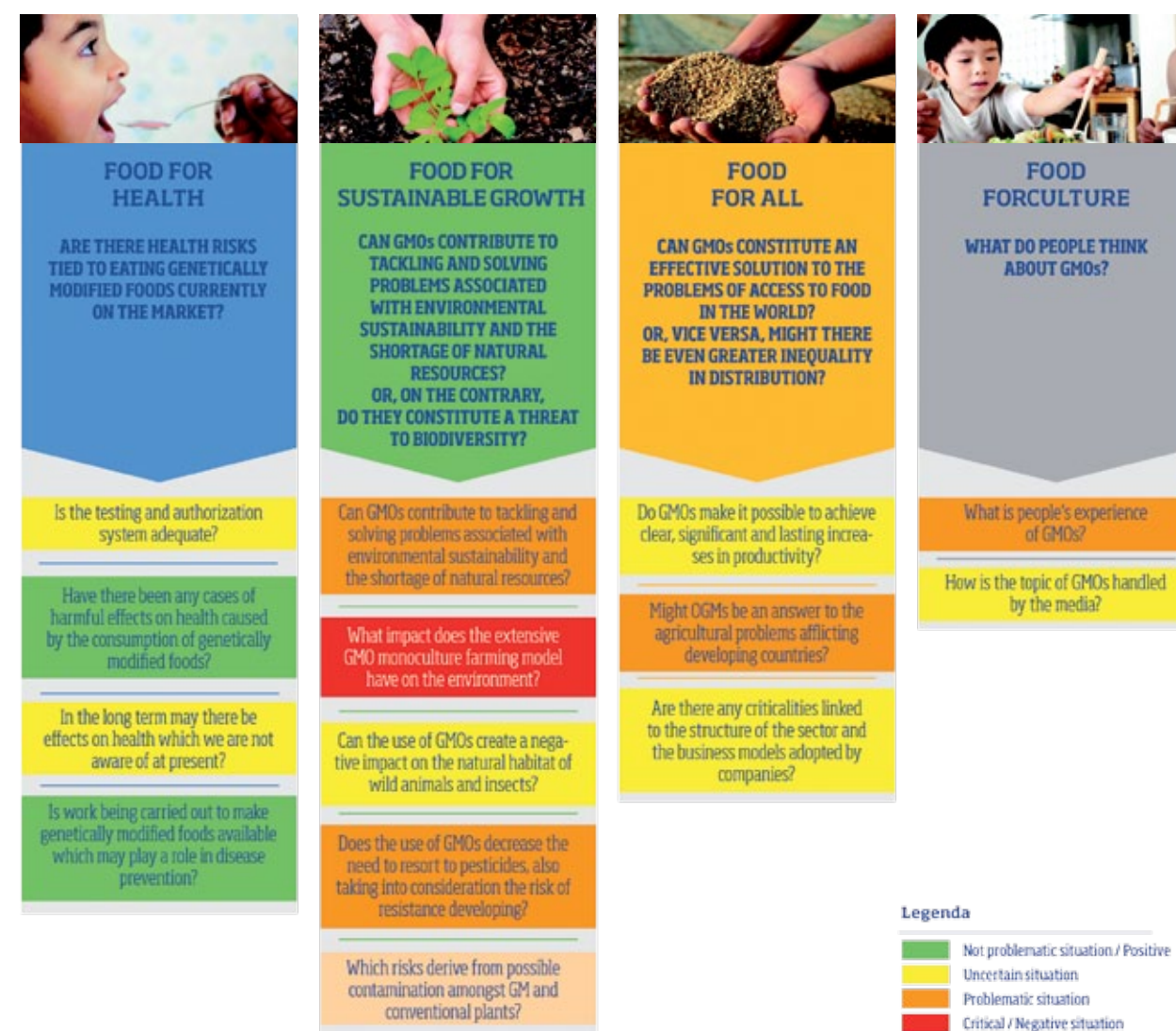
Although genetically modified soy has been produced on a large scale in some countries like Argentina and Brazil, it has essentially been useful for large producers and a type of agriculture that is not represented by the small-scale family farm, typical of many developing countries. So I think the real question is not only whether we should be for or against GMOs, but where to allocate the investments, whether or not the research has public funding and to try to promote innovation in agriculture. I think the money spent in the best way for innovation is that which is used to support the poorest families, whether it is being funded by the public sector or the private sector (this is not the crucial point).

What needs to be asked is: “Who will benefit and what will the impact on incomes be?” At the moment, I have to say that most of the research has been conducted with support from the private sector and for the benefit of the major agricultural entities, while too little has been done to support small farmers in developing countries. So there are many things that we could and should do regarding the issue of research, which probably could be best undertaken by public research centers, while still being partly financed by the private sector, if they meet the needs of small producers in developing countries.

In other words, I believe that GMO crops are actually a small part of a larger problem, which is figuring out what direction agricultural research should take and, from my point of view, that of helping the poorest farmers. Currently, GMO innovations have not had this kind of impact.

THE QUESTIONS ON GMOs POSED BY BARILLA CENTER FOR FOOD & NUTRITION

In the following pages you will find a detailed answer to all questions that are contained in the following scheme.



Currently, scientific studies carried out at the international level do not show evident acute effects on human health, at least in the short term. In the long term, there are elements that can give rise to the fear of negative effects, although studies are lacking for a final confirmation.

With regard to the concern for human health, there have been:

- the occurrence of some allergies, which the current European licensing system, however, seems to be able to identify;
- the antibiotic resistance, although the use of marker genes resistant to antibiotics has been the subject of a recommendation from the European Commission (but this is a recommendation that has not always been respected, as is evidenced by the case of the Amflora potato that contains them; the EMEA, the European Medicines Agency, has actually asked that it not be placed on the market);
- the risk of gene transfer; the results of scientific studies regarding this risk are still conflicting.

CAN GENETICALLY MODIFIED ORGANISMS HELP ADDRESS AND SOLVE THE PROBLEMS OF ENVIRONMENTAL SUSTAINABILITY AND THE SCARCITY OF NATURAL RESOURCES? OR, CONVERSELY, ARE THEY A THREAT TO BIODIVERSITY?

The most promising aspects of scientific research on this topic concern the creation of genetically modified foods with nutritional characteristics superior to traditional ones or even with protective properties against certain diseases.

This question has the least convergence between scientists and the highest rate of uncertainty.

On the other hand, the difficulty of obtaining reliable data depends on two factors:

- the *very nature of scientific research* in this open field, which makes it difficult to isolate the causes and effects and determine the correlations in a complex biological context;
- the *historical series of references*, which are still too short.

However, from the analysis of the scientific documents available, some risks clearly emerge that are associated with the introduction of GMOs into the environment, in particular:

- *loss of biodiversity*;
- *the risk of contamination* (particularly in areas of the species' origin);
- *increased use of pesticides/herbicides*;
- *an increase of the phenomenon of resistance to herbicides*;
- *damage to the natural habitat for wildlife*.

With the exception of the emerging phenomena of resistance to herbicides, there is currently no clear consensus by the scientific community on any of these risks.

But some recent episodes show that the simple introduction of GMOs, even if confined to experimental fields of limited size, may be the cause (even after years) of an unexpected and widespread contamination that affects not only the local market but also exports.

This justifies the heated debate at an institutional level over the criteria of regulation and control of the co-existence between GMO crops and traditional ones.

CAN GENETICALLY MODIFIED ORGANISMS BE AN EFFECTIVE SOLUTION TO THE PROBLEMS OF ACCESS TO FOOD IN THE WORLD? OR, VICE VERSA, COULD THEY CAUSE THE INEQUALITY TO INCREASE?

Access to food is a complex problem that brings a number of economic, social and political variables into play, interwoven within a framework that is difficult to interpret, even before any sort of intervention takes place. In this context, a single technology cannot claim to play a decisive role by itself in tackling the still unsolved problems.

To give a concrete contribution to resolving these problems, the products of genetic engineering should be consistent with the nature of the challenge and, thus, able to adapt to the local circumstances of different regional contexts.

Actually, GMO products on the market today were designed and developed “inside” and “for” capital-intensive, industrialized agricultural models, with large areas of cultivation, extreme mechanization and an intensive use of agrochemicals. The benefits they bring are more related to the effect of “insurance” than to the possibility of increasing the crop yield in a decisive way. Moreover, they tend to strengthen the single-crop vocation in many regions in the world.

We should remember that the GMOs on the market today are mainly used in the livestock, textiles and energy sectors, and therefore, their direct consumption by humans is marginal. Besides, we should remember that the GMOs on the market today are mainly used in the livestock, textiles and energy sectors, and therefore, their direct consumption by humans is marginal. They are characterized by a limited number of variants of plant species, mainly restricted to only two traits of interest (*Ht-herbicide tolerance* and *Bt-Bacillus thuringiensis*), consistent with highly integrated business models, in which the sale of agrochemical products plays a key role in ensuring the profitability of businesses.

Moreover, it is easy to see the scant interest of the industry in products or technologies to be allocated to marginal areas, which, instead, are those where the incidence of food insecurity is the greatest.

The picture is completed by considering the secondary role of public institutions in developing research on GMOs, not only because of political choices, but also due to the protection systems of property rights, which today are in the hands of a few multinationals.

In summary, GMOs – as we know them today – do not seem to play a significant role in alleviating hunger in the world, for a very simple reason: they were not developed with this goal in mind.

In summary, GMOs – as we know them today – do not seem to play a significant role in alleviating hunger in the world, for a very simple reason: they were not developed with this goal in mind. In contrast, there is higher concern about the risk of imbalances arising from the introduction of the intensive farming model in rural areas engaged in subsistence agriculture. To change this picture, we should fundamentally change the regulatory structure and incentives in the sector, in order to foster the development of initiatives specifically aimed at developing countries.

From the analysis of the choices that are sometimes made regarding the use of biotechnology and GMOs in food in Europe and elsewhere, a result emerges that is greatly influenced by a strong orientation toward the natural (understood as a lack or reduced intervention of human manipulation), which is closely related to health.

This shows a cross-cultural character and one can see that it does not reveal significant differences between Anglo-Saxon countries and continental European ones: people consider GMOs to be what is most “unnatural,” right from their original structure.

Especially when they are created through the transmission of genes between different species; the products modified with cisgenic techniques (the genes introduced into the DNA of the plant come from the same species) are more acceptable than the corresponding transgenic varieties.

According to Eurobarometer surveys, the degree of acceptance of GMOs has been decreasing in recent years. In particular, the decrease is very marked in countries (such as Spain, Portugal and the Czech Republic) where the cultivation of GMOs has been permitted for some time. This attitude also depends on the fact that, when faced with possible risks, the people do not perceive any direct benefit from the introduction of this new technology.

WHAT IS THE EXPERIENCE OF PEOPLE REGARDING BIOTECHNOLOGY AND GMOS?



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A first review of the position paper *Is GMO agriculture sustainable?*

Following the publication of the document under consideration, we felt it would be appropriate to subject the text to a review that involved several members of the national and international scientific community. While the outcome of this detailed review will be made public in a future reissue of the position paper, we wish to clarify two issues that are perhaps not yet entirely clear, which we have found to be particularly interesting to third parties, even those who are highly qualified.

The first aspect is the *criticism of the multidisciplinary formulation of the study*. There was disapproval of the strong characterization related to our choice of *framing* (approach to the problem): or rather, what was under dispute was our choice to link the different research perspectives together, combining scientific evidence with economic and social considerations. In this way, our work took on a certain perspective which was considered by some to be “unscientific.” While respecting the criticism in this regard, and having reflected at length on the merits of this fact, we believe that in order to understand the complexity of the problems today, it is essential to bring the different perspectives together in an interdisciplinary perspective. The facts are happening in the real world, and producing consequences. Sometimes, those same facts must be analyzed starting from their own consequences. Metaphors aside, if GMOs give rise – for deep-rooted causes of the economic model in the industry for which no one is individually responsible (and so there are both the good and the bad) – to

oligopolistic market structures and models of intensive single-crop agriculture, this is sufficiently clear to induce proposed solutions for overcoming those problems, outside the sterile logic of opposition. Without throwing the baby out with the bathwater, of course, but also without the easy absolution of those who argue that the socio-economic aspects cannot be subjected to proper scientific analysis.

The second aspect, instead, consists of the *criticism of the minor importance given to consensus documents elaborated by the scientific world*. That is to say, we have been reproached for not having adequately taken into account some *positions of consensus* expressed by the scientific community and have, therefore, neglected particularly significant texts of international scientific production which reduce the alarm concerning the potential impact on the environment and people's health. However, while we apologize for the bibliographic gaps (where they exist) and we thank the investigators who expressed possibly useful ideas for inclusion, we would like to clarify that – while we have very clearly presented the (moderately positive) position of the scientific community regarding the health risks – we continue to believe that the aspect of the assessment of environmental impact has not been fully addressed and we hope there will be a growing number of studies characterized by solid methodology and rigorous analysis. Given this persistent uncertainty regarding the environmental aspect, we prefer the adoption of practices that are at least partially prudent.



2. THE PRESENT AND FUTURE OF BIOTECHNOLOGY IN THE AGRICULTURE AND FOOD SECTOR

2.1 WHAT DOES BIOTECHNOLOGY IN THE AGRICULTURE AND FOOD SECTOR MEAN?¹

There is talk of biotechnology applications - in general - every time techniques are employed to “artificially induce changes in the structure and function of a living organism or a biological process for the end of practical usefulness.”² Among the possible definitions, on a deeper level, is that of the Convention on Biological Diversity, which defines biotechnology as “any technological application that employs biological systems, living organisms or derivatives of these to produce or modify products or processes for a specific purpose.”³ A similar interpretation is proposed by the FAO in its Glossary of Biotechnology.⁴

As can easily be seen by its definition, biotechnology includes a very wide range of technical and scientific applications that are used in various economic sectors, including agriculture. Modern agricultural biotechnology is a set of highly sophisticated techniques and tools used by scientists to *understand or manipulate the genetic makeup of organisms* for their use in the production or processing of agricultural goods. In fact, these techniques have their roots far back in time and are connected to a long history of attempts of crossbreeding and selection aimed at seeking the best and most profitable varieties.

Agriculture has always been closely linked with the progressive improvement of the species, the result of a continuous selection of desired characteristics. However, in recent decades, the progress made by scientific research has increased the potential of knowledge, as has intervention by humans, opening up prospects of development that were unimaginable before.

Various objectives may be pursued through the use of biotechnology in agriculture. In particular:

- *increase and stabilize yields;*
- *improve resistance* to pests, diseases and climatic stress phenomena such as drought and cold;
- *improve the nutritional characteristics* of food (healthy fruits, and a reduction of the toxicity of food and of allergens, increased nutritional components, such as vitamins);
- *increase productivity* of the factors and *economic returns;*
- *achieve acceptable returns even in partially unsuitable contexts.*

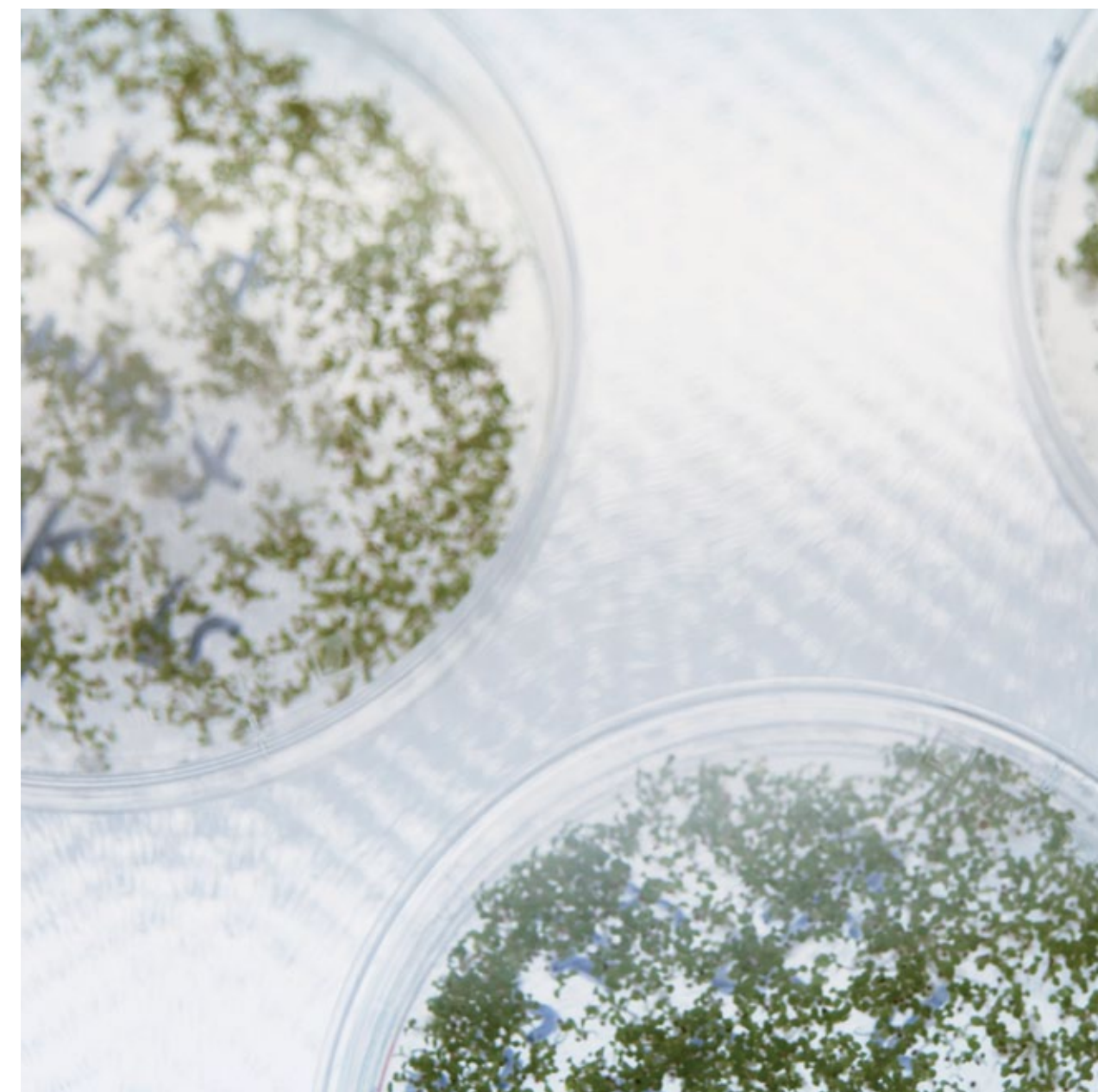
Also, considering possible targets related to its use, biotechnology is a tool of intervention that is not at all secondary among those that are useful for achieving the *productivity gains* necessary to adapt, over time, the offer of food products to the proportional increases in demand. Herein lies the main reason for the interest that it inspires today and the hopes that fuel it.

As mentioned in the first chapter (Section 1.3), a possible classification of biotechnology

used in the agri-food sector – particularly suited for understanding what different approaches are used – tends to identify two broad categories of intervention.

On the one hand, there are the *techniques of recombinant DNA*. These are more familiarly known as *genetic engineering* and refer to the modification of the genome of an organism through transgenesis, that is to say, the insertion, without sexual reproduction, of a foreign gene (called “transgene”) into the genome of a living organism that serves as a host, to change its outward manifestations.

On the other hand, there is the set of techniques whose contribution does not lie in the potential of genetic manipulation, but in *making information available to guide the traditional processes of analysis and selection of favorable genetic variants*. Knowing the characteristics of the genetic determinants of the traits of utility is, in fact, an essential precondition for effective actions for improvement.



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MODERN AGRICULTURAL BIOTECHNOLOGY CONSISTS OF A SET OF VERY SOPHISTICATED TECHNIQUES AND TOOLS FOR UNDERSTANDING AND MANIPULATING THE GENETIC MAKEUP OF ORGANISMS

2.2 BIOTECHNOLOGY IN THE AGRI-FOOD SECTOR: FROM ITS ORIGINS TO MODERN APPLICATIONS

2.2.1 A historical perspective

AGRI-FOOD BIOTECHNOLOGY HAS ANCIENT ORIGINS AND COMPRISES THREE PHASES OF STUDY: THE FIRST IS CALLED THE “UNAWARE AGE”

THE SECOND PHASE IS CHARACTERIZED BY THE STUDIES OF BIOLOGY AND BOTANY OF GREGOR MENDEL

THE THIRD PHASE IS LINKED TO THE DISCOVERY OF THE STRUCTURE OF DNA

Agri-food biotechnology has ancient origins. For many centuries they remained in a phase described by some historians of science as “old unawareness.” That is, a phase in which ranchers and farmers used empirical techniques, starting from attempts to improve crop yields, based on experience but without an adequate scientific basis.⁵ Only with the experiments of the Augustinian monk Gregor Mendel on the hybridization of plants in the nineteenth century were the first foundations laid for the future birth of a new branch of science, halfway between botany and biology, which will translate this knowledge into practical applications of technology: the so-called “conventional” biotechnology. In the monastery in Brno, Moravia, Mendel was devoted to the study of the hybridization of plants in order to understand the mechanisms and the scientific foundations of this practice used in agriculture⁶ and had shown that some of the characteristics of the plants he studied were transmitted to their offspring, as opposed to others. This is considered the second phase of biotechnological studies. However, the results of his studies on the inheritance of characteristics were long ignored by botanists of the time and were only taken up again in the twentieth century. In 1953, after the discovery of the structure of DNA,⁷ the third phase of biotechnology applications began, in which we find ourselves still today. The main object of study has become, precisely, DNA – the source of all essential information of any living being, either plant or animal, simple or complex, it also holds all the mechanisms of genetic inheritance. Needless to say, this is both a matter of a genuine revolution that preludes the first attempts at genetic engineering and the accumulation of an extraordinary amount of information used to support the “classical” processes of crossing, selection and hybridization.

2.2.2 Modern applications of biotechnology in the agri-food sector

HOWEVER, GMOS ARE JUST ONE OF THE OPTIONS THAT THE FOOD INDUSTRY CAN USE. IN FACT, A MULTITUDE OF OTHER MOLECULAR TOOLS AND TECHNIQUES EXIST THAT IMPROVE THE ABILITY OF CROPS TO ADAPT TO THE ENVIRONMENT

On another occasion,⁸ we explained in detail the technical characteristics of transgenic intervention on DNA, i.e., all those innovative practices designed to identify, manipulate and transfer genes from plants and animals. GMOs – which are one of the outcomes of genetic recombination techniques – are, however, just one of the options that the food industry can use. In fact, a multitude of other molecular tools and techniques exist, perhaps less known to the general public, which, without producing genetic alterations, can improve the ability of crops to adapt to the en-

BIOTECHNOLOGY	ERA	APPLICATIONS
Traditional	10,000 years B.C.	The first farmers begin to select the most useful wild varieties to improve crop yields.
	3,000 years B.C.	Production of beer and cheese, wine fermentation.
Conventional	Late 1800s	In 1865, identification of the laws of inheritance, thanks to Gregor Mendel, and the creation of the basis for the traditional methods of reproduction.
	1930	Development of the first commercial hybrid crops.
	1940-1960	Use of mutagenesis, tissue culture, regeneration of plants. Discovery of transformation and transduction. In 1953, the discovery of the DNA structure by Watson and Crick. Identification of genetic elements capable of moving from one location to another in the genome (transposons).
Modern	1970	Advent of gene transfer using recombinant DNA techniques. Use of embryo rescue and protoplast fusion in plant selection and artificial insemination for animal breeding.
	1980	Creation of insulin as the first commercial product derived from the transfer of genes. Tissue culture for mass propagation of plants and embryo transfer in animal husbandry.
	1990	Collecting the genetic footprint of a wide range of organisms. In 1990, the first tests in the field of genetically modified plant varieties, followed by the first commercial versions in 1992. Production of vaccines and hormones by genetic engineering.
	2000	Bioinformatics, genomics, proteomics, metabolomics.
	2010	Molecule markers, induced mutations, the characterization of germ plasm and tissue culture.

vironment. Among the main contributions in this regard, of primary importance is genomics,⁹ which has made it possible to characterize the germplasm, identifying the genes of interest and studying their behavior and interaction with other components of the genetic makeup. This, like many other developments in the understanding of the genome and its functioning, is the basis of the set of biotechnology aspects covered in this chapter. The following is a brief illustration of what are currently considered the main biotechnological applications in the agri-food sector that do not involve genetic modification. They

MOLECULAR MARKERS ARE IDENTIFIABLE DNA SEQUENCES THAT ARE TRANSMITTED FROM ONE GENERATION TO THE NEXT, ACCORDING TO TRADITIONAL MENDELIAN LAWS OF INHERITANCE

MARKER ASSISTED SELECTION (MAS) IS A METHOD OF ANALYSIS TO OPTIMIZE THE PERFORMANCE OF A PLANT VARIETY

are described individually, although in reality they are also combined with one another to maximize effectiveness. They are also divided into two groups that follow two main guidelines for using these technologies in the food sector: a) the analysis and selection of favorable genetic variations; and b) the creation of new genetic variations.

2.2.2.1 Analysis and selection of favorable genetic variants

Molecule makers

Molecular markers are identifiable DNA sequences, localized in specific points in the genome,¹⁰ that are transmitted from one generation to the next according to traditional Mendelian laws of inheritance. We are now aware of a large number of molecule markers¹¹ and in the last ten years, technology has significantly improved by developing more and more economic systems such as single-nucleotide polymorphism (SNP),¹² which is increasingly used today. Molecular markers have been used in research labs around the world since the late '70s and are used in most of the agri-food sectors. Versatile and functional in a variety of purposes, molecular markers are the basis for many technological applications that can vary greatly depending on specific technical characteristics, financial resources and technological intensity, as well as on the variety of genetic markers used.

The most widespread use of molecular markers is definitely aimed at genetic *improvement of a species* through the so-called marker assisted selection (MAS), a method of analysis that is able to optimize the performance of a plant variety through the use of molecular markers derived from DNA that orient the selection only to the traits of interest.

MAS (Marker Assisted Selection)

Marker assisted selection (MAS) is a technique that accelerates and simplifies the selection of the genotypes with the best features, mainly derived from crossings made in programs of genetic improvement of crops. All of this is achieved using the knowledge of genetics and molecular biology.

Specifically, it is a process by which a marker (morphological, biochemical, or based on changes in the DNA/RNA) is used for the indirect selection of a genetic determinant or determinants of a trait of interest. MAS is made possible and gradually improved thanks to the development of molecular marker maps made through the analysis of the DNA and thanks to experiments aimed at evaluating the statistics of possible associations between some variants of markers and certain features of interest. Maps of molecular markers are now available for a wide range of agricultural species and the most recent advances in the field of genomics¹³ are contributing more and more to generating information that is useful for the development of this application of biotechnology. In other words, through marker assisted selection, selection processes can be made faster and more effective thanks to a better management of available information.

If the main use of molecular markers is linked to the ability to select samples destined to become “parents” of future generations by implementing a selective process that can identify the organisms with desirable traits, it is not the only one. Molecular markers, in fact, are also used as effective research tools to discover the genetic basis of complex agronomic traits such as drought or salt tolerance or resistance to diseases and pests. They may eventually be useful for many other agricultural related applications, such

as the characterization of the germplasm of cultivated plants, the management of gene banks and the diagnosis of diseases. With the use of molecular markers, researchers can select a number of plant species at a very early stage and thereby save many years of hard work to develop new varieties.

Despite the technological advances of recent years, one of the major limitations of MAS is still the size of the initial investment. Even though cheaper and cheaper technologies are being developed, they are still very expensive if compared to traditional selective approaches. In the case of developing countries, there are still examples of applications of MAS to obtain new varieties, among which we can mention the “HHB 67,” a hybrid of pearl millet resistant to downy mildew (blue mold) or varieties of rice developed in India that are also resistant to mildew.

Characterization of germplasm

The characterization of germplasm consists of the *observation, measurement and documentation of inheritable traits of a plant species* intended for describing and understanding the genetic diversity of organisms. The characterization of the germplasm of the different species is the basis for many biotechnological applications that exploit acquired knowledge to strengthen the internal mechanisms of a plant and to more precisely address the traditional techniques of crossing and genetic improvement.

The developments in the field of molecular markers (MAS), as well as in genomics, have led to significant positive results in the study and management of molecular resources by increasing the level of detail of the analysis.

Thanks to the characterization of germplasm, it is possible to identify, select and then keep only the genetic traits of interest of the entire genome of a species, so that we can ensure its future reproduction. It must be stressed that these techniques are essential to ensuring broad access to the information collected and to guaranteeing an equitable sharing of the benefits deriving from them.

2.2.2.2 Creation of new genetic variations

Induced mutations

A mutation is called “induced” when it is caused by man and is not the result of a process of sexual reproduction. This is achieved, therefore, with all those techniques, including molecular biology, that – without adding new plant genes to the organism under study – enable the creation of new genetic variations. The type of induced mutation that is obtained is generally predictable, since each mutagen has its own specific mutations.

Nevertheless, it is very difficult to determine a priori where these mutations will occur and then determine what effect they will have on the whole organism. We now present the main technologies developed in this area.

MUTAGENESIS

Mutagenesis is a mutation induced at the DNA level, involving the use of mutagenic agents (physical or chemical, with or without the specific mutation). It is a matter of stable and inheritable changes that take place against the genome. The physical mutagens are mainly ionizing radiation (like X-rays and Gamma rays) and non-ionizing radiation (such as UV rays); chemical agents, however, are very numerous and belong to different classes of compounds.

THE CHARACTERIZATION OF GERMPLASM CONSISTS OF THE OBSERVATION, MEASUREMENT AND DOCUMENTATION OF INHERITABLE TRAITS OF A PLANT SPECIES INTENDED FOR DESCRIBING AND UNDERSTANDING THE GENETIC DIVERSITY OF ORGANISMS

A MUTATION IS CALLED “INDUCED” WHEN IT IS CAUSED BY MAN AND IS NOT THE RESULT OF A PROCESS OF SEXUAL REPRODUCTION

THE MOST WIDESPREAD INDUCED-MUTATION TECHNOLOGY IS MUTAGENESIS, WHICH INVOLVES THE USE OF MUTAGENIC AGENTS SUCH AS CHEMICALS OR RADIATION TO ALTER THE DNA

Certainly the most widespread induced-mutation technology is mutagenesis, which involves the use of mutagenic agents such as chemicals or radiation to alter the DNA and, thus, create new genotypes. This category also includes somatic mutagenesis, whereby tissue cultures or cells may undergo useful epigenetic modifications that are found later in stable traits in future generations. Induced mutagenesis has been carried out with success since 1930, but its scope and its usefulness have recently been strengthened and expanded by the discovery of TILLING.¹⁴ Using these technologies, it is possible to manipulate only the genes already present in the genome, without, as in genetic modification, adding any new component.

Almost all mutations result in a loss of function in the mutated gene. In other words, the mutagenesis is aimed at reducing the adverse effects of genes rather than at accentuating the expression of desirable genes. This limitation is only apparent, however, compared to the creation of new useful agronomic traits, since recent genomic studies have shown that, during the 10,000 years of agricultural history, the alleles of reduced functionality were at the basis of 9 out of the 19 key episodes of plant species improvement.¹⁵

Currently, mutagenesis is one of the few technologies used significantly more in developing countries¹⁶ than elsewhere. This is due to the fact that public agencies and universities, which originally were the advocates of some of the most effective modern techniques of mutagenesis, have not protected the intellectual property rights at all, with the consequence of not having hindered their public use in any way. As a result, many varieties of mutagenic crops have been produced by and for developing countries. Both mutations induced by chemical agents and those obtained through radiation have been used for crop improvement in these countries for more than seventy years and, by early 2009, more than 2,770 varieties derived from mutagenesis were being marketed in some 59 countries, mostly Asian. The most significant mutagenesis programs are implemented in China and India, but many other countries are also making use of these techniques.

The most widespread mutagenic crops are: Soghat wheat (Pakistan), Zhefu rice (Thailand), Shwewartun rice (Myanmar) and Bajra pearl millet (India). In Vietnam, thanks to mutagenesis, three new rice varieties have been developed; since 1996, they have helped the incomes of small landowners to increase about 350 U.S.\$/year, thanks to improved nutritional properties and an increased salt tolerance.

TILLING, ECO-TILLING

TILLING is a reverse-genetic system (from gene to phenotype) that allows the direct identification of point mutations in charge of a specific gene, thanks to various molecular biology techniques. TILLING is also very efficient in the identification of natural allelic variation in a gene of interest (in this case the technique is called Eco-TILLING).

TILLING CAN BE CONSIDERED THE NEW TECHNOLOGICALLY-ADVANCED VERSION OF CONVENTIONAL MUTAGENESIS

TILLING can be considered the new technologically-advanced version of conventional mutagenesis. Specifically, it is a molecular biology technique that allows the direct identification of mutations in a specific gene of interest through a methodology of semiautomatic and high-yield analysis of the DNA.

Used primarily as a technology in the analysis and selection of mutagenic species, TILLING can also be used to analyze the variations in natural populations not subject to any process of induced mutation, in which case we speak of Eco-TILLING.

Tissue culture

Tissue culture consists of a set of techniques for *in vitro culture* of plant cells or tissues within an artificial nourishing environment under sterile conditions. These applications have been widely used for over 50 years and have recently also been applied to improve some of the most important crops in developing countries (for example, rice and potatoes).

There are many molecular techniques that fall into this category and each responds to different specific purposes. Two of the most important are: *somatic hybridization* and *micropropagation*.

SOMATIC HYBRIDIZATION

Somatic hybridization is a technique by which we obtain hybrids called “somatic” from plants of these species and/or incompatible genres, in which traditional hybridization is impossible.

Somatic hybridization aims to broaden the range of possible changes in plant species through the importing of whole chromosomes or genes from other species that are not sufficiently predisposed for a normal sexual crossing. Similar to traditional hybridization techniques, *somatic hybridization* occurs using a more radical approach and with a more pronounced use of technology. Starting from the development of sophisticated techniques of microinjection and cell fusion, this application has made possible the fusion of whole cells, or parts of them, to create new cells from species that are not related to one another.

The cells thus obtained then become subject to different treatments (for example, colchicine or *in vitro* regeneration) to facilitate the multiplication of the chromosomes and the long-term stabilization of the new genome.

Currently, the main problem, which research related to this biotechnology has not yet managed to overcome, is precisely that of the instability in the succession of generations of the new genome derived from the combination of two unrelated species. Nevertheless, somatic hybridization is the subject of increasing attention, including from developing countries, and especially with regard to the crops of some species of fruit. The interest in this technology can be found not only in the successful results obtained so far, but also in the fact that it may resemble transgenesis, although it is not considered to be a genetic modification by the regulatory authorities. The varieties generated obtained with this approach are, therefore, not subject to inspection and testing requirements normally expected for the transgenic varieties, which opens up significant new business opportunities for farmers.

MICROPROPAGATION

Micropropagation is an “*in vitro*” propagation method of a plant which produces a series of clones with the same genetic heritage as the mother plant. It is, therefore, a “technological” method for cloning plants which is based on the same principle as traditional cuttings or layering. This technique is applied mainly in the nursery sector and permits the industrial proliferation of plants, primarily fruit, and those for ornamental and forestry use. It is also widely used to cure virus-infected plants.

Finally, among the various tissue cultures there is the so-called *micropropagation*, which is the technique of propagation of a plant that, through the use of modern methods of *in vitro*

TISSUE CULTURE CONSISTS OF A SET OF TECHNIQUES FOR IN VITRO CULTURE OF PLANT CELLS OR TISSUES WITHIN AN ARTIFICIAL NOURISHING ENVIRONMENT UNDER STERILE CONDITIONS

SIMILAR TO TRADITIONAL HYBRIDIZATION TECHNIQUES, SOMATIC HYBRIDIZATION OCCURS USING A MORE RADICAL APPROACH AND WITH A MORE PRONOUNCED USE OF TECHNOLOGY



NERICA rice: the potential of a grain of rice

One of the most recent achievements in the application of biotechnology in agriculture is the development of the new variety of NERICA rice in Africa. Developed in 1990 by a group of farmers/researchers of the Africa Rice Center in Bouaké, Ivory Coast, this variety is the result of hybridization between *O. glaberrima* and *O. sativa*, two species that are not sufficiently predisposed for natural crossbreeding. In fact, their crossing uses advanced techniques of tissue culture, creating embryos of plants that are able to survive and grow to maturity. The NERICA variety presents some characteristics that make it particularly interesting in the African context: a greater number of grains (75 to 100 grains per plant, up to 400 approximately), a higher yield (from 1T/ha to 2.5 t/ha up to 6-7T/ha with the optimal use of fertilizers), 2% more protein than the parental species, a better resistance to pests and weeds

and increased tolerance to drought and infertile soils.

If rice is a cash crop for most small-medium farmers of Southern and Eastern Africa, it is a subsistence crop in West Africa, instead, and in this area NERICA rice has had a more significant impact, contributing to a 50% increase in the yields of rice crops in the mountains. According to the Africa Rice Center, today the NERICA variety can be found in 30 African countries, covering a total area of about 0.2 Mha, mostly in the Ivory Coast, Guinea, Nigeria and Uganda. As well as bringing benefits to rural economies, NERICA rice contributes to supporting national economies with reduced liquidity by reducing the cost of food imports in hard currency. It has been estimated, for example, that the introduction of NERICA in Guinea led to a savings on imports of about 13 million U.S. dollars in 2003.

MICROPROPAGATION DIFFERS FROM OTHER PLANT PROPAGATION TECHNIQUES BECAUSE OF ITS SOPHISTICATION, WHICH PERMITS THE REPRODUCTION OF CLONES THAT ARE FREE OF VIRAL BACTERIAL INFECTIONS, AND ITS ABILITY TO OBTAIN AN ENORMOUS AMOUNT OF INDIVIDUALS FROM VERY LITTLE SOURCE MATERIAL

culture of plant cells and tissues, creates clones from the plant itself, i.e., a set of individuals with the same genetic heritage.

Micropropagation differs from other plant propagation techniques because of its sophistication, which permits the reproduction of clones that are free of viral bacterial infections, and its ability to obtain an enormous amount of individuals from very little source material. The specificity of this aspect is particularly interesting for those countries where climatic conditions or pestilence make the growth and development process of a crop slow and difficult. Today, this technology is used in developing countries in many food crops such as bananas, cassava, potatoes and sweet potatoes, etc. The main countries that have micropropagation programs include: Argentina, Cuba, Gabon, India, Indonesia, Kenya, Nigeria, Philippines, South Africa, Uganda and Vietnam.



Ira Block/National Geographic Stock

The micropropagation of oil palms: learning from mistakes

One of the most common risks in the mass propagation of clones obtained by micropropagation is the generation of anomalies during the process of tissue culture. In 1980 in Malaysia, an entire commercial program of mass propagation of palm plants for oil that descended from superior lines was jeopardized when, having matured, the trees proved to have a serious anomaly that compromised their fertility and, therefore, the development of flowers. This specific phenotype made it impossible for the generation of fruit needed for the production of oil, and millions of plants cultivated years before have also proven to be useless, causing significant losses to the entire Malaysian agricultural sector and throwing it into a critical situation of stalemate. In the specific case of palm plants, the problem was also compounded by the fact that, usually, the fruit takes 5 years to mature on the plant and this has contributed to lengthening the time for the diagnosis of abnormalities and proportionally increasing the maintenance costs of the plantations (which are substantially higher than the maintenance costs of a car!) of the plantation. Following this episode, the techniques

of mass propagation of palm plants for oil have gradually improved. Numerous public and private research programs have investigated the root causes of the phenotype responsible for the abnormalities during the process of tissue culture, thereby permitting more precise and accurate techniques to be developed. Thanks to specific knowledge of the mechanisms of tissue culture and possible epigenetic interactions, the use of the propagation of clones in the cultivation of palm oil plants has, thus, begun once more, albeit still on a small scale. Unusual flowering still occurs, but, thanks to advances in technology, now it can often be identified and removed at an early stage, resulting in a higher percentage of success in the production of fertile plants.

The Malaysian case illustrates some of the problems that can arise from tissue culture when the manipulation aimed at the regeneration of plants causes developmental abnormalities. Even with these limitations, which research is focusing on today, tissue culture and mass propagation are, nevertheless, applications that are very important for developing countries.

2.3 THE ROLE OF BIOTECHNOLOGY INNOVATION: WHAT CHALLENGES AND WHAT ANSWERS?

TO ANSWER THE QUESTION “WHAT INNOVATIONS DO WE HAVE AND WHAT INNOVATIONS DO WE NEED IN AGRICULTURE?,” ONE MUST IDENTIFY THE NEEDS, PROBLEMS AND CHALLENGES THAT THE GLOBAL AGRICULTURAL SECTOR WILL FACE IN THE FUTURE

To answer the question “what innovations do we have and what innovations do we need in agriculture?,” one must identify the needs, problems and challenges that the global agricultural sector – as a whole and particularly in developing countries – will face in the future.¹⁷

On the one hand, the issue of controlling crop diseases and pests – to ensure adequate yields, stability of production and food security – will continue to be central; on the other hand, what sharply emerges is the need to identify approaches and techniques that allow us to cope with the changes which are taking place (and are expected to increase) in relation to two key factors: the availability of water and soil quality.

However, there is still a central issue in agricultural productivity: if it is true that, currently, the problems – as acknowledged by many experts – lie more in the distribution of global agricultural production than in its absolute size, it is also clear – and highlighted by such bodies as the FAO – that in some parts of the world, agricultural yields still constitute a serious problem, reaching levels below those achieved in the past in developed countries, a fact which is attributable to different development paths. The issue of the optimization of agricultural techniques (even basic ones) aimed at improving yields is undoubtedly at the center of the debate on innovation in agriculture, especially when considering that part of the world – more than others – requires a significant process of improvement in the average living conditions.

Directly and indirectly linked to all the topics listed above, the *quality of food* seems to emerge as one of the main problems identified by all experts in relation to global food security. The issue is not easily stated, since the current situation presents one of the largest imbalances and – in some ways – the greatest concern in recent decades. Faced with a growing number of people with overweight conditions and obesity (especially in developed countries), there is the unsolved problem of entire populations that are undernourished and malnourished (especially in developing countries), with serious implications in terms of the lack of macro- and micro-nutrients which are essential for a healthy life and, often, even survival. This issue is central and is linked to all the other major challenges to which world agriculture will be called to respond.

All innovations – whether technological, technical, processes or simply the rediscovery of mistakenly abandoned agricultural approaches – must henceforth be judged not only on whether or not they have achieved the purposes for which they are employed, but they must also demonstrate the extent to which they will be able to contribute to promote – directly and indirectly – the overall sustainability (environmental, economic and social) of the agri-food system in the coming decades. In this regard, it is also worth pointing out how long-term sustainability cannot help but be “dynamic,” that is, constantly reinterpre-

ted and redefined in light of changes occurring on the social, economic, environmental and technological levels. There is, therefore, no “one” definition of sustainability that remains unchanged in its constituent parts. In this sense, it should be stressed that *each agricultural practice and any technology can be, in itself, a useful piece for composing the big picture of sustainability; every innovation is necessary if, and to the extent that, it helps to shape – either directly or indirectly – a scenario for the future sustainability of food and agriculture worldwide*. Recognizing this principle, of course, does not mean giving up pinpointing, case by case, any doubts about the real possibility that some approaches and technologies can contribute significantly to overall sustainability, even and especially in more fragile agricultural contexts.¹⁸

One of the key issues relating to sustainability is the identification of techniques, practices and technologies to improve food security and the socio-economic stability of agricultural sectors in relation to the spreading – there are fears of this happening on an ever-larger scale – of plant diseases, insects and pests. The theme is certainly not new, the history of agriculture has always been characterized by a continuous struggle of man to protect his crops from attacks by nature itself. Chemical tools and agronomic practices have been identified over the centuries and are currently being used to cope with the many events of this type. However, one aspect of concern raised by experts in the world (and the FAO itself) is represented by the occurrence (and possible intensification) of far-reaching attacks by viruses, with serious effects on agriculture, as well as economic and social consequences in the affected areas (think of the case of the papaya in Hawaii). In the medium term, one of the areas of research that seems to achieve good results deals with the development of resistance to viruses through the use of MAS. Besides the ability to cope with the spread of viruses, what is interesting is the development of endogenous resistance to insect pests and pathogens, which is obtained by using traditional breeding techniques, assisted – where possible and appropriate – by molecular genetics.¹⁹ In this regard, an example is the use of MAS in a *breeding* program in India designed to generate bacterial resistance in a variety of local rice which is particularly at risk.²⁰ Finally, progress has been made in the development of resistance to fungi: although, as noted by the FAO, it is hard to find solutions which are able to guarantee resistance that is of a broad spectrum and long-term. Fungi grow wild in the fields in new forms for which the types of resistance previously developed by the plants are ineffective. In general, the development of effective and durable resistance to bacterial and fungal pathogens involves the transfer of a significant number of genes; however, each agricultural context represents a case apart. In light of these considerations, the FAO thought it best to use non-transgenic technologies and approaches, based on the knowledge and experience that is currently available.

Similarly, experiments aimed at conferring resistance to forms of insects have not been able to guarantee long-term coverage against this risk, since they face critical issues similar to those identified for fungi and bacteria. Moreover, according to many experts, strategies for the improvement of plants that rely on the use of antibiotics against possible attack by insects constitute a possible threat to biodiversity, because they run the risk of influencing both the target organisms and the *non-target* organisms which are found simultaneously in the field. Research and experimentation aimed at developing resistance to insects are those related to *antixenosis*, or rather, the development of plant characteristics that make them inhospitable to insects, producing effects that cause the insects themselves to avoid them. Though complex, research in this field has been carried out successfully in recent years (on wheat, for example), thus foreshadowing possible future and positive developments (even if – at present – a practical application seems remote).

One of the areas where it is expected that research will focus its greatest efforts from

ONE OF THE AREAS OF RESEARCH THAT SEEMS TO ACHIEVE GOOD RESULTS DEALS WITH THE DEVELOPMENT OF RESISTANCE TO VIRUSES THROUGH THE USE OF MAS

ALL INNOVATIONS MUST NOT ONLY BE JUDGED ON WHETHER OR NOT THEY HAVE ACHIEVED THE PURPOSES FOR WHICH THEY ARE EMPLOYED, THEY MUST ALSO DEMONSTRATE THE OVERALL SUSTAINABILITY OF THE AGRICULTURAL SECTOR IN THE COMING DECADES



now on – also thanks to the support given by biotechnology – is the prevention and monitoring of the onset and spreading of new diseases and new species of insect pests, even more so today since the agricultural sector worldwide is increasingly globalized, creating a serious risk of contagion among geographic areas that are far from one another.²¹ Through the use of modern biotechnology, molecular kits can and should be developed that enable teams of experts (and non-experts) a better, less expensive and more timely monitoring of the health status of crops in different parts of the world, including those in developing countries. In addition, biotechnology will be crucial in the rapid identification of new pathogens (and their genomic sequences), facilitating the development of control and defense strategies.

Along with controlling diseases, insects and pests, one of the key issues in terms of innovation will be represented by the identification of effective and efficient responses to abiotic stresses that – in part due to the current and expected effects of climate change on agriculture – probably represent the greatest challenge to agricultural sustainability in the coming decades, especially in areas of the world such as Africa and the Middle East. The combination of lack of water and gradual salinization of the soil is the main problem in terms of agricultural productivity and a leading cause of phenomena of famine in arid and semi-arid regions of the planet. Far from being a problem confined to arid regions and developing countries, the progressive deterioration in the average quality of the soil basically involves – in more or less serious ways – the entire agricultural sector worldwide. The issue of the efficient use of scarce water resources concerns the whole world.

Although abiotic stresses are often considered “exogenous factors” to agricultural productivity, many experts believe there is ample room for research and experimentation in the improvement and genetic selection of the plants themselves in response to such stresses.²² In particular, the genetic diversity within the single families of plants (whether identified in the wild variants or in other genetic crops) may represent, also in the future, a source of “variability” useful in developing forms of tolerance to abiotic stresses. Modern biotechnology (in this case, especially the characterization and screening of the germplasm) has a central role in the development of this line of research.

A field which is still largely unexplored, but which might see significant development in the years to come, is represented by research on the *rhizosphere*, i.e., the portion of soil immediately in contact with the roots of plants. Research on the flora itself in the rhizosphere, on the possibility of creating strains with inocula particularly suited to specific soil conditions and, finally, their possible role in mitigating the impact of drought, salinity and nutrient-poor soil appear to be – at least in perspective – of particular interest, especially in developing contexts characterized by semi-arid/arid conditions.

If, in general, biotechnology plays a supporting role in the development of plants which are better able to tolerate abiotic stress, transgenic approaches, however, do not appear to have proven to be particularly interesting.

On the one hand, knowledge of plant metabolism associated with the occurrence of abiotic stresses is still largely incomplete, thus limiting the possibilities of genetic manipulation. On the other hand, there is – always – the presence of significant synergistic effects of different stresses on the health and productivity of plants: often, the combination in the field of multiple abiotic stress represents the most critical one, making it difficult to isolate a single factor in the laboratory. In addition, tolerance to salt and drought seems to be represented, in both cases, by a complex multi-gene trait characterized by an evolution in several different plant families. In an open environment, this complexity renders inefficient the approaches that are based on genetic engineering – which today is often focused on one critical factor – and suggests the adoption of more multi-dimensional approaches.

THE COMBINATION OF LACK OF WATER AND GRADUAL SALINIZATION OF THE SOIL IS THE MAIN PROBLEM IN TERMS OF AGRICULTURAL PRODUCTIVITY AND A LEADING CAUSE OF PHENOMENA OF FAMINE IN ARID AND SEMI-ARID REGIONS OF THE PLANET

IF, IN GENERAL, BIOTECHNOLOGY PLAYS A SUPPORTING ROLE IN THE DEVELOPMENT OF PLANTS WHICH ARE BETTER ABLE TO TOLERATE ABIOTIC STRESS, TRANSGENIC APPROACHES, HOWEVER, DO NOT APPEAR TO HAVE PROVEN TO BE PARTICULARLY INTERESTING

Some results in the development of tolerance to salinity and drought have been obtained in the laboratory, but it is not yet clear whether such research will be successful in the complex reality of “actual” farming systems.

In this regard, in 2004, Tim Flowers of the University of Sussex recalled that “after ten years of research using transgenic plants to alter salt tolerance, the value of this approach has yet to be established in the field;”²³ a few years later, this statement remains valid. Moreover, contrary to what is recorded with respect to the resistance to soil salinity, not many significant research efforts appear to have been carried out regarding drought resistance – until relatively recently – not even by public organizations.²⁴ In the latter case, the research is strongly influenced by the extreme complexity of the multifactorial relationships underlying the resistance to drought: the FAO summarizes this complexity in the concept of “genotype * environment * management,” to highlight the need for an integrated approach to the problem.²⁵

In the future, biotechnology (such as MAS) will make it possible to have a better understanding of the complexity associated with the resistance to drought and salinity of plants, of the interaction between different kinds of stress, and the coping mechanisms that are expressed in particular species or stages of development. In this sense, many experts have expressed their support to focus resources on non-transgenic breeding approaches, rather than on research of the physiology and the molecular genetics of tolerance to abiotic stresses.

Non-transgenic *breeding* methods are available for understanding and improving the agronomic performance of plants which are already relatively tolerant to salinity and drought, found in more “extreme” environments as the manifestation of these stresses: in particular, MAS or tissue culture methods could be used effectively to introduce the traits of salinity and drought tolerance in different local varieties.

At the basis of research and innovations for improving plant resistance to the critical issues that the external environment can present (whether they are pathogens, the lack of water or the degradation of soil quality), there is the issue of *agricultural productivity*: innovative biotechnology applications are able to help – at least in part – with the improvement in yields, even and especially in developing countries.

If two of the areas of greater innovation are identifiable in the *manipulation of seed development* (higher yields through seeds that are larger and/or able to accumulate a larger amount of items deemed desirable, such as starch, for example) and in the *manipulation of plant architecture* (in order to reduce unproductive, inedible or noncommercial parts), a great deal of innovation in agriculture – especially in non-advanced contexts – should be made through the study and introduction of technical and agronomic practices (not necessarily new, probably adapted from the past) aimed at achieving the productivity gains which were never achieved in the past by many developing countries.

As noted by Vernon Ruttan, “substantial gains in productivity are feasible [in many contexts] due to a strategy that emphasizes the use of traditional breeding combined with the use of better technology, with the improvement of soil quality, with an effective management of crops, and through the use of biotechnology for the first generation aimed at the protection of crops.”²⁶

The best formula, as also observed by the FAO, seems to be a combination of breeding approaches based on modern biotechnology and agricultural management techniques borrowed from the experience gathered over the decades in the agricultural context in developed countries.

Research on productivity improvements through the use of biotechnology is developing at the global level.

On the one hand, research for productivity improvements through the use of biotechnology that is developing at the global level, is now also a reality in developing countries worldwide. On the other hand, genetic engineering has shown – especially in temperate climates, where it has had its greatest practical application – to be able to compete only in a way that is relative to the inherent increase in the yield under standard conditions.²⁷

The FAO points out that, by analyzing the factors underlying the increase in yields of corn in the U.S. from the '20s to the '90s, an estimated 60% of the increase was attributable to improvements in breeding and 40% to improvements in the management of all other factors (agricultural practices, effective use of inputs, mechanization, etc.).

The research to improve crop yields, even and especially in developing countries, must be combined with the use of more advanced tools for breeding (MAS, TILLING etc.), assessment processes, improvement of farming techniques and crop management. In less developed contexts, improved agricultural practices must be accompanied by mechanization, while in the more developed contexts, we should focus on improving breeding, so that the ongoing research can achieve better results than those conducted so far in the field of genetic engineering.

In general terms, on the one hand, the use of molecular markers seems to generate high expectations for the future; on the other hand, the combined focus on genotypes and their interaction with the environment and the attention to approaches for sustainable management will lead to a common challenge for developing and developed countries.

However, the issue of improving agricultural production cannot be confined to simple quantitative data. Improvement of agricultural production also means – and this is one of the main challenges that the agri-food sector is asked to respond to – improving the quality of food; to respond both to a Western world increasingly characterized by the diffusion of overweight conditions and obesity, and to a set of developing countries characterized – to varying degrees and intensities – by a widespread condition of malnutrition, or that is to say, the lack of essential macro- and micro-nutrients.

Improvement of the nutritional quality of what is grown has always been sought: specific varieties of different plants have historically been selected to obtain certain amounts of macro- and micro-nutrients. Modern biotechnology has been viewed by some experts and researchers as extremely useful and effective for obtaining similar improvements over time and with significantly lower costs than those experienced in the past. Nevertheless, even though some of these experiments have been in progress for years – in part through the use of transgenic techniques – no plant variant with these characteristics has yet been marketed. Several experiments are being conducted (for example, regarding the possibility of including omega-3 fatty acids within the plant for the production of vegetable oils²⁸), but most of these attempts represent an effort in research and innovation that will see – possibly – a practical application only in the medium to long term.

One of the most debated aspects, and the focus of public opinion, in terms of improving the nutritional quality of crops regards the use of biotechnology to alleviate conditions of severe malnutrition in those areas of the world where an integrated approach – aimed at the diversification of the average diet – is not easily feasible (due to the very absence of alternative foods).

Different techniques of biofortification have been used for attempting to increase levels of some key nutrients within the crops found in some areas of the world which are particularly at risk of malnutrition. In recent years, several methods have been used for attempting to increase the levels of some key nutrients (especially vitamins and minerals) within the crops found in some areas of the world which are particularly at risk of malnutrition: these are the so-called *biofortification* techniques.

RESEARCH ON PRODUCTIVITY IMPROVEMENTS THROUGH THE USE OF BIOTECHNOLOGY IS DEVELOPING AT THE GLOBAL LEVEL

THE COMBINED FOCUS ON GENOTYPES AND THEIR INTERACTION WITH THE ENVIRONMENT WILL LEAD TO A COMMON CHALLENGE FOR DEVELOPING AND DEVELOPED COUNTRIES

ONE OF THE MOST DEBATED ASPECTS, AND THE FOCUS OF PUBLIC OPINION, IN TERMS OF IMPROVING THE NUTRITIONAL QUALITY OF CROPS REGARDS THE USE OF BIOTECHNOLOGY TO ALLEVIATE CONDITIONS OF SEVERE MALNUTRITION

THE IDEAL SOLUTION TO THESE SERIOUS PROBLEMS OF MALNUTRITION REMAINS THE CREATION OF STRUCTURED AND SYSTEMIC INTERVENTIONS TO REDUCE POVERTY, EDUCATE, AND TRANSFER KNOWLEDGE AND BASIC AGRICULTURAL TECHNIQUES

The most famous case of biofortification is the “Golden Rice Project,” which has been carried out since the early nineties by a mixed public-private consortium. For a discussion of specific problems and opportunities of this project, please refer to the position paper *Is GMO agriculture sustainable?*, published by the BCFN in 2010. We limit ourselves here to mentioning that the experience has not yet led to a commercialization of the product and that some experts have pointed out a number of critical issues regarding the overall socioeconomic-agricultural impact of the project. The benefits, and any of its possible problems, have yet to be fully assessed in light of the actual introduction into different geographic areas.

Some experiments are under way in Africa. The HarvestPlus consortium has undertaken some breeding programs (based on the use of all available biotechnologies, including MAS), focusing on three key elements for nutrition: iron, zinc and vitamin A.

A characteristic that is particular to this program is the focus dedicated to the analysis of the availability of essential micro-nutrients, even within the existing crops and the food actually consumed in the areas considered, in order to broaden the food base and help foster a gradual balance between agricultural/food habits and biofortification.

Also in Africa, “Vitamin A for Africa partnership” (VITAA) is pioneering the introduction of vitamin A in the sweet potato (which is widespread in the continent), through the use of conventional breeding techniques. For the future development of this crop, micropropagation techniques are being evaluated (recognized by the FAO as a tool for success in the African context²⁹).

In general, the ideal solution to these serious problems of malnutrition remains the creation of structured and systemic interventions to reduce poverty, educate, and transfer knowledge and basic agricultural techniques. A solution that is able to bring significant benefits in the long run can only be based on a process of gradual diversification of the diet and the introduction, where necessary, of those crops that could support – from the inside – the process itself. However, in some cases of particular gravity, and in which there have been crucial problems in actually obtaining food that is different from what is normally consumed, the FAO also recognizes the merit in approaches that – alongside a systemic intervention – provide forms of biofortification in crops which are commonly used by local populations, in order to alleviate short-term situations of serious food insecurity.

If biotic stress, abiotic stress, productivity and food quality are the four major macro-issues that innovation in the use of biotechnology is being directed to, there is still the basic large cross-cutting issue of *sustainable agriculture*, which will play an important role mainly for the choices, the applications and the innovations that the agri-food world will put into act.

The answers to the great challenges cannot disregard the fact that the world is approaching the limits both of the amount of land available for cultivation and the use of models of intensive cultivation, with their high use of inputs and high dependence on the use of fossil fuels.

There are two areas related to the role of biotechnology for sustainability that are particularly critical at the moment: on the one hand, the possibility emerges of replacing inorganic inputs with biological agents, with positive effects in terms of reducing the energy used for cultivation, the environmental impact and the management costs associated with the use of large-scale chemistry; and on the other hand, there is an area of research and innovation that is emerging in recent years which is defined by the FAO as “agroecological system dynamics,” characterized by a fundamental change of approach to the concepts of adaptation, uncertainty, vulnerability and resilience in agriculture.³⁰



MODERN BIOTECHNOLOGY SEEMS TO GUARANTEE A SET OF INSTRUMENTS WITH GOOD POTENTIAL FOR THEIR APPLICATION, BUT WHICH MAY NOT BE THE ONLY ASPECT OF "INNOVATION" FOR RESPONDING TO BOTH PROBLEMS AND OPPORTUNITIES, PRESENT AND FUTURE

There is still the unresolved problem of how to balance the attention given to the sustainability of world agricultural production with the needs (old and new) of productivity and the response from the agricultural world to the challenges posed by climate change.

Modern biotechnology seems to guarantee a set of instruments with good potential for their application, but which may not be the only aspect of "innovation" for responding to both problems and opportunities, present and future. It is, thus, necessary to identify – through the modern techniques at the forefront of agricultural biotechnology that will surely develop further in the future³¹ – an integrated approach in which they play a central role within a wider framework and in which innovation and adaptation of approaches and agricultural techniques, crop management and dissemination of basic agricultural skills which are found on a vast scale worldwide all converge.

Another big question remains open, regarding the future participants and future resources of research and innovation in the agri-food sector. This will inevitably have implications on the choices in terms of the destination of resources (human and financial), areas of study and the more or less extended involvement of the actors in the local agricultural sectors, especially in relation to less-developed geographical contexts.

Alongside the public-private relationship, there is the one between research and innovation which has been created in advanced countries and developing countries. Through which channels can a transfer and adaptation of technology be made that is both a real development of approaches and technologies which directly address individual local agricultural contexts? Is long-term sustainability of entire areas of the world possible without the on-site presence of the relevant institutions at the forefront of agricultural research?

A study conducted in 2011 by the research institutes JRC-IHCP IPTS-European Commission (*New plant breeding techniques. State-of-the-art and prospects for commercial development*) showed that, on the basis of the information gathered, of the world's top ten institutions in the field of cutting-edge agricultural biotechnology research, four are American, two are Dutch, two are German, one is British and one is Austrian.

According to the European Commission, the search for excellence in the latest biotech is confined to the United States and Europe. The same study also identifies the ten leading organizations worldwide in agricultural biotechnology patents: eight of these are private, while only two are public. In all, seven organizations are American, two are Dutch and one is English. The boundaries of the leaders in the field of biotechnology patents on innovation in agriculture are clear: they are included, essentially, within the private sector in the United States and Europe.

Innovation in the field of agricultural biotechnology and its practical application will probably also pass through a rebalancing and an alliance between public and private (in this regard, the PPP models can be further encouraged and developed), and through achieving a balance between advanced countries and developing countries in the dissemination and financing of agricultural research, both public and private.

INNOVATION IN THE FIELD OF AGRICULTURAL BIOTECHNOLOGY AND ITS PRACTICAL APPLICATION WILL PROBABLY ALSO PASS THROUGH A REBALANCING AND AN ALLIANCE BETWEEN PUBLIC

2.4 FACTS & FIGURES

We have already mentioned that the distinction between GMOs and other biotechnology has significant implications, including the difficulty in finding adequate quantitative information about the diffusion of the latter, as opposed to the former.

This is a field of activity that would require prompt and thorough investigation and that, precisely because it is widespread, capillary and transversal, fails to attract the attention of the media and non-experts. Unlike GMOs, for which – thanks to mapping work conducted by ISAAA³² (International Service for the Acquisition of Agri-Biotech Applications) – the association of producers of transgenic seeds – the details of their diffusion are known.

Given the impossibility of producing a comprehensive picture of global facts and figures, and in light of the strong differences in key geographic areas in different countries, we felt it appropriate to submit some of its most dynamic components:³³ Argentina, Brazil, China and India. A short focus will cover Europe, which apparently has not yet found a unified strategy for research on these issues, and the United States.



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3. THE MAIN COUNTRY-CONTEXTS OF AGRI-FOOD BIOTECHNOLOGY WORLDWIDE



In this chapter, we present an in-depth study of the framework of the biotechnology sector in some geographic areas that – because of history, size or role in the overall geo-political and economic scenario – play a role of *leadership*. We have tried to understand, from the point of view of current realities, what the trajectories and future prospects may be.



David Doubilet/National Geographic Stock

3.1 AGRI-FOOD BIOTECHNOLOGY IN THE EUROPEAN UNION

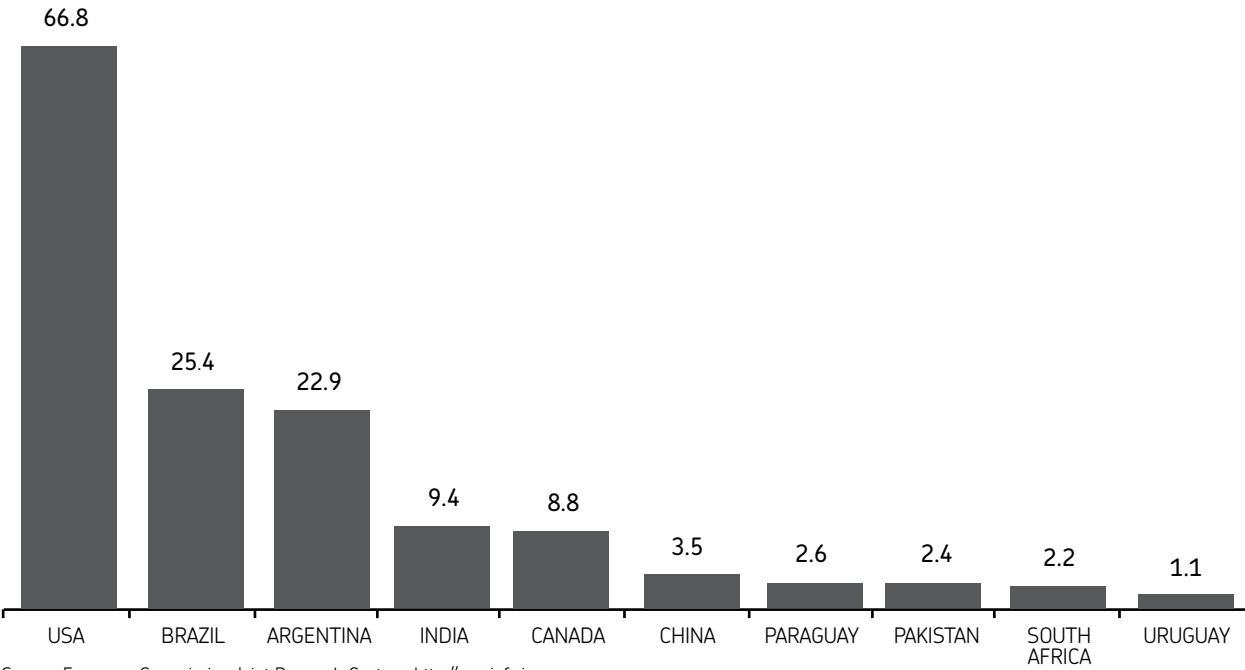
3.1.1 Facts & figures

The European Union looks with great interest at biotechnology in different sectors of activity. This is demonstrated by the policies that encouraged a *knowledge-based economy* adopted in the last decade and – more generally – by a strategic plan that pays great attention to biotechnology. This interest, in fact, has been made evident both by the official documents (we will quote their most significant aspects) and the amount of investments made available by the Framework Programmes of the different DGs of the European Commission. In addition, the number of patent applications related to biotechnology presented at the EPO (European Patent Office) allows us to understand just how this reality is thriving in the different sectors of research.

At the same time, Europe decided – a decade ago, at this point – to refrain from making transgenic biotechnology (GMOs) one of the strategic drivers of its agriculture development, on the basis of the precautionary principle. Since 2000, the activities of field testing of GMO products have, in fact, dropped to 79 trials per year, against more than 200 in the years between 1995 and 1999.

THE EUROPEAN UNION LOOKS WITH GREAT INTEREST AT BIOTECHNOLOGY IN DIFFERENT SECTORS OF ACTIVITY

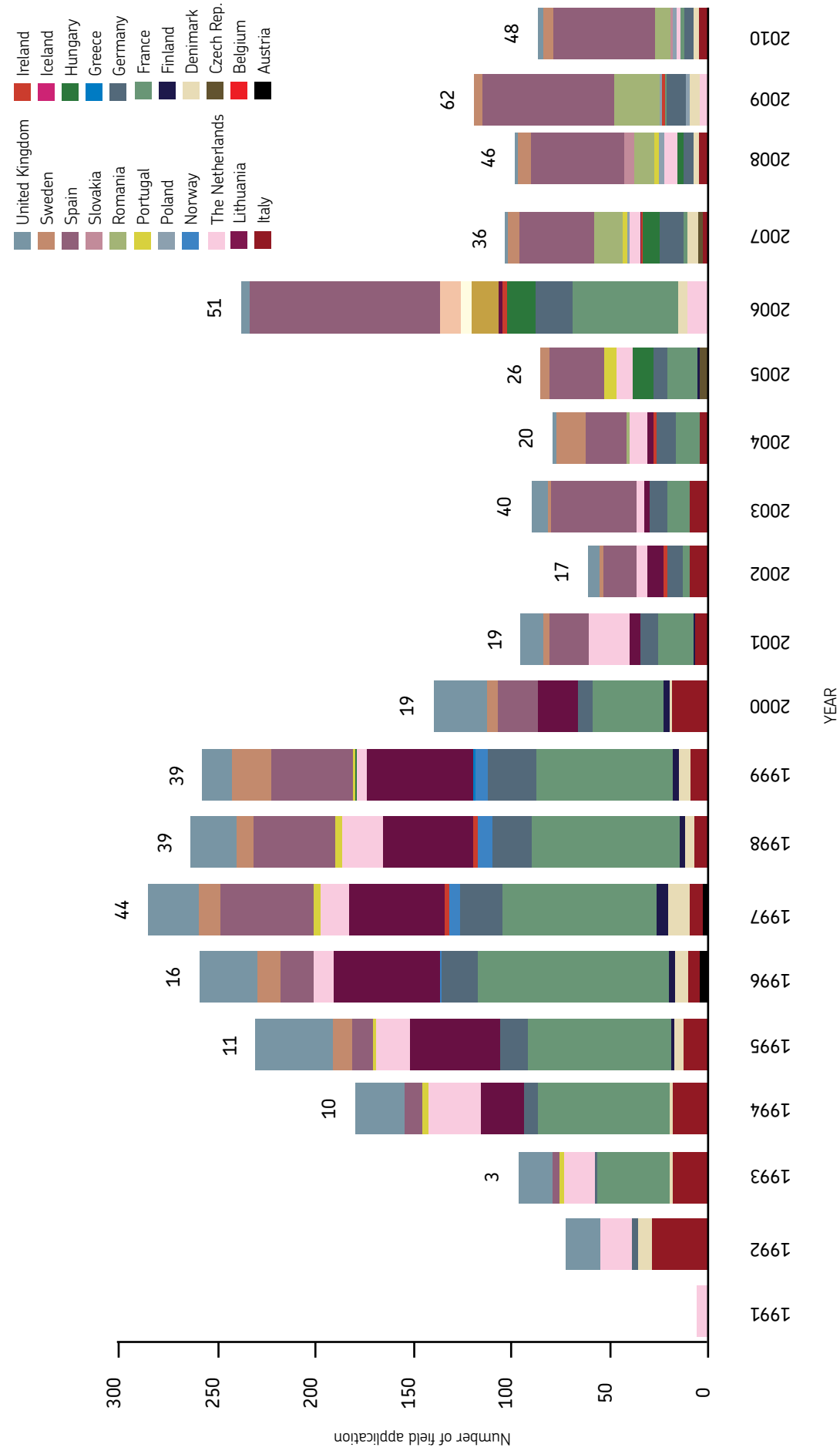
Figure 3.1. Countries that cultivate more than 1 million hectares of land with biotech crops (millions of hectares)



Source: European Commission Joint Research Center; <<http://gmoinfo.jrc.ec.europa.eu>>



Figure 3.2. EU: experiments in the field of transgenic crops (there were 79 trials in the European Union, more than half of them in Spain, the fifth lowest number since 1991)



Source: European Commission Joint Research Center; <<http://gmoinfo.jrc.ec.europa.eu>>

EIGHT EUROPEAN COUNTRIES USED GENETICALLY MODIFIED SEEDS IN 2010

Moreover, the picture is even clearer if we look at the figures for the cultivation of transgenic products. In fact, analyzing the area under cultivation on a global scale, what is highlighted is the absence of European countries among those that have cultivated more than 1 million hectares of GM crops in 2010. GMO production is now concentrated in 10 countries, which have 96% of their land devoted to cultivating GM crops. 19 other countries produce 4% of the total.

Among the latter, there are 8 European countries that used genetically modified seeds in 2010. They are Germany, Poland, Portugal, the Czech Republic, Slovakia, Romania, Spain and Sweden, for a total of about 100,000 hectares, compared to the 148 million hectares cultivated in the world.¹

To give a sense to the prudence of the European institutions on this delicate matter, it should be noted that approval has been formally given (as a non-food) to the Amflora potato only this year: the first approval granted in 13 years.²

EU institutions have extensive powers of legislation on GMOs and the entire legislation refers to regulations and directives of the European Union. Insofar as it relates to only one crop, there is a stalemate, since a large number of member states prefer not to admit it into their country. In any case, this is not discouraging biotech research, but only – and in part – a reconsideration of GMOs.

With regard to other kinds of biotechnology used in agriculture, the picture is very sketchy. In the absence of a satisfactory monitoring process, the data available is not recent. The last effort sponsored by the European Commission to provide an overall organic framework of the biological techniques used in farming within the boundaries of the continent dates back to 2003.³

The study, though dated, is still significant. What emerges is the fact that molecular markers, although adopted in research in almost all sectors relating to agriculture, were used mainly in commercial crops, especially maize (corn) and vegetables. The European Commission estimated at the time that a volume of between 2.2% and 6.6% of the total turnover of maize within the European Union was created by the application of molecular markers (0.01 -0.03% turnover of the agri-food sector).

The data on micropropagation was also very interesting, since this biotech technique has come to cover a range between 39 and 313 million euros of turnover, coinciding with 0.6 to 5% of the total value of annual production in nurseries.

More recent studies seem to confirm the registration of some progress made in the adoption of this technology; *The Analysis Report of 2007* – produced by the Commission with the support of the Institute for Prospective Technological Studies of Seville, entitled *Contributions of modern biotechnology to European policy objectives* – counted 388 European companies which are active in biotechnology and the agri-food sector and estimated the share resulting from the use of biotechnology for the improvement of agricultural seed to be 2.1% of the total turnover of European agriculture.

However, this data is consistent and is the result of estimates: what can be deduced is that the industry is moving forward, although not comparable with the rates and progressions of the United States, China or India.

In summary, Europe seems to look upon GM crops with great caution, while simultaneously promoting a slow process of the introduction into the agricultural sector of non-GMO biotechnology (not subject to special regulations), in the belief – based on widespread public opinion in member countries – that not all the problems relating to genetic engineering (impact on health, environment, economy, society) have found an answer yet.

THE ORGANIC FRAMEWORK OF THE BIOLOGICAL TECHNIQUES USED IN AGRICULTURE WITHIN THE BORDERS OF EUROPE DATES BACK TO 2003

EUROPE SEEMS TO LOOK UPON GM CROPS WITH GREAT CAUTION, PROMOTING THE INTRODUCTION OF NON-GM BIOTECHNOLOGY TECHNIQUES INTO THE AGRICULTURAL SECTOR

3.1.2 Public policies and regulations

Agri-food biotechnology techniques are regulated by the regulatory framework provided by the European Union in the field of biotechnology, which led to the adoption of the initiative *Life sciences and biotechnology - A strategy for Europe* in 2002. This was a strategic line that was to be followed until 2010; it provided a roadmap consisting of a set of general guidelines and a program plan outlined in 30 points to promote its application. This strategy was designed to allow Europe to benefit from the positive potential of biotechnology, to ensure proper governance and to address Europe's global responsibilities. The initiative considered the life sciences and biotechnology – as very promising advanced technology – to be important contributions for achieving the goals set by the European Summit in Lisbon, in which the goal had been set to develop a cutting-edge, knowledge-based economy.

In 2007, in the mid-term review of the *Strategy on life sciences and biotechnology 2002-2010*, the European Commission redefined the Plan of Action necessary to promote a competitive, sustainable and knowledge-based European bio-economy. The focus concerned innovation, research and market development and the debate of society on ethical issues in biotechnology.

Despite the overall positive orientation toward biotechnology, the European Union has always been very cautious about the adoption of transgenic crop varieties. With specific regard to GMOs, the recent regulatory context is, in fact, based on the precautionary principle and is made up of the Directive 2001/18/EC, two Regulations (1829 and 1830/2003/CE) governing the authorization and labeling/traceability of food and feed consisting of or derived from GMOs, and the Recommendation 556/2003 regarding the guidelines on the coexistence between GM crops and conventional crops. In this context, Member States are obliged to transpose the EU directives and comply with the Regulations, in order to obtain a common alignment.

With regard to the latter question, in March of 2011, an amendment to the Directive 2001/18/EC was approved in order to achieve the right balance between maintaining the European Union system of permits – based on the scientific assessment of the environmental and health risks – and the need to ensure Member States the freedom to address the national, regional or local aspects specific to the cultivation of GMOs, in the maintenance of guarantees for all stakeholders.

The dialectic between the different actors and stakeholders is still ongoing and has been enriched over time by the contributions of a certain interest, including, for example, the white paper, *The European Bioeconomy in 2030*, in which attention is given to the possible role of biotechnology for an improved management of natural resources, to produce solutions to promote environmental sustainability and for the mitigation of the effects of climate change.

The European Union's legislative process is always consistent with the precautionary principle, which remains the central notion of reference for the introduction of new transgenic plant varieties. This precautionary principle, in fact, provides the need for the proof of the absence of undesirable effects on human health and the environment by the producer of genetically modified organisms.

The reasoning about the future development of biotechnology in the agri-food sector is now framed within the broader debate on the revision of the Common Agricultural Policy.

In November 2010, the European Union found itself redefining the strategies and policy guidelines with which to guide the future choices in agriculture.

In this context, the Commission's document, *The CAP in 2020: meeting the future challenges of food, natural resources and territory*, provides an important key to understanding the present scenario, with particular reference to the recognition and identification of what are considered

AGRI-FOOD BIOTECHNOLOGY TECHNIQUES ARE REGULATED BY THE REGULATORY FRAMEWORK PROVIDED BY THE EUROPEAN UNION IN THE FIELD OF BIOTECHNOLOGY

IN 2007, THE EUROPEAN COMMISSION REDEFINED THE PLAN OF ACTION NECESSARY TO PROMOTE A COMPETITIVE, SUSTAINABLE AND KNOWLEDGE-BASED EUROPEAN BIO-ECONOMY

IN NOVEMBER 2010, THE EUROPEAN UNION FOUND ITSELF REDEFINING THE STRATEGIES AND POLICY GUIDELINES WITH WHICH TO GUIDE FUTURE CHOICES IN AGRICULTURE

BIOTECHNOLOGY TECHNIQUES IN AGRICULTURE ARE VIEWED FAVORABLY, PROVIDED, HOWEVER, THAT THEY ARE CONSIDERED AS ONE OF THE ELEMENTS OF A MORE COMPLEX AND ARTICULATED SYSTEM

THERE IS NO PREJUDICIAL PRECLUSION TOWARD AGRI-FOOD BIOTECHNOLOGIES, BUT RATHER, STRONG CAUTION AND ATTENTION PAID TO THE FUTURE DEVELOPMENT OF GMOS

the major challenges and key objectives for the agricultural sector at present and in the future. In this regard, it is important to highlight how agriculture in the European Union is embedded in a highly competitive, globalized environment, due both to the progressive integration of the world's economy, the increasing liberalization of trade and the high degree of uncertainty and volatility that characterizes agricultural markets. Because of these dynamics, it is necessary that the EU continue to contribute to meeting the increasing global demand for food: Europe's agricultural sector, in fact, must maintain and increase its production capacity, thus strengthening the foundations also in the food sector, and enhance its strategic position covered in the global scenario.

Two additional challenges facing European agriculture concern the areas of climate change and territorial balance.

In this regard, it is important that the Common Agricultural Policy continue to honor its commitment to reduce greenhouse gas emissions from agriculture, even though at the European level, they have already decreased by 20% since 1990, and that it not lose sight of the crucial role played by agriculture in vitalizing and strengthening the many rural areas that are still highly dependent on the primary sector. Finally, in drawing up an overview on the challenges which have an impact on future agricultural sustainability, the consideration of the scarcity of natural resources (water and, especially, soil) cannot be ignored, as it tends to increase gradually and to generate critical conditions, with particular reference to the challenge of meeting the increasing demand for food *commodities*.

Therefore, it is important to understand that the aspects related to the pioneering research on biotechnology are not the main focus of political debate on this issue. In other words, a picture emerges in which biotechnology techniques in agriculture are viewed favorably, provided, however, that they are considered as one of the elements of a more complex and articulated system, that cannot be put into question or unbalanced in any way.

Also, from the numerous interviews with various experts of agricultural policy within the EU, there has been an approach to the subject of biotechnology that differs from that prevailing in other parts of the world, where it is still seen as a possible means to increase agricultural yields. In contrast, in Europe the element that is indicated as a real added value is its possible future contribution to agricultural sustainability, with an evolution toward the efficient use of resources and the mitigation of the impact of climate change.

There is no prejudicial preclusion toward agri-food biotechnologies, but rather, strong caution and attention paid to the future development of GMOs.

In a nutshell, in Europe, the legal and cultural context is fairly well defined and is recognized transversely as appropriate by the great majority of Member States: there is no prejudicial preclusion toward agri-food biotechnologies, but rather, strong caution and attention paid to the future development of GMOs.

The main concerns arise, if anything, relating to the sustainability of the European Union's position in an international context that is still in motion, where the moves of the major international *players* have not yet been fully defined. While the United States, Argentina and Brazil have firmly committed to the path of the transgenic, on the strength of a seed industry that occupies a leading position in the sector, other major producers such as China and India are still largely questioning their future choices.

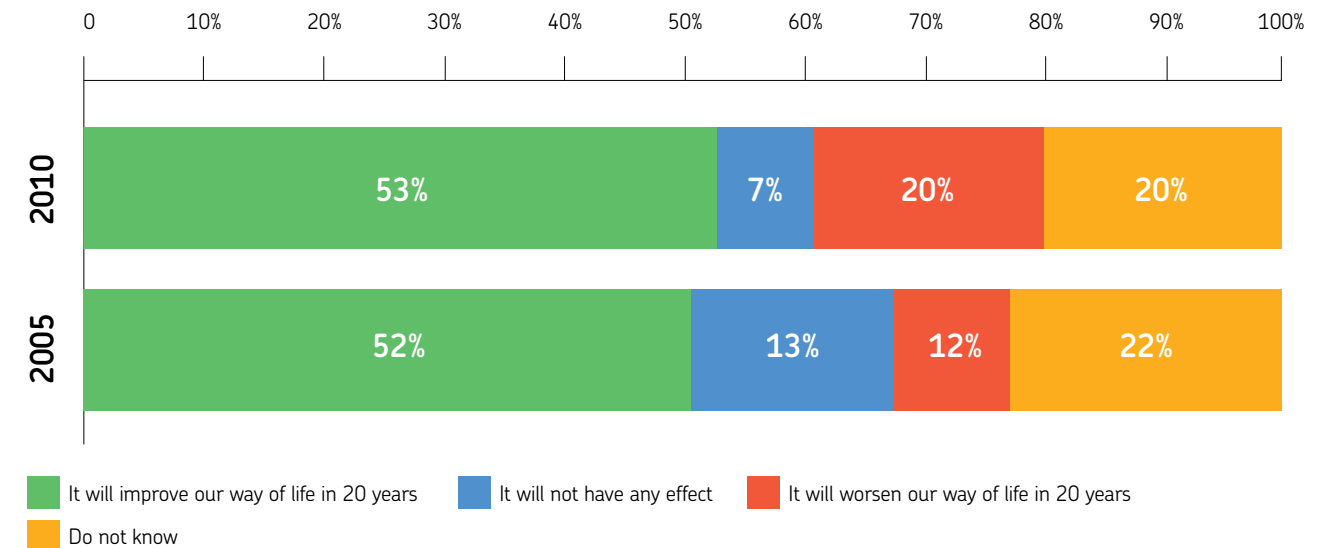
3.1.3 Public opinion regarding agri-food biotechnology

The choices made in Europe also depend on the weight of overall public opinion, that is against the adoption of biotechnology of a transgenic character in the food sector. The recent survey

by Eurobarometro⁴ on life sciences and biotechnology reveals that Europeans are optimistic about the innovations in the field of life science and biotechnology. In this regard, in fact, the results of the polls seem to leave no doubt that 53% of respondents believe that biotechnology will be beneficial in the future, while only 20% think that its effects will be negative.

PUBLIC OPINION IN EUROPE TENDS TO BE CONTRARY TOWARD THE ADOPTION OF BIOTECHNOLOGY IN THE FOOD SECTOR

Figure 3.3. What effect will biotechnology and genetic engineering produce?

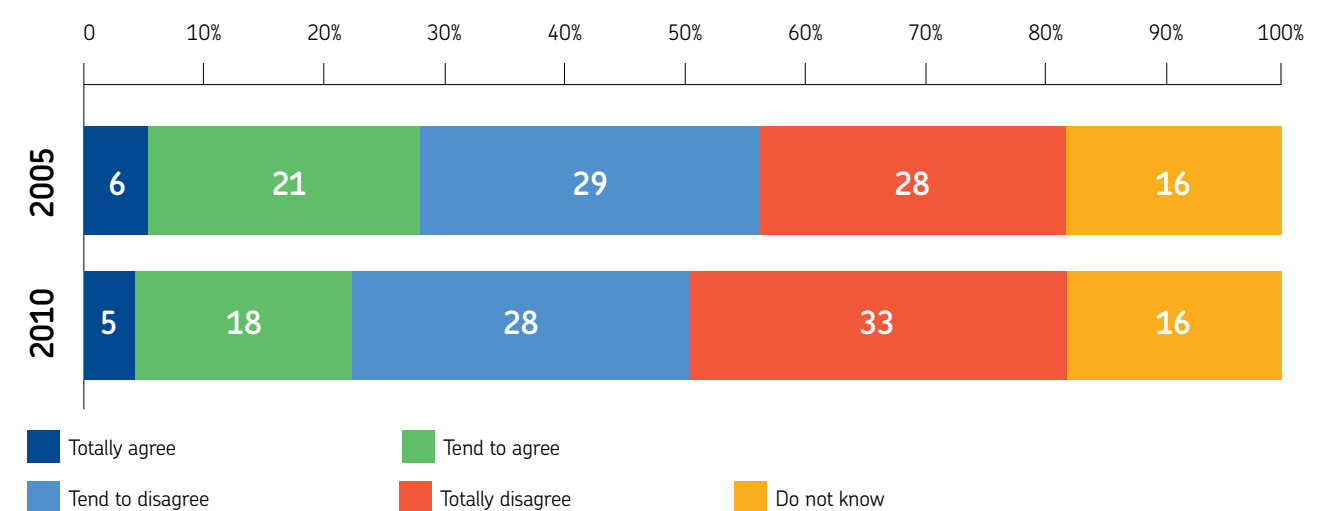


Source: European Commission, *Europeans and Biotechnology in 2005: Patterns and trends*, Eurobarometer, July 2005.

However, if we look more specifically at the perception related to GMOs, the data expressing strong opposition is probably linked (as discussed elsewhere⁵) to the failure to perceive a benefit in respect to a risk profile associated with their adoption. Europeans who are open to the prospect of a growing adoption of biotechnology, are opposed to the use of GMOs.

EUROPEANS WHO ARE OPEN TO THE PROSPECT OF A GROWING ADOPTION OF BIOTECHNOLOGY ARE OPPOSED TO THE USE OF GMOS

Figure 3.4. Degree of agreement/disagreement regarding GMO food products in 2005 and 2010



Source: European Commission, *Europeans and Biotechnology in 2005: Patterns and trends*, Eurobarometer, July 2005.

It is interesting to see how confidence in GM crops has progressively diminished over the years, to the point where 2010 was the first year in which the people in all European countries who favored the use of GM crops became a minority (<40%).



Figure 3.5. Trends in support for GM foods (excluding Dks)

% RESPONDENTS WHO AGREE OR TOTALLY AGREE THAT GM FOOD SHOULD BE ENCOURAGED					
	1996	1999	2002	2005	2010
UNITED KINGDOM	52	37	46	35	44
IRELAND	57	45	57	43	37
PORTUGAL	63	47	56	56	37
SPAIN	66	58	61	53	35
DENMARK	33	33	35	31	32
NETHERLANDS	59	53	52	27	30
NORWAY	37	30			30
FINLAND	65	57	56	38	30
BELGIUM	57	40	39	28	28
SWEDEN	35	33	41	24	28
ITALY	51	42	35	42	24
AUSTRIA	22	26	33	24	23
GERMANY	47	42	40	22	22
SWITZERLAND	34				20
LUXEMBOURG	44	29	26	16	19
FRANCE	43	28	28	23	16
GREECE	49	21	26	14	10
CZECH REP.				57	41
SLOVAKIA				38	38
MALTA				51	32
HUNGARY				29	32
POLAND				28	30
ESTONIA				25	28
SLOVENIA				23	21
LATVIA				19	14
LITHUANIA				42	11
CIPRUS				19	10
ICELAND					39
ROMANIA					16
BULGARIA					13
CROATIA					13
TURKEY					7

Source: European Commission, *Europeans and Biotechnology in 2010*, Eurobarometer, November 2010.



3.2 AGRI-FOOD BIOTECHNOLOGY IN THE UNITED STATES

3.2.1 Facts & figures

Among the countries that have contributed to the development of agro-food biotechnology, the United States is the one that has made a more convinced and decisive choice aimed at structuring an advanced biotechnology sector in the field of agriculture. In particular, U.S. companies active in the biotech sector have focused on the production of transgenic organisms, thanks to an extraordinary wealth of scientific knowledge made available by a country-wide system and an agricultural sector that immediately proved to be very receptive to the new GM seeds. In North America, the process of marketing genetically modified corn, soybeans, cotton and potatoes had already begun in 1996.

In 2010, the United States was confirmed as the leader of the GMO industry, for both supply and demand. This sector, in a geographical context, is characterized by orders of magnitude significantly higher than those in other countries: the total area cultivated with biotech amounted to 66.8 million hectares in 2010,⁶ more than double that of Brazil, which ranks in second place. The United States mainly cultivated corn, soybean, cotton, rapeseed, sugar beet, papaya and squash. The increase of 2.8 million hectares of cultivated area recorded between 2009 and 2010 is the second most significant⁷ in the world, proving once again how this country is focusing on the development of transgenic biotechnology.

The penetration rates of these plant varieties are, however, so high⁸ and the extensive single-crop model so optimized that they make further increases in yield and productivity possible only through the joint development of multiple traits in a single variety (also providing an opportunity to increase royalties applied to the variety for the benefit of the company selling it) and thanks to new experiments in the plurality of the existing technological applications.

The high amount of investments in research related to agriculture is among the main factors responsible for the leadership of the country in this area. U.S. investments in R&D (research and development) in agriculture are, in fact, the highest in the world.⁹ In 2006, expenditure amounted to approximately \$9.4 billion, with a clear predominance of the private sector, responsible for 49% of the investments,¹⁰ unlike the other countries analyzed here.

Among the research which is traditionally focused on the use and improvement of transgenic techniques, the appearance of new lines of research should be noted which, although difficult to quantify and not always clearly documented, will bring new solutions to the agricultural challenges of the country in the future. This openness to new techniques is demonstrated by what emerged from a recent study conducted in 2011 by the research institutes JRC-IHCP IPTS of the European Commission.¹¹ The survey shows, in fact, that the U.S. scientific community is one of the most active in the publication of

IN 2010, THE UNITED STATES WAS CONFIRMED AS THE LEADER OF THE GMO INDUSTRY, FOR BOTH SUPPLY AND DEMAND

U.S. INVESTMENTS IN R&D IN AGRICULTURE ARE THE HIGHEST IN THE WORLD

THE U.S. SCIENTIFIC COMMUNITY IS ONE OF THE MOST ACTIVE IN THE PUBLICATION OF STUDIES ON NEW BREEDING TECHNIQUES

studies on new *breeding* techniques,¹² with about 30% of the total publications produced between 1991 and 2010. It also appears that, among the top ten global institutions in the field of pioneering agricultural biotechnology research, four are American, including three which are public (University of California, Iowa State University, University of Michigan) and one which is private (J.R. Simplot Company) and specializes exclusively in the investigation of transgenic techniques. The data concerning the registration of patents on new technology applications related to breeding also confirms what was mentioned before. With 65% of the patents filed between 1991 and 2009, the United States is the country that holds the largest wealth of knowledge on pioneering agri-food biotechnology protected by intellectual property rights.

It is, therefore, clear that, on the international scene, the U.S. is the most important driver of development in the sector and the one that has most decisively and consistently chosen – since the late ‘80s – to assume leadership.

3.2.2 Public policies and regulations

It is commonly considered that the birth of commercial biotechnology dates back to the 1980 ruling of the Supreme Court of the United States, which established (in reference to the case *Diamond vs. Chackrabarty*) that a genetically modified organism can be patented. Ananda Mohan Chackrabarty, a researcher for General Electric, had developed a bacteria capable of “breaking down” and then “eating” oil, to be used in case of accidental leakage. The patent, which is required for the United States, was initially refused to him because the law stated that living things could not be patented.

It was a decisive decision for initiating the industrial exploitation of genetic engineering, which laid the foundation for the production of transgenic organisms. The path of patent protection, in fact, is essential, given the high costs associated with the development of new GMO varieties. What with the intervention of genetic engineering, marketing, research and development costs, protection of intellectual property rights, technology transfer and regulatory compliance, an estimated 100 to 200 million dollars are required. Therefore, it was precisely the model created in the United States that would define the structure of the industry worldwide for decades to come: namely, that the high costs of research are accompanied by legal safeguards for the protection of the registered patent and the investments made.

In addition, in the United States there is another important aspect in reference to transgenic organisms, and that is the presence of a permit system that favors the rapid creation of a large domestic market. With regard to health risks, in the United States the concept of substantial equivalence prevails: upon completion of the analysis required for its approval, a product is considered safe until its danger has been demonstrated.¹³ In Europe, by contrast, the precautionary principle applies: a product should be considered dangerous until it has been proven that it is safe. Regarding products of such recent history, the difference of perspective can lead to very different results.

In fact, at this time in the U.S., the cultivation and marketing for 52 types of genetically modified products has been approved, intended both for human consumption and animal feed. In this overview, we must not forget those critical issues – which are the subject of attention and intervention proposals – relating to the occurrence of resistance (especially among wild plants), the result of the scale of adoption of transgenic technology, and the substantial deregulation of the trials, which has led to pollution of the supply chain, as in the case of LL Rice.¹⁴

IN THE UNITED STATES, THE CONCEPT OF SUBSTANTIAL EQUIVALENCE PREVAILS: UPON COMPLETION OF THE ANALYSIS REQUIRED FOR ITS APPROVAL, A PRODUCT IS CONSIDERED SAFE UNTIL ITS DANGER HAS BEEN DEMONSTRATED

THERE ARE ALSO CRITICAL ISSUES RELATED TO THE ONSET OF RESISTANCE AND THE SUBSTANTIAL DEREGULATION OF THE TRIALS

Considering the activities of the scientific community, it is possible to observe a progressive widening of field testing, in terms of finding concrete solutions, of all the biotechnology techniques that can be used profitably in the agri-food sector, just as, in parallel, on the side of the regulation of competition, initiatives are being established to significantly influence the structure and future characteristics of the sector.

A considerable amount of controversy that has inflamed the public debate on GMOs is, in fact, linked to the level of concentration in the sector in which the so-called life science companies operate, concerning precisely the United States and its companies. It is known that consultations are taking place that also involve the Department of Justice – the authority for compliance with antitrust regulations – on any actions to protect the proper functioning of markets, against the possible abuse of dominant positions.

In short, as a system, the United States has favored an approach to biotechnology that is markedly orientated to modified organisms, thanks to:

- a vast wealth of available knowledge, resulting from scientific research in universities and research centers;
- the ability to create a regulatory framework for the introduction of GMOs that is more favorable as compared to other contexts;
- the predisposition of a highly effective regulatory framework concerning the protection of property rights;
- the willingness of large companies already active in the seed sector and agrochemical sectors to integrate their business models, making significant investments in biotechnology;
- the decision to favor the aggregation of companies in the sector up to very high levels of concentration;
- the strong political support of the administration, not only in terms of domestic policies, but also for international promotion;
- the high degree of acceptance of new products by farmers and public opinion.

Although there do not seem to be any signs so far of a rethinking of this approach, we are beginning to see the first signs of an extension (which is possibly physiological) of the analysis framework, by means of the correction of some excesses and the desire to exploit the potential of biotechnology in all its forms.

Despite the increasing convergence of public and private investments in non-GM agri-food biotechnology techniques, the fact that they have less patent protection than the GMOs is putting the brakes on developments in this direction. An interesting example in this regard is provided by Monsanto’s VISTIVE soybeans (with low linolenic acid to reduce trans fats), which was obtained by MAS, but whose trait was incorporated into the RR soybean varieties.

3.2.3 Public opinion regarding agri-food biotechnology

Considering the long history of biotechnology in the United States, the public perception of consumers has long been studied and monitored in the belief that it is a critical variable that can also significantly affect the return on investments made in agri-food research.

Recent studies show that the level of awareness reached by U.S. consumers with regard to food biotechnology and, more specifically, to genetically modified organisms, is among the highest of the countries producing biotech.¹⁵ It also highlights how the American public harbors far fewer concerns about GMOs than, say, Europeans.¹⁶ Two-thirds of the U.S. population, in fact, say that the benefits of GM foods outweigh the risks that are potentially associated with them.¹⁷

A CONSIDERABLE AMOUNT OF CONTROVERSY THAT HAS INFLAMED THE PUBLIC DEBATE ON GMOS IS, IN FACT, LINKED TO THE LEVEL OF CONCENTRATION IN THE SECTOR OF THE SO-CALLED LIFE SCIENCE COMPANIES

THE LEVEL OF AWARENESS REACHED BY U.S. CONSUMERS WITH REGARD TO FOOD BIOTECHNOLOGY AND GMOS IS AMONG THE HIGHEST OF THE COUNTRIES PRODUCING BIOTECH

THERE IS LIMITED AWARENESS, HOWEVER, OF JUST HOW MUCH BIOTECHNOLOGY IS ALREADY PART OF THE PRODUCTION CHAIN, AND THIS IS PERHAPS DUE TO THE LACK OF LABELING OF THE PRODUCT

However, wide public acceptance is threatened by a limited knowledge of the plurality of aspects and facets of the phenomenon of food biotechnology. On this basis, public opinion that does not have the help of a solid knowledge base is easily influenced and potentially risky for future developments in the sector. Looking at the results of studies conducted on the level of knowledge of biotechnology, it is evident that it has fluctuated greatly over time (1992-2003), reaching a peak in 2001 (53%), and then continuing to decrease over time with the appearance of new events on the public agenda.

This limited awareness is also reflected by the limited knowledge of just how much biotechnology is already part of the production chain. Only 14% of consumers believe, rightly, that more than half of the food they buy contains genetically modified ingredients, and few Americans recognize that they have already been consuming them.

The absence of mandatory product/process labeling that informs consumers about the presence of GM ingredients in foods does not help in this matter.



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3.3 AGRI-FOOD BIOTECHNOLOGY IN CHINA

In the wake of favorable public policy and thanks to a regulation that is still being developed, China now holds a leadership position in the field of food biotechnology.

The significant amount of investments in research and the growth trend that has characterized its evolution in recent years, make this country a center of excellence in the development of some technological applications, as well as a potential future competitor of the United States.

INVESTMENTS IN RESEARCH AND ITS GROWTH TREND MAKE CHINA A CENTER OF EXCELLENCE AS WELL AS A POTENTIAL FUTURE COMPETITOR OF THE UNITED STATES

3.3.1 Facts & figures

According to the ISAAA,¹⁸ China now ranks sixth among world powers producing GM food biotechnology, in terms of cultivated acreage (after the United States, Brazil, Argentina, India and Canada), with about 3.5 million hectares in 2010. Since 1997, the country has marketed six species of genetically modified plants (cotton, tomato, pepper, petunia, poplar and papaya), including insect-resistant Bt cotton, which represents the most widespread crop.¹⁹ Almost all of the remaining genetically modified crops approved for marketing are currently not being produced because of the non-renewal of their bio-safety certificates, due to the absence of markets.²⁰

Resistance to pests is the most sought after trait, and the others, related to improving the quality of food (relative to rice and wheat), have only recently been gaining importance due to the growing demand.

As a result of continued rapid population growth and the evermore urgent need for the government to ensure that the entire population has access to food,²¹ most of the R&D in food biotechnology in China is carried out by research institutes and public universities. Public investments in this country represent one of the most significant research efforts in the world²² and follow a trend of continuous growth, reaching a peak, in 2010, of 500 million US dollars.²³ These substantial investments in research are at the basis of much of the economic growth of China, which, in the field of agriculture, has adopted a complex strategy aimed at achieving self-sufficiency of some crops (cereals), in part thanks to the results obtained in biotechnology research, renouncing the agricultural production of those goods that are not considered strategic.

There are numerous programs to support R&D related to agricultural biotechnology.

Among those most recently launched, we wish to point out a special program for the development of new biotech varieties with an investment of 3.5 billion USD²⁴ over 12 years that the State Council approved in July, 2008. The *Long and Mid-term National Development Plan for Science and Technology 2006-2020* focuses to a large extent on research in

CHINA NOW RANKS SIXTH AMONG WORLD POWERS THAT ARE PRODUCING GM FOOD BIOTECHNOLOGY, IN TERMS OF CULTIVATED ACREAGE

MOST OF THE R&D IN FOOD BIOTECHNOLOGY IN CHINA IS CARRIED OUT BY RESEARCH INSTITUTES AND PUBLIC UNIVERSITIES



agricultural plant species (rice, wheat, corn and cotton), with the aim of developing new varieties with traits of resistance to insects, diseases and external stresses.

The presence of private sectors in R&D on food biotechnology is limited and strictly regulated. While the research activities are mostly carried out by institutions funded by various levels of public administration, marketing, instead, is often left to private companies affiliated with these institutions. Foreign investments in research and development of plant (and animal) biotechnology are still prohibited. The only area in which they are allowed is the traditional production of hybrid seeds, provided that a portion (51%) of the shareholding is owned by Chinese.

If China has not yet exported biotech species, it has, instead, officially approved five for import, intended for animal feed or as input of transformation processes: soybeans, corn, rapeseed, cotton and sugar beet.

China also stands out for important research programs in tissue culture and mutagenesis. Finally, among the different technological applications of transgenesis, China also stands out for important research programs in tissue culture and mutagenesis.²⁵ More specifically, since 2003, in this country more than 2M have been cultivated with diploid species,²⁶ obtained from in vitro culture techniques, the most important of which are rice, wheat, tobacco and pepper.

3.3.2 Public policies and regulations

The primacy of China in biotechnology in the agri-food sector is also the result of favorable public policies that over the years have stimulated developments even though solid and structured regulation is lacking. The Chinese government has long recognized that agrifood biotechnology plays a strategic role in the growth of the country.²⁷ With the aim of fully exploiting the benefits of these technological applications and making China the leading country in their design and testing, promotional policies have been implemented that have stimulated the development, without, however, paying sufficient attention to biosafety, the environment and the consumers.²⁸

However, the perception of the lack of adequate regulation in the development of biotechnology in the agri-food sector characterized only the first few years of experimentation; instead, today, a monitoring system in transformation has been established which is intended to be as global and comprehensive as possible. Following the signing of the Convention on Biological Biodiversity (CBD) in 1992, the first biosafety regulation was adopted, *Safety Administration and Regulation on Genetic Engineering*, issued by the Ministry of Science and Technology in 1993. Since then, the history of the regulation of food biotechnology in China has undergone a succession of legislative refinements, accompanied by the formation of inter-governmental bodies appointed to ensure compliance and to monitor the safety of biotech products.²⁹

The policy directions that the country has followed in recent years are outlined in the *11th Five Year Plan³⁰ on the Development of Biotech Industry (2007-2012)*³¹ and in the relative guidelines adopted by the State Council, *Policies to Promote Accelerated Development of the Biotech Industry*. Among the strategic areas of intervention is agricultural biotechnology (understood as chemical products for agriculture, animal feed, feed additives and fertilizers) and the key development actions that are desired include:

- transferring technology from public institutions to leading private businesses in the sector;
- increasing incentives for the investments of foreign companies in order to create infrastructures for research or for the joint development of research programs;

CHINA HAS NOT YET EXPORTED BIOTECH SPECIES; INSTEAD, IT HAS OFFICIALLY APPROVED FIVE FOR IMPORT: SOYBEANS, CORN, RAPESEED, COTTON AND SUGAR BEET

THE PRIMACY OF CHINA IN BIOTECHNOLOGY IN THE AGRI-FOOD SECTOR IS ALSO THE RESULT OF FAVORABLE PUBLIC POLICIES, WHICH, HOWEVER, LACK SOLID AND STRUCTURED REGULATION

THE FIRST REGULATION ON BIOSAFETY, THE SAFETY ADMINISTRATION REGULATION ON GENETIC ENGINEERING, WAS ISSUED BY THE MINISTRY OF SCIENCE AND TECHNOLOGY IN 1993

THE POLICY DIRECTIONS THAT THE COUNTRY HAS FOLLOWED IN RECENT YEARS ARE OUTLINED IN THE 11TH FIVE YEAR PLAN ON THE DEVELOPMENT OF BIOTECH INDUSTRY (2007-2012)

THE MAIN ACTOR IN DEFINING POLICIES AND REGULATION OF THE SECTOR IS THE MINISTRY OF AGRICULTURE (MOA)

IN 2009, THE MOA GRANTED CERTIFICATES OF BIOSAFETY TO TWO VARIETIES OF RICE WHICH ARE RESISTANT TO INSECTS AND A VARIETY OF MAIZE WITH A HIGH CONCENTRATION OF PHYTASE

- the increase in local public funding for the R&D of new transgenic crops;
- the designing of R&D programs that favor technological innovations applied to local crops;
- tax relief on expenditures on R&D for new biotech products (50%) and on revenues of the companies (15%).

Despite the attempts at opening and reorganizing the sector, at the beginning of the new period of programming (2011), biotechnology remains a key area with recognized potential, but which is still distinguished by its closure toward what is on the outside. So far, in fact, China does not really have any variety of marketed biotechnology for its internal market (with the exception of Bt cotton, as mentioned above), it does not export any biotech crop nor can any private company be characterized as an actor in the sector, since all the R&D is conducted in public labs. Confirming the evidence of the importance of food biotechnology on China's policy agenda is the fact that, in the next five years, the country has planned to launch the *Agri-Science Technology Introduction Program*,³² a program to encourage technological development in sectors such as biological resources for agriculture, the transformation of industrial processes and new techniques and methodologies of R&D applied to agriculture. Through a combination of technological development and innovation, this program aims, on the one hand, to consolidate the leadership position of China in the field of plant genomics, transgenesis, and technological innovation applied to rice; to promote the progress of the seed industry in the sectors of plant genomics, transgenesis, and technological innovation applied to rice; and also to promote progress in the seed industry, in reduced carbon emissions in agriculture and in biofuels.

The main actor in defining the policies and regulation of the sector is the Ministry of Agriculture (MOA), which is responsible, in particular, for the approval of biotech crops for internal use and import, as well as the management and allocation of public funds, governing the institutes and universities in China for R&D.

In 2009, the MOA granted certificates of biosafety to two varieties of rice which are resistant to insects and a variety of maize with a high concentration of phytase.

The current planning of the biotechnology applied to the agri-food sector is determined primarily by the State Council regulations, *Food and Agricultural Import Regulations and Standard and Agricultural Genetically Modified Organisms Safety Administration Regulations* 2001.³³ However, the framework for this sector is evolving. The Chinese government has, in fact, initiated a process of revision and updating of this sector in order to increase the level of controls and more effectively communicate the security benefits and impacts associated with the latest technological innovations. Among the changes to report, in 2009, the MOA granted biosafety certificates for two varieties of which are rice resistant to insects and a variety of maize with a high concentration of phytase. It is the first time that this type of certification was affixed to primary crops for the country. In addition to receiving the certification, the products must also complete the registration process before they can be officially sold (a process that can last 2-3 years).

Currently, the regulatory infrastructure of agri-food biotechnology in China is an evolving reality that still has internal contradictions which will be resolved as soon as possible, in order to maintain the growth rates of recent years. Among these obstacles, deserving special attention are: the process of approval which requires that a product must first have completed the approval process in the country of origin before being subjected to evaluation in China; inadequate protection and enhancement of intellectual property rights as well as the absence of a specific policy on multiple traits could lead in the long term to impeding innovation.

3.3.3 Public opinion regarding agri-food biotechnology

Although some previous studies and surveys³⁴ could give the impression that Chinese consumers were favorable overall to the use of products that are the result of biotech modifications, it should be noted that the positions seem to be more heterogeneous today. Following the liberalization of Bt rice and corn with the phytase enzyme in 2009, a lively debate has begun on the safety of foods derived from biotechnology products, communication of the risks involved and the deregulation process. The information provided by some Chinese media and some non-governmental organizations has gained a large following among the public, which is now beginning to develop different and articulated opinions.

One of the most recent surveys, conducted by the Asian Food Information Centre (AFIC),³⁵ shows that, although Chinese consumers are among the most confident³⁶ in the safety of genetically modified foods, the level of knowledge about the applications of this technology and products derived from them is still very low, and only 45% of China's population is aware that GMO products can be purchased in grocery stores. Despite this limited knowledge, and despite a reduced awareness of issues related to the sustainability of crops,³⁷ Chinese consumers are also among the most positive (55%) regarding the benefits that might result from the use of biotechnology in the coming years and, specifically, they emphasize the possibility of obtaining a better quality of food and higher yields. Therefore, it appears necessary that an effort be made regarding institutional and scientific communication, so that public opinion, which is beginning to develop different and sometimes conflicting positions, can be aware of all the information relating to the sector.

THE CHINESE CONSUMERS ARE AMONG THE MOST CONFIDENT IN THE SAFETY OF GMOS, BUT KNOWLEDGE ABOUT THEIR TECHNICAL APPLICATION IS VERY LIMITED



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3.4 AGRI-FOOD BIOTECHNOLOGY IN INDIA

The field of biotechnology in the agri-food sector of India represents one of the paths identified by the government to encourage the development of the nation. The presence of highly qualified human resources, a fair and transparent framework for the protection of intellectual property rights, infrastructures for advanced research and increased investments by the public and private sectors are some of the factors that have prompted this choice. However, following the introduction of Bt cotton on the market, there have been numerous disputes³⁸ and protests within the country, a sign that some decisions are difficult to accept and that this industry needs even more transparent information.

3.4.1 Facts & figures

India is the fourth largest producer of GMO food products (after the U.S., Brazil and Argentina)³⁹ but Bt cotton is the only biotech crop approved for trade so far.⁴⁰ Since 2002, the year this variety of cotton was introduced on the market, the Indian government has approved about six events and 300 hybrids for cultivation in different climate zones.⁴¹ Most of the hybrids come from two events previously approved in the U.S. by the Monsanto company, while only one event has been recently developed and approved locally (Event 9124), thus stemming the imbalance toward the big multinational players in the market. The case of Bt cotton⁴² is cited by some studies as a successful event for India, because for the ninth consecutive year there has been continuous growth of the areas cultivated with this variety, affecting, with reference to 2010 data, an area of 9.4 million hectares,⁴³ 86% of the total area devoted to cotton: India has thus become the second largest producer and exporter of cotton in the world. 6.3 million farmers are engaged in this type of cultivation and, for the most part, they are small farmers with a reduced availability of resources. However, closer analysis of these figures shows that it is a more complex phenomenon of difficult interpretation, and it has given rise to a lively scientific debate. It seems appropriate, in fact, to remember that, despite the progressive increase in acreage, the yield has significantly declined over the past three years.⁴⁴ This phenomenon was explained by the conjunction of unfavorable climatic conditions and the use of impure seed varieties resulting from the illegal and uncontrolled trading of cotton seeds in some regions of India. It can be said, therefore, that the cultivation of Bt cotton, which was officially approved in 2002, has been the driver for the development of the biotechnology sector.⁴⁵ Today, this represents approximately 14% of the most globalized industry of biotechnology (and the third after bio-pharmaceuticals and bio-services), with revenues of \$310 million

THE FIELD OF BIOTECHNOLOGY IN THE AGRI-FOOD SECTOR OF INDIA REPRESENTS ONE OF THE PATHS FOR ENCOURAGING THE DEVELOPMENT OF THE NATION

INDIA IS THE FOURTH LARGEST PRODUCER OF GM FOOD PRODUCTS, BUT BT COTTON IS THE ONLY BIOTECH CROP APPROVED FOR TRADE SO FAR

THANKS TO THE CULTIVATION OF BT COTTON, INDIA HAS BECOME THE SECOND LARGEST PRODUCER AND EXPORTER OF COTTON IN THE WORLD

THE CULTIVATION OF BT COTTON, WHICH WAS OFFICIALLY APPROVED IN 2002, HAS BEEN THE DRIVER FOR THE DEVELOPMENT OF THE BIOTECHNOLOGY SECTOR

THE PRESENCE OF PRIVATE ENTERPRISES IN THE DEVELOPMENT AND MARKETING OF AGRICULTURAL AND FOOD BIOTECHNOLOGY IN INDIA HAS BEEN CONSOLIDATING OVER TIME, THANKS TO A STRUCTURED AND TRANSPARENT REGULATION OF THE SECTOR

(equivalent to 19.4 billion Rs) in 2009 and a 37% increase over the previous year, showing a significantly better performance compared to other sectors of biotechnology. Revenues from exports (581 million Rs) are still low compared to the size of the internal market, though it, too, is growing,⁴⁶ and relate mainly to cotton and cotton seeds. With regard to imports, however, the only food product currently approved is soybean oil derived from the Round-up Ready species.⁴⁷

The presence of private enterprises in the development and marketing of agricultural and food biotechnology in India has been consolidating over time, thanks to a structured and transparent regulation of the sector. In 1995, the first attempt was made by the Maharashtra Hybrid Seed Company (MAHYCO) to obtain approval for the importation of Bt cotton seeds from the U.S. multinational Monsanto and then to cross them with local species and develop hybrids resistant to biotic stresses. Currently, more than ten large private companies are actively involved in R&D in the field of food biotechnology and can be divided into three categories:

- the *large integrated seed firms* that develop the transgenic varieties internally;⁴⁸
- the *small/medium businesses that employ alternative techniques*, such as tissue culture, for the development of new species;⁴⁹
- the *highly specialized technology companies that offer services* in the area of specific research projects in American and European laboratories or companies.

The agri-food biotechnology field is very dense and concentrated, to the point that the three major companies in the sector (Rasi Seeds, and Mahyco Seeds Nuziveedu) are responsible for more than 72% of total revenues.

In addition to cotton, private seed companies and public research institutes are now working on the development of new biotech crops, mainly focusing on traits of resistance to pests, nutritional improvement, drought tolerance and increased yields.⁵⁰

Among the most widespread technological applications differing from conventional transgenesis and genetic engineering, to be highlighted are tissue culture and micropropagation, exploitation of heterosis and the development of new hybrids and plants with desirable traits.⁵¹ The successful results achieved in using these technologies have led the Indian government to promote this local excellence with the recent creation of the Micropropagation Technology Parks, platforms for technology transfer between companies, laboratories and research centers which facilitate the consolidation of specialization know-how, thanks to which they intend to speed up market entry and the spreading of new techniques for mass propagation of horticultural crops and trees. Within these platforms, important results have been obtained on the vanilla and cardamom plants. In particular, regarding the latter, it was possible to increase the yield by 40% with the use of tissue culture techniques.⁵²

Among the achievements in research on food biotechnology during the last programmed period (2002-2007), the most significant are those for rice, a key-food for the food security of the country; specifically, to be remembered are: the decoding of genomic information of chromosome No. 11 and the development of traits of resistance to salinity and drought.

Others are: molecular markers for quality traits of wheat, a transgenic virus-resistant tomato and high-performance GM mustard.⁵³

In conclusion, it should be emphasized that, in addition to technological applications for the development of improved varieties of plants and crops, India is experiencing a growing interest among public and private organizations in the development of products such as biodiesel, bio-pesticides and biofertilizers.⁵⁴

THE INDIAN GOVERNMENT IS PROMOTING THIS LOCAL EXCELLENCE WITH THE RECENT CREATION OF THE MICROPROPAGATION TECHNOLOGY PARKS

RICE HAS ACHIEVED THE MOST SIGNIFICANT RESULTS IN RESEARCH ON FOOD BIOTECHNOLOGY DURING THE LAST PROGRAMMED PERIOD (2002-2007)

3.4.2 Public policies and regulations

Agriculture still plays a key role in the Indian economy today. Despite the gradual reduction of the weight percentage of the GDP, in fact, it directly or indirectly involves approximately 70% of the population⁵⁵ and is not only the main source of livelihood, but also the main context in which daily social life takes place.

For years, R&D in agriculture has been an important area for public intervention and investment trends demonstrate that it is a growing field.⁵⁶

Today India ranks fourth for public investments in agricultural R&D, after the United States, Japan and China.⁵⁷ The main actors in this type of research are ICAR (Indian Council of Agricultural Research) and the State Universities of Agriculture (SAU). In 2005, the total expenditure on research amounted to about \$1.4 billion of international purchasing power and of this sum, 43% was carried by ICAR and 50% by universities. The progressive reduction of arable land, excessive use of fertilizers and chemicals and high levels of malnutrition of the population⁵⁸ have led to a growing interest in modern biotechnology as a privileged field of agricultural research and as a possible answer to the country's main problems.

Recognizing the potential of biotechnology, in 1982 the Government of India established the National Biotechnology Board, which later became an official governmental department (Department of Biotechnology, DBT) within the Ministry of Science and Technology, as well as the leading agency responsible for supporting R&D in agricultural biotechnology and the creation of adequate infrastructures. Since 1990, the DBT has funded the construction of 7 Centers for Molecular Biology of Plants for the development of research and the training of qualified personnel in the field.⁵⁹ Today, there are about 50 public research institutions that use and develop biotechnological applications in plants; it is estimated that the government invests an average of 15 million US dollars a year in the sector⁶⁰ and the trend of investments is growing. Despite a significant presence in the private sector, most R&D still remains concentrated in the public institutions funded by the government and in the universities. In addition, the National Centre for Plant Genome Research (NCPGR) was established in New Delhi to further the consolidation of research activities in this area.

The Environmental Protection Act (EPA)⁶¹ of 1986 laid the foundations of the regulatory framework for biotechnology in India and established the rules for the research, development, large-scale use and importation of genetically modified organisms, as well as the breakdown of responsibilities of institutional actors (Ministry of Environment, Ministry of Agriculture, Ministry of Science and Technology, Ministry of Health, etc.). Over the years, more detailed guidelines to regulate the specific needs arising from the evolution of technology have also been added⁶² and several bodies/committees for the control of various aspects of the phenomenon have been created.

In a regulatory environment populated by numerous laws and different actors, the efforts of the Government of India today are, therefore, mainly directed toward the rationalization and optimization of the overall system. Among recent developments worthy of attention is the National Strategies on Biotechnology,⁶³ presented in 2007 by the Ministry of Science and Technology. One of its main points is the establishment of the *National Regulatory Authority on Biotechnology* (NBRA), which will be the sole interface for the authorization and control of biotechnology products and will cancel the division of powers designed by the EPA.

The *Food Safety and Standards Act* of 2006 was created with the same goal of simplification; with it, the government has united all applicable laws and existing regulations

AGRICULTURE STILL PLAYS A KEY ROLE IN THE INDIAN ECONOMY TODAY AND IS NOT ONLY THE MAIN SOURCE OF LIVELIHOOD, BUT ALSO THE MAIN CONTEXT IN WHICH DAILY SOCIAL LIFE TAKES PLACE

TODAY, INDIA RANKS FOURTH FOR PUBLIC INVESTMENTS IN AGRICULTURAL R&D, AFTER THE UNITED STATES, JAPAN AND CHINA

IN 1982, THE GOVERNMENT OF INDIA ESTABLISHED THE NATIONAL BIOTECHNOLOGY BOARD, WHICH LATER BECAME AN OFFICIAL GOVERNMENTAL DEPARTMENT

THE ENVIRONMENTAL PROTECTION ACT ESTABLISHED THE RULES FOR THE RESEARCH, DEVELOPMENT, LARGE-SCALE USE AND IMPORTATION OF GENETICALLY MODIFIED ORGANISMS

THE GOVERNMENT HAS UNITED ALL APPLICABLE LAWS AND EXISTING REGULATIONS WITH REGARD TO FOODSTUFFS UNDER A SINGLE AUTHORITY, THE FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

THE MINISTRY OF SCIENCE AND TECHNOLOGY HAS DECIDED TO CREATE PLATFORMS THAT ENCOURAGE INDUSTRIAL COOPERATION AND THE MEETING OF PUBLIC AND PRIVATE SECTORS

INDIA DOES NOT REGULATE THE PRICES OF SEEDS AND DOES NOT IMPOSE TARIFFS ON TECHNOLOGY

INDIAN FARMERS ARE GENERALLY UNAWARE OF THE PRESENT LEVEL OF DEVELOPMENT AND DIFFUSION OF BIOTECHNOLOGY IN THE AGRO-FOOD SECTOR.

with regard to foodstuffs under a single authority, the Food Safety and Standards Authority of India (FSSAI), which is responsible for establishing the scientific standards for food and for the alignment of existing standards with international ones.⁶⁴

It, therefore, confirms the central role given to agriculture and research to improve its performance. In the *11th Five Year Plan (2007-2012)*, among the many strategic areas, those identified as priorities for agri-food biotechnology are:

- the *genomics of rice*, with particular attention given to the study of genetic variation linked to increases in yields;
- the *molecular maps* of rice, wheat and the main legumes;
- the *improvement of the nutritional properties* of the main crops.

To meet the new challenges of agriculture and develop successful R&D in biotechnology projects that are becoming increasingly complex and expensive, the Ministry of Science and Technology has finally decided to create platforms that encourage industrial cooperation and the meeting of public and private sectors regarding these issues. Among these, Agricultural Biotechnology⁶⁵ is the first that will be formally constituted and on which resources and the first projects are being catalyzed right now.

Currently, India does not regulate the prices of seeds and does not impose tariffs on technology. This means that seed companies, as a provider of technology, can set their own tariffs. This aspect has created a number of disputes and grievances over time on the part of states which complained of situations of effective monopoly.⁶⁶ While the situation has not yet been formally addressed by a legislative measure, the business community has the growing fear that government interference in pricing could be a deterrent to investments in new technologies.

3.4.3 Public opinion regarding agri-food biotechnology

With the exception of the case of Bt cotton, Indian farmers are generally unaware of the development and diffusion of biotechnology in the agri-food sector. According to a recent study by the Asian Food Information Center,⁶⁷ only 32% of the population is, in fact, aware that biotech products can be purchased in grocery stores. There is a widespread confidence⁶⁸ toward foods derived from biotechnology and a positive attitude⁶⁹ toward the benefits that these techniques can bring in the coming years. Among the main benefits highlighted is the potential improvement of the quality of food, followed by the availability of healthier foods which are able to solve the serious problem of malnutrition that afflicts the country. As in other Asian countries, in India the concept of sustainability in the food production chain is only now becoming more widespread and less than 10% of the population claims to be aware of it. However, Indian farmers are rapidly reaching an indirect awareness of these issues, thanks to the increasingly frequent relations they have with foreign firms and their agricultural models oriented to exportation and profit.

If, on the whole, the public and the scientific community can be considered favorable to the use and further development of biotechnology in the agri-food sector, there are still some reservations relating, instead, to the interests of multinational companies that, in growing number, have chosen India as their area of choice. Starting in 1991, when the Indian government began its process of economic liberalization, there have been numerous expressions of disappointment and concern on the part of Indian farmers concerning the ever-growing presence of these actors, who have introduced hybrid seeds at higher prices and with an annual turnover.⁷⁰ Indian farmers are, however, traditionally accustomed to

using seed varieties developed by public research institutes, which are, thus, available at lower prices and which can be reused year after year. Emblematic in this regard is the position of Vandana Shiva,⁷¹ one of the main leaders of thought in India, who in recent years has increasingly contributed to public debate by proposing the topic of the future of food. Among the key elements of her studies, is precisely the role of multinational seed companies which, with the crops proposed to farmers, would trigger a dependency on transgenic seeds, chemical fertilizers and toxic pesticides, with high costs for farmers. The new hybrid crops would tend, in fact, to be more susceptible to pest attacks. The expensive seeds would not adapt to local conditions and, therefore, would require more investments in chemicals and irrigation. In this way, the farmers would become impoverished to the advantage of the seed companies because, in the long term, the greater revenues would not cover the additional expense. This would have led to suicide for hundreds of Indian farmers, overwhelmed by debts.⁷²



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3.5 AGRI-FOOD BIOTECHNOLOGY IN ARGENTINA

ARGENTINA IS STUDYING HOW OTHER AGRI-FOOD APPLICATIONS CAN CONTRIBUTE POSITIVELY TO SUSTAINABLE GROWTH IN THE AGRICULTURAL SECTOR

The recent loss of its competitive advantage with respect to countries producing biotech and the growing concerns of companies which complain about the excessive slowness of authorization procedures and controls, have led Argentina, one of the leading countries in the world for biotech food, to begin a process of reflection to investigate how other technological applications, less restrictive with respect to the sedimented regulations, can contribute positively to sustainable growth in the agricultural sector. In this transitional phase, the evidence is still limited, though the potential for development seems high, if only the country is able to seize upon it.

3.5.1 Facts & figures

AFTER 12 YEARS OF PRIMACY, SECOND ONLY TO THE U.S., ARGENTINA IS NOW THE THIRD WORLD POWER, SURPASSED ALSO BY BRAZIL, IN THE PRODUCTION OF GENETICALLY MODIFIED ORGANISMS

After 12 years of primacy, second only to the U.S., Argentina is now the third world power, surpassed also by Brazil, in the production of genetically modified organisms⁷³ in terms of cultivated area, amounting to 22.9 million hectares in 2010. There are 17 varieties of crops approved for trade: one is for soybeans, thirteen for corn and the remaining three for cotton. Penetration rates are high, making this country the one with the highest percentage of arable land planted with biotech crops. Almost all of the area used for soybeans is, in fact, devoted to biotech,⁷⁴ as is 97% of that allocated to cotton and 83% of the area for corn.

Argentina places eighth in the ranking of countries as to the number of companies investing in biotechnology.

ARGENTINA PLACES EIGHTH PLACE IN THE RANKING OF COUNTRIES FOR THE NUMBER OF COMPANIES THAT INVEST IN BIOTECHNOLOGY

Argentina places eighth in the ranking of countries as to the number of companies investing in biotechnology.⁷⁵ There are more than 80 companies, covering all sectors of the industry, generating a total turnover of about U.S. \$400 million, and employing 5,000 workers.⁷⁶ The agri-food sector⁷⁷ is in many ways the most important: it comprises 65% of the companies, representing 64% of total revenues, employs 55% of the workforce and is responsible for almost 45% of export revenues.⁷⁸ Differing from other countries where the entry of multinationals has progressively inhibited the development of local business actors, Argentina has come to create a positive co-existence over time between foreign and local firms,⁷⁹ also thanks to a model for the protection of intellectual property rights that is different from North America's. The major international companies in the country include: Bayer Crop Science, Dow AgroScience, Nidera, Monsanto and Pioneer, whereas the national ones include: Bioceres, BioSidus and Indear.

The large multinational companies are those that traditionally develop new GMO varieties and then later introduce them into the country for their adaptation to specific environmental conditions. Instead, local businesses, with just a few exceptions, focus their

research projects on the use of techniques that are not related to the use of recombinant DNA and on which the Argentine government has now focused attention, considering it to be very solid and fertile ground for new development of the local businesses.

In Argentina, the research activities in agriculture are mainly carried out by national research institutes, universities and some local businesses.⁸⁰ There are 74 public agencies⁸¹ working in the sector that altogether employ about 3,940 FTE researchers,⁸² having generated in 2005 an expenditure of \$448 million at constant prices and international purchasing power parity. The National Institute of Agricultural Technology (INTA) is the main player in agricultural R&D. It occupies about half of the workforce in the sector and carries nearly 60% of the total expenditure.⁸³ Organized into 15 regional centers that work closely with local producers and orient the research to local needs, the INTA is a decentralized public organization with operational and financial autonomy that reports to the Secretariat of Agriculture, Livestock and Fisheries of the Ministry of Economy and Industry. After the significant slowdown of the economic crisis of 1999-2002, and thanks to increased investments of the INTA, the country has now more than doubled the levels of spending in agricultural R&D and qualifies, for this specific area, as the third system in Latin America, after Brazil and Mexico.

In the specific sector of agri-food biotechnology, there are approximately 28⁸⁴ active institutions,⁸⁵ including public centers and private foundations. The presence of local excellence, combined with the growing interest of companies toward these issues and the adoption of increasingly competitive incentive schemes, has also gradually led to the emergence of many initiatives for cooperation between the public and private sectors. In this regard, one model which is recently emerging and being consolidated, is "technology hubs," or rather, platforms specialized in R&D related to areas of priority for the territory, in which public and private sectors work together not only in the development of joint projects, but also in the actual implementation of the infrastructures, the creation of a skilled workforce and consolidation of the industrial chain connected to it. Testifying to the importance given to the issue of food biotechnology is the fact one of these hubs is the Rosario Biotechnological Hub, in the Province of Santa Fe. Made up of several institutions specializing primarily in plant biotechnology, this hub is the largest biotechnology center in Latin America.

Despite the skilled workforce in the country,⁸⁶ the scientific and technological infrastructures that are being developed (bio-park, incubators, etc.) and the growing importance given to agri-food biotechnology, the public and private expenditure on R&D for this sector is still considered too low, compared to that of other countries producing biotech.⁸⁷ However, the research activities conducted on biotechnology are quite varied and, according to a survey conducted by the ISNAR (International Service for National Agricultural Research), range from traditional genetic engineering, the diagnosis of plant pathogens and molecular markers, up to techniques of micropropagation and tissue culture⁸⁸ applied to numerous crops including: garlic, onion, potato, sunflower, corn, wheat, strawberry, tomato, rye, citrus and blueberry. Specifically with regard to the food sector, some local excellences⁸⁹ have gone into the production of high-fructose corn syrup and an intermediate glucose syrup.

RESEARCH ACTIVITIES IN AGRICULTURE ARE MAINLY CARRIED OUT BY NATIONAL RESEARCH INSTITUTES, UNIVERSITIES AND SOME LOCAL BUSINESSES.

THE RESEARCH ACTIVITIES ON BIOTECHNOLOGY TECHNIQUES ARE QUITE VARIED AND ARE APPLIED TO MANY CROPS, INCLUDING GARLIC, ONION, POTATO, SUNFLOWER, CORN, WHEAT, STRAWBERRY, TOMATO, RYE, CITRUS AND BLUEBERRY



3.5.2 Public policies and regulations

One of the factors that led Argentina to quickly climb to its position among the producing countries in the field of biotech food is the presence of a solid regulatory framework which was structured right at the start of the process of technology development. Just think, by way of example, that when the first GMO variety was introduced on the U.S. market, Argentina had already defined the regulatory mechanisms necessary for the evaluation of this technology, thus making the country-context highly attractive to businesses looking for rapid returns on investments. To manage the development of this sector, which was still in its infancy, the National Institute of Seeds (INASE)⁹⁰ and the National Commission for Agricultural Biotechnology (CONABIA)⁹¹ were created in 1991.

Subsequently, with the rapid evolution of technological applications and the corresponding increase in the need for their control, the regulatory system has become increasingly detailed, enriched with a plurality of actors with shared roles that are not always unique. Central and superordinate to all is the Biotechnology Directorate of the Ministry of Agriculture, founded in 2009, which coordinates the areas of biosafety, policy analysis and the definition of regulations. A traditional process of approval of a new species of biotechnology, which usually lasts 42 months in Argentina, now involves several agencies inside the Ministry, more specifically:

- the *National Commission for Agricultural Biotechnology* (CONABIA): A multidisciplinary and inter-institutional organization with supporting duties in the evaluation of the impact of the new variety on the agricultural ecosystem, from both a technical and a scientific point of view;
- the *National Service for Health and Quality of Food* (SENASA)⁹²: an organization that controls the biosafety of products derived from biotech crops;
- the *Directorate General for Agriculture and Food Markets* (DNMA)⁹³: an organization that evaluates the sales impact of the new product on export markets;
- the *National Institute of Seeds* (INASE)⁹⁴: responsible for defining the requirements for inclusion in the National Register of Crops.

Although the other Latin American countries have adopted a law on the bio-safety of crops and food, Argentina has not yet done so, representing an anomaly in this respect, especially because of the importance agriculture has in its economy⁹⁵ and for the primary role of biotechnology in the country. There are a number of laws and guidelines under discussion on issues such as bio-safety, risk assessment and labeling,⁹⁶ but no significant progress has been made so far in this direction.

Another of the most controversial aspects of the regulatory framework in Argentina, a cause of numerous complaints from the business world, is the discipline of the protection of intellectual property rights (IPR) and related royalties. Despite the country's leadership position in food biotechnology, there actually is still no adequate and efficient system of protection of the IPR for the new plant species developed or for any of the new technological applications that are developed.⁹⁷ The penalties for the unauthorized use of new seed varieties are not sufficiently disincentive and judicial enforcement mechanisms have not proven to be effective over time.⁹⁸ This lack in the regulatory system is, thus, gradually eroding the initial competitive advantage of the country in the eyes of the businesses in this sector.⁹⁹

Among the latest innovations in the Argentine regulatory system, two are of particular interest: the draft law for the support of biotechnology (aimed at promoting and developing the sector through tax incentives and specialized services) and the Strategic Plan of Development of Agricultural Biotechnology 2005-2015, through which Argentina has officially entered a new phase of development of biotechnology techniques.

THE REGULATORY FRAMEWORK IS SOUND AND WAS STRUCTURED RIGHT AT THE START OF THE PROCESS OF TECHNOLOGY DEVELOPMENT

THE BIOTECHNOLOGY DIRECTORATE OF THE MINISTRY OF AGRICULTURE, FOUNDED IN 2009, COORDINATES THE AREAS OF BIOSAFETY, POLICY ANALYSIS AND THE DEFINITION OF REGULATIONS

THE LACK OF AN ADEQUATE SYSTEM OF PROTECTION OF THE INTELLECTUAL PROPERTY RIGHTS FOR THE NEW SPECIES DEVELOPED IS ERODING ARGENTINA'S INITIAL COMPETITIVE ADVANTAGE

THROUGH THE STRATEGIC PLAN OF DEVELOPMENT OF AGRICULTURAL BIOTECHNOLOGY 2005-2015, ARGENTINA HAS OFFICIALLY ENTERED A NEW PHASE OF DEVELOPMENT OF BIOTECHNOLOGY TECHNIQUES

ARGENTINA'S APPROACH TO THIS ISSUE DEMONSTRATES HOW THE GOVERNMENT WANTS TO GIVE VALUE NOT ONLY TO THE TECHNOLOGICAL ELEMENTS, BUT ALSO TO POLITICAL, REGULATORY AND FINANCIAL ONES

Specifically, the Plan¹⁰⁰ proposes a broader range of biotechnological applications (not just transgenesis) to offer the country, traditionally an importer and adapter of technologies from the outside, a new role and new prospects for development, expressing the hope that modern techniques can become a common component in all areas of agricultural production in Argentina. It is, thus, promoting the creation of an enabling environment in political, legal and public acceptance terms, in order to fully exploit the potential of the sector and encourage the creation of firms specializing in biotechnology with different instruments, as well as the strengthening of existing ones. The definition of a Plan, specifically focused on agricultural biotechnology and, therefore, not mixed with other kinds of strategic development, as with most of the countries analyzed here, is a testament to the importance attached by the government to this set of technological applications, regarded as one of the main responses to the challenges of the future of agriculture in Argentina. In the participatory process¹⁰¹ that has characterized its birth and will accompany a flexible development in time, it is a further demonstration of how Argentina's approach to this issue is integrated, that is, able to give value not only to the technological elements, but also to political, regulatory and financial aspects, placing them in a systemic perspective which is able to make the most of the industry.

3.5.3 Public opinion regarding agri-food biotechnology

SCIENTISTS AND REPRESENTATIVES OF INDUSTRY ARE OPTIMISTIC ABOUT THE USE OF BIOTECHNOLOGY, WHEREAS CONSUMERS DO NOT SEE ANY DIRECT BENEFIT FROM IT

In Argentina, the majority of scientists and representatives of industry are optimistic about the future use of biotechnology to increase crop yields and for the improvement of the nutritional properties of food.¹⁰² Consumers, however, do not yet see the use of biotechnology as being able to bring them a direct benefit, but rather, as an area that is potentially profitable for the companies.

A survey¹⁰³ conducted by the SAGPyA¹⁰⁴ in 2005 within the international project UNEPGEF¹⁰⁵ on producers and consumers confirms this dichotomy. In fact, 82% of the producers said that biotechnology is a tool that contributes significantly to the resolution of some critical aspects of the agricultural sector to which no answer had yet been given. 75% also added that the consumption of biotech products does not pose any health risks. However, this confidence in new molecular technological applications is supported by a real understanding of the sector regulation, which is demonstrated by the fact that today there are numerous complaints and a growing discontent in the business world. Only 12% of respondents, in fact, declared they were aware of the regulatory system.

From the perspective of consumers, however, it is evident how a cursory knowledge of the plurality of meanings embodied in the term "biotech food"¹⁰⁶ brings a basic insecurity with it that characterizes the consumers' approach to products resulting from the use of biotechnology. 40% said, in fact, that the consumption of this type of product is the cause of risks to human health.

A widespread need for communication about the risks and potential benefits of these new technological applications emerged in the end from almost all of those interviewed.¹⁰⁷ The realization of the future development plan proposed in the Strategic Plan (which sees Argentina as the pioneer in the development of biotechnology alternatives to transgenesis) will necessarily have to pass through pervasive communication actions, capable of illustrating all the aspects of this kind of technology that are still largely unknown to the general public.¹⁰⁸

THERE IS A WIDESPREAD NEED FOR COMMUNICATION ABOUT THE RISKS AND POTENTIAL BENEFITS OF THESE NEW TECHNOLOGICAL APPLICATIONS



3.6 AGRI-FOOD BIOTECHNOLOGY IN BRAZIL

BRAZIL IS ONE OF THE MOST INTERESTING COUNTRY-CONTEXTS TO WATCH IN THE PANORAMA OF AGRICULTURE AND AGRICULTURAL TECHNOLOGIES WORLDWIDE

Brazil is one of the most significant countries worldwide in the field of agriculture and agrifood research. The extent of its farmed areas, the impressive level of the biodiversity found, that of its food production and the size and ubiquity of its R&D in the agri-food sector help to rank Brazil as one of the most interesting country-contexts to watch in the panorama of agriculture and agricultural technologies worldwide.

3.6.1 Facts & figures

BRAZIL HAS AN EFFECTIVE INFRASTRUCTURE OF RESEARCH, TRAINING, DIRECTION AND REGULATION WITHIN THE AGRI-FOOD SECTOR, AMONG THE MOST STRUCTURED GLOBALLY

Brazil – starting in 1972, the year of the founding of the Brazilian Company for Agricultural Research (EMBRAPA), the main body of research and development in the agri-food sector at the national level – has set up an effective infrastructure of research, training, direction and regulation within the agri-food sector; it is reviewed periodically as to its actors, roles and relationships and is among the most structured globally. This attention to the subject of research and experimentation in the field of food has led to the emergence of a wide network of research centers active in the field of biotechnology oriented, on the one hand, to the improvement of agricultural techniques and plant selection through “conventional” breeding techniques, and on the other, research in the field of transgenic techniques as applied to agriculture.

BRAZIL IS ONE OF THE HUBS OF GLOBAL SIGNIFICANCE IN THE FIELD OF PRIVATE RESEARCH AND EXPERIMENTATION

In addition to public research centers, the opening of the country to the cultivation of transgenic seeds has attracted some of the major international companies to the country that are active in research and marketing within the food industry, helping to make Brazil one of the hubs of global significance in the field of private research and experimentation, especially with regard to transgenic applications.

AMONG DEVELOPING COUNTRIES, TODAY BRAZIL IS THIRD, AFTER CHINA AND INDIA, FOR THE LEVEL OF PUBLIC INVESTMENTS IN RESEARCH AND DEVELOPMENT IN AGRICULTURE

The agri-food sector has always been identified, and even more so since the early nineties, as being strategic within the government guidelines for the development of the country. Following this recognition, significant public investment was allocated to the sector and, in particular, to research. Among developing countries, today Brazil is third, after China and India, for the level of public investments in research and development in agriculture.

In addition, experiments carried out with success regarding the adaptation of crops typical of temperate climates (such as soybeans) to the tropical climate of the country – also through the use of innovative agricultural techniques (*zero-tillage*) – have been widely reported, and (as also recognized by members of the EMBRAPA) the science world and the media seem to be able to open up interesting opportunities for future si-

tuations that until now were deemed far less suitable to the development of an efficient agricultural sector (parts of Africa, for example).

All this – combined with a number of important scientific achievements (think of the clamor generated in 2000 following the publication in “Nature” of the genetic code of the pathogen *Xylella fastidiosa*, particularly damaging for orange trees, which even earned the cover of the famous scientific magazine¹⁰⁹) – helps to explain the attention Brazil pays to biotechnology, both for its existing applications as well as for possible future developments.

The area of arable land in the country amounts to 59.6 million hectares and the most common crops are soybeans, corn, cassava, sugar cane and oranges. According to the “Economist,”¹¹⁰ 50% of the active farms in Brazil are very small and produce only 7% of the total national agricultural production; 32% of the farmers of significant size produce 76% of the total national agricultural output.

In 2010 – according to estimates made by the ISAAA¹¹¹ – 25.4 million hectares of land were used for the cultivation of genetically modified plants: an increase of 19% (4 million hectares) with respect to 2009. The main varieties marketed are HT soybean, Bt cotton and Bt maize. According to the USDA, (the figure is from July 2010) there are 21 genetically modified plants approved in Brazil: 11 varieties of corn, 6 of cotton and 4 of soybean.

Most private companies active in the field of agricultural biotechnology are localized in three major areas of the country: Sao Paulo, Rio de Janeiro and Minas Gerais. In terms of size, many of these companies are classified as micro or small enterprises, often linked to the presence – widespread in the country – of incubators and science parks of agricultural biotechnology.

The USDA, in its latest report on *Brazilian Annual Biotechnology Production & Outlook* (2010), predicts a further increase in the use of genetically modified crops in the country (today, Brazil is the world’s second largest user of these varieties, after the USA). The area occupied by the genetically modified variants is, therefore as follows: 55% of the total area planted with maize, 78% in the case of soybeans, 22% for cotton. The expected increase in the use of genetically modified plants is related to the definition, by the Brazilian government, of an agricultural credit package worth \$64 billion for the year (agricultural) 2010/2011 and to the recent approval of the use of some new variants of GM maize.

Brazil also appears to have invested significantly in recent years in the production of biofuels, ranking among the top producing countries worldwide, together with the U.S. In terms of research in biotechnology (not necessarily transgenic), in recent years Brazil has achieved significant results in the selection of new crops and plant varieties, adapted to the climatic conditions of the Brazilian territory, ensuring the achievement of an increase in yields.¹¹² This increase seems to have been achieved without an equally large expansion of cultivated land.¹¹³ However, some experts have pointed out that the introduction and expansion of large-scale cultivation of various crops (mainly soybeans and sugar cane) are progressively enlarging the portion of land intended for agricultural cultivation, to the detriment of the conservation of the original local natural environment (forest or otherwise).

One of the most successful areas has been the collection, preservation and management of the genetic resources in the sector of plants: special attention has been paid to the preservation of those elements of native vegetation at higher risk of disappearance and to the plant species suitable for human consumption traditionally used by farmers. Following the ratification of the Convention on Biological Diversity in Brazil, the National System of Conservation Units was created; it has led the country to now have

THERE ARE 21 GENETICALLY MODIFIED PLANTS APPROVED IN BRAZIL: 11 VARIETIES OF CORN, 6 OF COTTON AND 4 OF SOYBEAN

THE PRIVATE COMPANIES OF THE BIOTECHNOLOGY SECTOR ARE LOCATED IN THREE MAIN AREAS: SAO PAULO, RIO DE JANEIRO AND MINAS GERAIS

THE INTRODUCTION AND EXPANSION OF LARGE-SCALE CROPS ARE GRADUALLY EXPANDING THE PORTION OF LAND ALLOCATED TO AGRICULTURAL PRODUCTION, UNDERMINING THE ORIGINAL NATURAL ENVIRONMENTS

IMPORTANT RESEARCH HAS BEEN CONDUCTED TO IMPROVE THE NUTRITIONAL COMPOSITION OF THE CROPS AND TO GUARANTEE THE REDUCTION OF POST-HARVEST LOSSES

one of the most detailed systems for the preservation of protected areas in the world. In order to promote the conservation of the genetic resources of plants related to the more traditional cultivation and consumption of local populations, the implementation of “participatory breeding” interventions have been promoted, as well as seed fairs, local seed banks and centers for the dissemination of agricultural biodiversity at the local level.

The knowledge gained from the great work of the collection and characterization of germplasm has been the basis of several breeding programs of particular interest, such as the project *Orygens* (rice) and the *Latin American Maize Project* (corn).

Public agencies and public-private partnerships have conducted research activity regarding the development of crops resistant to diseases and insects, and tolerant to abiotic stress. From this point of view, the huge project of the collection and conservation of germplasm has allowed for the identification of the wild varieties that – more so than others – were able to naturally develop resistance to abiotic stress.¹¹⁴

In this sense, particularly interesting research regards the selection and improvement of resistance to abiotic stress that will be able to be conducted from the results obtained from a project launched by the Brazilian Environment Ministry for the identification and mapping of Creole varieties and their relative wild variants in reference to some of the major crops grown in Brazil; today, the screening has already been concluded for some important crops such as cotton, peanuts, rice, cucurbits, cassava and maize.

A field in which significant resources in terms of research have been invested – especially by the Center of Applied Biology of the EMBRAPA – is the improvement of the nutritional composition of crops (particularly in relation to corn). Other important research that has been done is aimed at guaranteeing the reduction of post-harvest losses. Finally, in particular at the Campinas Agronomic Institute (IAC) and in collaboration with EMBRAPA, research projects were conducted on the genome of the coffee plant (also thanks to the work in the collection and preservation of germplasm) and the recovery of contaminated soils and rhizosphere.

3.6.2 Public policies and regulations

The regulatory system of public research in relation to agricultural biotechnology in Brazil is complex, also and especially, because of the existence in the country of a two-tier system, composed of federal and state agencies.¹¹⁵

Since the '70s, the biotechnology sector has recorded a significant and largely preponderant direct public presence.

Public intervention in this field has not been limited – historically – to a simple definition of the legal and regulatory framework: since the '70s, the biotechnology sector has recorded a significant and largely preponderant direct public presence. Government agencies in this field, starting with EMBRAPA, play a key role in the development of biotechnology innovation and experimentation, the production/marketing of seeds, the definition and implementation of technology transfer,¹¹⁶ and the structuring of cooperation agreements (with private entities and with other public bodies, both Brazilian and non-Brazilian).

A number of initiatives related to R&D in agricultural biotechnology have also seen the direct presence of public agencies in addition to private companies present in the country, precisely because of the importance that the guidelines and public investments have in this sector.¹¹⁷

THE REGULATORY SYSTEM OF AGRICULTURAL BIOTECHNOLOGY IS COMPLEX, BECAUSE OF THE EXISTENCE OF A TWO-TIER SYSTEM, COMPOSED OF FEDERAL AND STATE AGENCIES

The EMBRAPA is the principal government agency in Brazil: it is a semi-autonomous agency at the federal level and is administered directly by the MAPA.

The EMBRAPA is the principal government agency in Brazil: it is a semi-autonomous agency at the federal level and is administered directly by the Ministry of Agriculture, Livestock and Food (MAPA). This is the largest agency of R&D in agriculture in all of Latin America, both for staff and budget. The agency is based in Brasilia and operates 15 central units and 42 research centers across the country.

Alongside this, there are agricultural research agencies in 17 of the 26 states that make up Brazil, even though most of the activities that are not conducted at the federal level are concentrated in the State of Sao Paulo. The public agency of the State of Sao Paulo – the Agency for Food Technology (APTA) – was founded in 2002 and coordinates all research activities on crops; it is organized into four major strategic programs: environmental sustainability, organization of rural areas, food security and bio-energy. The research is carried out by 6 research departments and a network of 15 regional research centers located throughout the state. Completing the system of agricultural research of the state are two centers of excellence, the Campinas Agronomic Institute (IAC) and the Biology Institute (IB), founded in 1887 and 1927, respectively.

Brazil also has a large number of public universities (mostly federal and state), in which research is carried out in the field of agronomy in more than 100 faculties or schools of agricultural sciences.

The role that Brazil has given to progress in biotechnology research has also been confirmed by the plan, *National Policy for Biotechnology: Brazil to Seek Global Leadership*, signed by President Lula da Silva in 2007, in order to make the country, within a decade, a global leader in biotechnology (not just in agriculture). To this end, investments of almost \$6 billion over ten years are expected, in part to provide a significant boost to the creation of start-up programs and academic research in this area.

From a regulatory standpoint, the framework on agri-food biotechnology is defined by Law 11,105 of 2005, as amended by Law 11,460 of 2007 and later by Decree number 5,591 in 2006.

The legislation that has been passed since 2005 also fills a lack of regulations regarding the use of biotech crops, leading to a situation of great confusion in the relevant legal and administrative framework: the cultivation of transgenic soy in Brazil, in fact, took place illegally for the first years, especially in the State of Rio Grande do Sul. The difficulty of sustainability of such a regulatory void and widespread illegality helped define the choice of the *Biosafety Law* in 2005.

The two main government bodies that regulate agricultural biotechnology in Brazil are:

- the *National Biosafety Council* (CNBS), that acts under the direct supervision of the Office of the President and is responsible for the formulation and implementation of the National Biosafety Policy (PNB): it establishes principles and guidelines for the administrative action for federal agencies involved in issues related to agricultural biotechnology and assesses the socio-economic implications and the overall national interests in relation to the approval of biotechnology products for commercial use;
- the *National Technical Commission of Biosafety* (CTNBio), initially established in 1995 within the framework defined by the first Brazilian biosafety law (Law 8,974); at the present, under the current regulations, it has increased its members from 18 to 27 to include representatives of the competent federal ministries, specialists with scientific backgrounds and technicians and experts on the issues of the defense of consumers and small farmers. The commission, which is subject to coordination by the Minister of Science and Technology, discusses and approves all technical aspects

THE EMBRAPA IS THE PRINCIPAL GOVERNMENT AGENCY IN BRAZIL: IT IS A SEMI-AUTONOMOUS AGENCY AT THE FEDERAL LEVEL AND IS ADMINISTERED DIRECTLY BY THE MAPA

THERE ARE AGRICULTURAL RESEARCH AGENCIES IN 17 OF THE 26 STATES THAT MAKE UP BRAZIL; HOWEVER, MOST OF THE ACTIVITIES THAT ARE NOT CONDUCTED AT THE FEDERAL LEVEL ARE CONCENTRATED IN THE STATE OF SAO PAULO

THE NATIONAL POLICY FOR BIOTECHNOLOGY: BRAZIL TO SEEK GLOBAL LEADERSHIP PLAN, SIGNED BY PRESIDENT LULA DA SILVA IN 2007, AIMS TO MAKE BRAZIL A LEADER IN BIOTECHNOLOGY

THE NATIONAL BIOSAFETY COUNCIL AND THE NATIONAL TECHNICAL COMMISSION OF BIOSAFETY ARE THE TWO MAIN GOVERNMENT BODIES THAT REGULATE AGRICULTURAL BIOTECHNOLOGY IN BRAZIL

THE APPLICATION FOR APPROVAL FOR THE SALE OF AGRICULTURAL BIOTECH PRODUCTS MUST PASS THE SCRUTINY OF CTNBIO AND THREE MINISTRIES, DEPENDING ON THE TYPE OF PRODUCT

AT THE BASE OF BRAZIL'S DEVELOPMENT IN BIOTECHNOLOGY, ARE ITS STRONG SCIENTIFIC TRADITION, THE PUBLIC FUNDING AND THE REGULATORY FRAMEWORK

related to biotechnology, and every agricultural commodity, whether intended for human consumption, for animal nutrition or industrial processing, must be pre-approved by the Committee, based on a case by case basis. Law 11,460 of March 21, 2007 amended Article 11 of Law 11,105 of March 24, 2005 and has determined that a simple majority of votes is required to approve new biotech products.

In June, 2008, the National Biosafety Council (CNBS) decided it would consider only the administrative appeals of national interest, on issues of social or economic importance. The CNBS would not assess the technical decisions on individual biotech events approved by the National Technical Commission of Biosafety (CTNBio), considering the approval to be final. This decision, together with the change of majority voting for the CTNBio, lowers the constraints present in Brazil for the approval of biotech events.

In operational terms, for the registration of a biotech event in Brazil, an application must be submitted for approval of the sale of agricultural biotechnology products to the CTNBio, which assesses the need for further environmental impact studies. After approval by the CTNBio, three other ministries have an important role in the registration process: the Ministry of Agriculture, Livestock, and Food (MAPA), for products used in agriculture, livestock and food (processing); the Ministry of Health, regarding the use of products for direct human or pharmaceutical use; the Ministry of Environment, for products that require registration and inspection for use in the natural ecosystem. From the standpoint of Intellectual Property Rights (IPR), the *Biosafety Law* - providing a clear regulatory framework for research and commercialization of biotech crops in the country - has outlined a strategy for high overall protection by the federal government of Brazil concerning the products of biotechnology in agriculture. Some multinational companies (like Monsanto, Syngenta and BASF) have entered into licensing agreements with EMBRAPA for the joint development of plant biotech crops, particularly in relation to soy, corn and cotton.

At the base of Brazil's great development in research and applications in biotechnology, are, in a nutshell:¹¹⁸ its strong scientific tradition in biotechnology, the significant public funding allocated to basic research and the presence of a regulatory framework that is generally favorable to biotechnological research.

3.6.3 Public opinion regarding agri-food biotechnology

BRAZILIAN FARMERS WILLINGLY ACCEPT BIOTECH CROPS

HOWEVER, BIOTECH PRODUCTS HAVE NOT BEEN GLADLY ACCEPTED IN THE FOOD INDUSTRY

IT WAS NOT POSSIBLE TO DETECT WHAT THE ATTITUDE OF CONSUMERS TOWARD BIOTECH PRODUCTS MAY BE, HOWEVER, HAVING FOUND ONLY A SUBSTANTIAL DISREGARD OF PUBLIC OPINION ON THE ISSUE

According to the USDA in its latest report, Brazilian Annual Biotechnology Production & Outlook (2010), acceptance of biotech crops in Brazil is strong among producers. According to the Brazilian Farm Bureau (CNA), the last full-scale survey among farmers in Brazil (dating back to 2001) showed an 80% acceptance rate of biotech crops. However, the USDA shows that the acceptance of plant products obtained through the use of biotechnology is, on the whole, low among the exponents of the food industry. In particular, there is a widespread fear of the possibility of advertising campaigns against their products. Even the big players of Brazilian consumer goods have proven reluctant to accept biotech products.

The USDA believes that reliable information on consumer attitudes toward products from agricultural biotechnology in Brazil is not available at present. In general, the USDA reported a general indifference of public opinion toward the debate about the use of biotechnology in agriculture.

At any rate, a marketing campaign has been created, Brazil Better without Transgenic, against the use of genetically modified crops in Brazil, sponsored by Greenpeace and

supported by various environmental groups and consumers, with the involvement of some government officials at the Ministry of Environment, some political parties, the Catholic Church and the Landless Movement. In general, the campaign against plant biotechnology products in Brazil, however, is more effective against large-scale retailers and food processing than toward Brazilian consumers.



Taylor S. Kennedy/National Geographic Stock

4. CONCLUDING REMARKS

4. CONCLUDING REMARKS

When we prepared the work plan for this document, we set the goal of understanding what the future developments of food biotechnology could be, both in technical terms, with reference to their role in supporting environmental, social and economic sustainability, and in geopolitical terms, recognizing that biotechnology will play a very important role that will influence the future structure of the global agriculture and food sector.

Below, we have summarized the main conclusions of our investigation.

As long as GMOs continue, by their intrinsic nature, to be located primarily within an intensive, large-scale agricultural model with a high use of chemicals, they will pose a conflict between different visions of agricultural activity. On the one hand, there is the belief that, supported by different logic and tools (yesterday chemistry, today biotechnology associated with chemistry), the models of the recent past can be extended, including in ways that are undifferentiated from a geographical viewpoint. On the other hand, however, some people believe it would be opportune to rethink the whole food system, considering the lack of natural resources today that are the basis of farming (from basic materials for fertilizers to water) and taking into account the consequences of climate change.

It will be possible to re-evaluate the role of GMOs once they have demonstrated that they also provide appropriate responses as models of sustainable agriculture, capable of adapting to local and agricultural contexts that are accessible and functional to a wider audience of farmers.

Too often, research on agricultural productivity is a goal that is sought in order to justify the adoption of standardized solutions that do not take into account the geographical and social contexts in which they are applied. There is a problem of productivity in many parts of the world today and technology can provide an effective response only in some circumstances. There are situations in which other factors play a greater role: a better organization of work and family life, the consideration of all the factors of production, the application of effective and sustainable agricultural practices, improved infrastructures, more efficient and democratic market structures, modern irrigation systems, etc. The point is to choose the most appropriate intervention strategy for the specific geographical context.

Furthermore, we must not forget that a significant proportion of what is produced in agriculture today is destined for use by farm animals or, more recently, in non-food industrial uses, as in the case of biofuels.

The issue of sustainability is, therefore, very complex and includes matters relating to the use of agricultural production, the geographical distribution of food, lifestyles and con-

sumption (not only in Western countries), and research aimed at increasing productivity, always within a logic of both economic and social sustainability.

The criticism that is often aimed at the most important companies in the transgenic sector is that of focusing on maximizing their profits, leveraging business models that integrate biotechnology and chemical products,¹ and mainly working on those features that help optimize these models. Starting from this basis, the question today is quite broad on behalf of normally large farms that have adopted the model of intensive monoculture in countries like the United States, Canada, Argentina and Brazil. Furthermore, the recent choice to facilitate the cultivation of agricultural products for biofuel production in various areas of the world, as in the case of first-generation biofuels, has further strengthened the intensive model for some crops, such as corn, creating a greater demand for genetically modified seeds.²

This historical moment is complex and interesting because the structure of the food biotechnology industry is still being defined, even in the transgenic field. Only a small number of countries are completely open to GMOs, even though they are authentic giants, and not only in agriculture: the USA, Canada, China, India, Brazil and Argentina. In developed countries, research is basically supported by private multinational companies; in emerging countries, research is conducted almost exclusively by public structures which are independent of the American and European multinationals, which are dedicated to satisfying the specific needs of their own national territories. Even the norms governing the biotechnology sector differ greatly between developed and emerging countries.

In 10 years, the field of agricultural biotechnology will be very different from what we know today (plus, a greater decisional power will come from emerging countries), and there will certainly be a more extensive use of techniques.

In the meantime, public-private partnerships in biotechnology research are slowly becoming the norm once again.

The limitations placed on access to and use of information mainly depend on how the intellectual property rights are regulated. This is a matter of genes, uses and techniques that revolve around the production of genetically modified organisms. The limited sharing of these assets by public scientific institutions and among the several private companies active in the field, associated with the development costs and, therefore, with the burden of their adoption, affect research and the availability of the results. The future potential of the sector mainly depends on the possibility of establishing a different regulatory regime for intellectual property.

The consolidation of public-private partnerships in biotechnology research is slowly resuming. Perhaps, it is the beginning of the end of a sector which is “drugged” by a questionable interpretation of restrictive intellectual property rights, that has created a very rich market protected by almost insurmountable barriers of entry. The roles and responsibilities of different partners in the process of research and development are still required for a better qualification.

The non-transgenic biotechnologies (non-GM) are of growing importance and their use is seen as a possible method that is complementary to the traditional techniques of crossing and hybridization. This is a very different use of biotechnology: here, the technology becomes an accelerator of processes, increasing the efficiency and effectiveness (in terms of time and cost) of already-known techniques. The non-GM bio-

GMOS ARE IMPORTANT FOR AN INTENSIVE SINGLE-CROP AGRICULTURAL MODEL

THE ENTRANCE OF EMERGING COUNTRIES IS BEGINNING TO CHANGE THE STRUCTURE OF THE BIOTECHNOLOGY SECTOR

PROPERTY RIGHTS ARE UNDULY LIMITING THE ABILITY TO EXPLOIT KNOWLEDGE IN THE FIELD OF BIOTECHNOLOGY

THE DEVELOPMENT OF PUBLIC-PRIVATE RESEARCH PARTNERSHIPS TO REDUCE LIMITATIONS IN RESEARCH

NON-GM TECHNOLOGY THAT IS ABLE TO ACCELERATE THE TRADITIONAL PROCESSES OF CROSSING AND HYBRIDIZATION IS BEING INCREASINGLY USED

THERE HAS BEEN INTEREST
IN DEVELOPING VARIETIES
THAT ARE RESISTANT TO
DROUGHT OR SUITABLE FOR
SALINE SOILS

technologies have obtained results that, over time, have been well above those achieved by genetically modified organisms, and this with only their modest number of traits.

The combination of the lack of water and the gradual salinization of the soil is the main problem in terms of agricultural productivity and a leading cause of phenomena of famine in arid and semi-arid regions of the planet.

The progressive deterioration of the average quality of the land – in more or less serious forms – basically involves the entire agricultural sector worldwide. If biotechnology in general seems to play a possible role of support in the development of plants that are better able to tolerate abiotic stress, transgenic approaches have not, however, had satisfactory results so far, despite announcements made by the large multinational companies.

Incomplete knowledge of plant metabolism associated with the occurrence of abiotic stress, in conjunction with the frequent combination of multiple factors in the field, make the approaches based on genetic engineering – which are currently often focused on a single, critical factor – not very effective in the open environment and lead to considering more multi-dimensional approaches instead, based on a combination of biotechnology and non-GM farming techniques.





NOTES AND BIBLIOGRAPHY

CHAPTER 1

1. "Food production that makes the best use of nature's goods and services while not damaging these assets" (Pretty, 2005).
2. FAO, 2008.
3. We confine ourselves here to a brief mention, since it is not the appropriate forum for detailed discussion of the topic. A position paper on the topic of sustainable agriculture will be completed by the Barilla Center for Food & Nutrition by the end of 2011.
4. The intensive agricultural models of the green revolution are based on intensive consumption of fossil fuels, necessary not only for the obvious field activities and logistics, but also for the production of fertilizers and agrochemicals.
5. Soil erosion, water contamination, pollution of rivers and seas, deforestation and loss of biodiversity.
6. Evaluating the current and future prospects of access to food, environmental sustainability, health impact and impact on society.
7. The FAO estimates that there are 1.3 billion tons of waste worldwide.
8. President of Bocconi University, former European Commissioner for Competition, a member of the Advisory Board of the Barilla Center for Food & Nutrition.
9. Genetically Modified Economics.
10. Olivier De Schutter, who we appreciate for the availability granted us, is Special Rapporteur on the Right to Food for the United Nations, and Professor of Law at the University of Leuven.
11. Composed of Barbara Buchner, Claude Fischler, Mario Monti, John Reilly, Gabriele Riccardi, Camillo Ricordi and Umberto Veronesi. The Advisory Board oversees the activities of analysis of the Barilla Center for Food & Nutrition. The official position statements, expressed through documents and declarations, are not directly attributable to the members of the board.

CHAPTER 2

1. For any further study, see – among other important documents – the "FAO International Conference" in Guadalajara, held last March 4, 2010, having as its object the subject of biotechnology in agriculture and the significant amount of supporting documentation. For a brief historical overview to the inner section, the reference text is *State of Food & Agriculture* (FAO, 2003–2004).
2. "Convention on Biological Diversity," FAO Biotechnology Glossary.
3. Secretariat of the Convention on Biological Biodiversity, 1992.
4. Zaid, A., H.G. Hughes, E. Porceddu, F. Nicholas, Glossary of Biotechnology for Food and Agriculture – A Revised and Augmented Edition of the Glossary of Biotechnology and Genetic Engineering, FAO, 2001.
5. For at least 10,000 years, man has been changing plants and animals to adapt them to his

needs. As evidence of this, researchers of the "Max Planck" Institute in Cologne, Germany, found fossils of wild wheat in the Fertile Crescent (the Middle East region, now mostly Turkey, where agriculture was born 10–11,000 years ago). The seeds of wheat, properly treated by the first farmers, gave rise to the different varieties grown during the Bronze Age. Studies have shown that wheat is diploid, that is, with two sets of chromosomes, and therefore, resulting from one of the first interventions of genetic manipulation.

6. Between 1856 and 1863, Mendel crossbred over 30,000 species of plants and then presented and published the results on several occasions in his studies.
7. Deoxyribonucleic acid.
8. *Is GMO agriculture sustainable?*, Barilla Center for Food & Nutrition, 2010.
9. Genomics is a branch of molecular biology that deals with the study of the genomes of living organisms and, in particular, deals with the structure, content, function and evolution of the genome.
10. Set of chromosomes in each cell of an organism.
11. By way of example, we mention: the polymorphisms for restriction fragment length (RFLP), randomly amplified polymorphic DNA (RAPD), the amplified fragment length polymorphisms (AFLP) and micro-satellites.
12. A single nucleotide polymorphism (SNP) is a polymorphism, that is to say, a variation of genetic material at the expense of a single nucleotide, such that the polymorphic allele is present in the population in a proportion greater than 1%. Below this threshold, it is customary to speak of mutation.
13. Genomics is the study of the genome of an organism.
14. Or, Targeting Induced Local Lesions in Genomes.
15. Doebley, J.F., B.S. Gaut, B.D. Smith, *The Molecular Genetics of Crop Domestication*, in "Cell," December, 2006.
16. In 1950, the FAO initiated a collaboration with the International Atomic Energy Agency ("Atoms for Food Global Partnership") in order to make the irradiation technology more accessible for developing countries.
17. For a comprehensive overview of the major challenges to which the global agricultural sector (through agricultural innovation) will be called upon to give an answer, also see, among others: the *Final Report and background documents*, FAO International Technical Conference "Agricultural Biotechnologies in Developing Countries: Options and Opportunities in Crops, Forestry, Livestock, Fisheries and Agro-industry to Face the Challenges of Food Insecurity and Climate Change," 2010; Chikelu Mba, *Harnessing PGRFA for Enhanced Crop Productivity. Challenges and Opportunities*, FAO, 2010; Dr. Kakoli Ghosh, *Towards a Strategic and Integrated Management of Plant Genetic Resources for Food Security and Sustainable Development*, FAO, 2009; Ruane, J., A. Sonnino, *The Role of Biotechnology in Exploring and Protecting Agricultural Genetic Resources*, FAO, 2006; *The CAP in 2020: meeting the future challenges of food, natural resources and territory*, the European Commission, 2010; *The Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture*, The Commission on Genetic Resources for Food and Agriculture, FAO, 2009; Fears, R., *Genomics and Genetic Resources for Food and Agriculture*, background paper for the Commission on Genetic Resources for Food and Agriculture, FAO, 2007; Martínez, A., A. Amri, *Managing Plant Genetic Resources in the Agro-ecosystem: Global Change, Crop-associated Biodiversity and Ecosystem Services*, 2008.
18. For a brief analysis of opportunities and concerns that the use/adaptation in the context of developing major biotechnology in agriculture of MAS (but the considerations can be, to some extent, generalized), see Guimaraes, EP *et al.*, *Marker-Assisted Selection. Current status and future perspectives in crops, livestock, forestry and fish*, pp. 10–13, FAO, 2007.
19. In this regard also see: Gurr, S.J., P.J. Rushton, *Engineering Plants with Increased Disease Resistance: What are We Going to Express?*, in "Trends Biotechnol.," 23, pp. 275–282, 2005a;

Gurr, S.J., P.J. Rushton, *Engineering Plants with Increased Disease Resistance: How are, We Going, to Express, it?*, in "Trends Biotechnol," 23, pp. 283-290, 2005b.

20. In this regard also see: Sundaram, R.M. *et al.*, *Introduction of Bacterial Blight Resistance into Triguna a High Yielding, Mid-early Duration Rice Variety*, in "Biotechnol," J. 4(3), pp. 400-407, 2009.

21. Consider, as a prime example, the case of "Ug99" rust in wheat, upon which - because of its prevalence and impact - a research program established at the international level, including FAO, USDA-ARS, CIMMYT, the Gates Foundation and ICARDA, is currently working.

22. With regard to this also see the works of: Boyer, J.S., *Plant Productivity and Environment*, in "Science," 218, pp. 443-448, 1982; Ribaut, J.-M., J. Betrán, *Single Large-scale Marker-assisted Selection (SLS-MAS)*, in "Mol. Breed," 5, pp. 531-541, 1999; Forster, B.P. *et al.*, *The Development and Application of Molecular Markers for Abiotic Stress Tolerance in Barley*, in "Journal of Experimental Botany," 51, pp. 19-27, 2000; Ribaut, J.-M., G. Edmeades, E. Perotti, D. Hoisington, *QTL Analyses, MAS results, and Perspectives for Drought-tolerance Improvement in Tropical Maize*, in "Molecular Approaches for the Genetic Improvement of Cereals for Stable Production in Water-limited Environments," pp. 131-136, CIMMYT, Mexico, 2000; Bänziger, M., P.S. Settimela, D. Hodson, B. Vivek, *Breeding for Improved Abiotic Stress Tolerance in Maize Adapted to Southern Africa*, in "Agricultural Water Management," 80, pp. 212-224, 2006; Harris, P., *Abiotic Stresses: Plant Resistance Through Breeding and Molecular Approaches*, CRC Press, Boca Raton, Florida, 2005; Almekinders, C.J.M., P.C. Struik, *Diversity in Different Components and at Different Scales*, in Almekinders, C., W. de Boef (eds), *Encouraging Diversity: The Conservation and Development of Plant Genetic Resources*, Intermediate Technology Publications, London, 2000; Singh, K.B., B. Ocampo, L.D. Robertson, *Diversity for Abiotic and Biotic Stress Resistance in the Wild Annual Cicer species*, in "Genetic Resources and Crop Evolution," 45, pp. 9-17, 1998; Langridge, P., N. Paltridge, G. Fincher, *Functional Genomics of Abiotic Stress Tolerance in Cereals*, in "Briefings in Functional Genomics and Proteomics," 4, pp. 343-354, 2006.

23. Flowers, T.J., *Improving Crop Salt Tolerance*, in "Journal of Experimental Botany," 55, pp. 307-319, 2004.

24. The main work in this direction has been carried out within the private sector (with the use of both traditional breeding approaches, and techniques of genetic modification). Such approaches, to be tested in the field, might in any case - in the opinion of the FAO - not be directly applicable in less intensive agricultural contexts (and characterized by minor public resources to improve agriculture) in developing countries. An initiative that seems potentially able to lead to a positive effect - in the long term - is represented by the Public-Private-Partnership between CIMMYT, Monsanto and the Gates Foundation to develop maize varieties resistant to drought in Africa.

25. In this regard, also see: Ruane, J., A. Sonnino, P. Steduto, C. Deane, *Coping with Water Scarcity: What Role for Biotechnologies?*, FAO, Rome, 2008.

26. Ruttan, V.W., *Biotechnology and Agriculture: A Skeptical Perspective*, in "AgBioForum," 2, pp. 54-60, 1999.

27. In this regard, also see the analysis and discussions contained in the document published in 2010 by the Barilla Center for Food & Nutrition, entitled *Is GMO agriculture sustainable?*

28. In this regard, also see: Murphy, D.J., *Molecular Breeding Strategies for the Modification of Lipid Composition*, in "Vitro Cell. Devel. Biol.-Plant," 42, pp. 89-99, 2006.

29. With regard to this, also see: Sonnino, A., Z. Dhlamini, F.M. Santucci, P. Warren, *Socio-economic Impacts of Non-transgenic Biotechnologies in Developing Countries*, FAO, 2009.

30. With regard to this, also see: Thompson, J., I. Scoones, *Addressing the Dynamics of Agri-food Systems: An Emerging Agenda for Social Science Research*, in "Environmental Science and Policy," 12, pp. 386-397, 2009.

31. For an overview of what is currently considered the technical frontier in terms of agricultural biotechnology, it is possible to refer to a document produced in 2011 by the research institutes JRC-IHCP IPTS of the European Commission, *New Plant Breeding Techniques: State-of-the-art and*

Prospects for Commercial Development; also of interest is the document produced in 2010 - in reference to cisgenesis, one of the techniques that appears most promising for the future - by RIKILT Institute of Food Safety, at the request of the Dutch Government, *Food and Feed Aspects of Cisgenic Crop Plant Varieties*.

32. *Global Status of Commercialized Biotech/GM Crops*, ISAAA, 2010.

33. Avoiding, by choice, an in-depth examination of what is happening in the United States (which alone merits an entire document-long discussion and is also best represented in terms of what is produced by the scientific community) and Africa (to which we will devote further investigation).

CHAPTER 3

1. *Global Status of Commercialized Biotech/GM Crops*, ISAAA, 2010.

2. Today, in Europe, only the cultivation of GM plant varieties is allowed: maize produced by Monsanto, Mon810, and the aforementioned potato produced by BASF.

3. *Consequences, opportunities and challenges of Modern Biotechnology for Europe*, in "Joint Research Center Reference Report," 2007.

4. The Eurobarometer survey, conducted in February 2010, is the seventh in a series begun in 1991 and is based on representative samples. *Europeans and Biotechnology in 2005: Patterns and Trends*, Eurobarometer, European Commission, July 2005; *Europeans and Biotechnology in 2010*, Eurobarometer, European Commission, November 2010.

5. See, *Is GMO agriculture sustainable?*, Barilla Center for Food & Nutrition, 2010.

6. *Global Status of Commercialized Biotech/GM Crops*, ISAAA, 2010.

7. In Brazil, the increase in biotech acreage was 4 million hectares (ISAAA, 2010).

8. 93% for soy and cotton, 86% for maize, 96% for sugar beet and 88% for rapeseed (ISAAA, 2010).

9. Beintema, N., P. Adhiguru, P.S. BIRTHAL, A.K. Bawa, *Public Agricultural Research Investments: India in a Global Context*, National Center for Agricultural Economics and Policy Research, ICAR Policy Brief, 2008.

10. Pardey, P.G., *Agricultural Research and Productivity for the future*, Farm Foundation Conference, University of Minnesota, 2009.

11. Lusser, M., C. Parisi, D. Plan, E.R. Cerezo, *New Plant Breeding Techniques: State-of-the-art and Prospects for Commercial Development*, JRC Report, 2011.

12. The techniques of breeding taken into consideration by the study include: mutagenesis, cisgenesis, grafting, agroinfiltration, synthetic genomics, etc.

13. Public authorities having a role in the approval process of new plant organisms that result from biotechnology (not just GM) are the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).

14. These are aspects that we have documented elsewhere (*Is GMO agriculture sustainable?*, Barilla Center for Food & Nutrition, 2010).

15. Fritz, S. *et al.*, *Awareness and Acceptance of Biotechnology Issues among Youth, Undergraduates and Adults*, in "AgBioForum," 6 (4), 2003.

16. Sittenfeld, A., A. Espinoza, *Revealing Data on Public Perception of GM Crops*, in "Trend in Plant Science," 2002.

17. Hoban, T.J., *Public Attitudes towards Agricultural Biotechnology*, ESA working Paper, 2004.

18. International Service for the Acquisition of Agro-biotech Applications.
19. Among all the biotech plant varieties that have been approved for commercial production in China, there are over 200 varieties of Bt cotton. (Lagos, J.E., W. Bugang, *China-People Republic of Biotechnology, GE Plants and Animals*, G.A.I.N Report USDA Foreign Agricultural Service, 2010).
20. Only one species of virus-resistant papaya is still produced in Guangdong, covering an area of 3,500 hectares. (Lagos, J.E., W. Bugang, *China-People Republic of Biotechnology, GE Plants and Animals*, G.A.I.N Report USDA Foreign Agricultural Service, 2010).
21. It is estimated that China's population will have reached 1.6 billion by 2030 and the consequent demand for food production will increase by at least 60%. The current process of urbanization will also lead to a gradual reduction in the arable land and the sustainability of the quality of food. (Zhang, Q., *China: Agricultural Biotechnology Opportunities to Meet the Challenge of Food Production*, in "Agricultural Biotechnology and the Poor," 2002).
22. Huang J., Q. Wang, *Agricultural Biotechnology Development and Policy in China*, in "AgBio-Forum," 2002.
23. FAO International Technical Conference, "Agricultural Biotechnologies in Developing Countries," March 2010.
24. Partly financed by the central government and partly by local ones.
25. FAO International Technical Conference, "Agricultural Biotechnologies in Developing Countries," March 2010.
26. Among the applications of in vitro culture, one of the most interesting concerns the possibility of obtaining fully homozygous individuals, as an alternative to the long and not always possible (due to the onset of phenomena of depression from inbreeding) process that involves repeated self-fertilization. It involves the in vitro cultivation of haploid cells, such as pollen grains, and inducing cell multiplication through environmental and hormonal stimuli. Therefore, it will produce a haploid plant, since there was no gamete fusion. The little haploid plant is very delicate and weak, but it is possible to make sure that it will regain normal level of ploidy. It interacts with products (the one used the most is colchicine, an alkaloid that is obtained from a flower) that, during mitosis, prevent cell division but not chromosome replication. Thus, diploid cells will be obtained once again, with pairs of homologous chromosomes that are perfectly identical to the one originated by replication of the other.
27. Since 1986, R&D in agricultural biotechnology has been significantly supported by the research programs at the state level. Among these, the most important are: the *National Program on High Technology Development* (also known as *Program 863*) and the *National Program on the Development of Basic Research* (also known as *Program 973*). Also see: Lu, C., *Agriculture Biotechnology and its Management in China*, Oilcrops Research Institute, CAAS, 2005.
28. Huang, J., Q. Wang, *Agricultural Biotechnology Development and Policy in China*, in "AgBio-Forum," 2002.
29. We mention, by way of example, the "National Biosafety Committee" (NBC), a multidisciplinary committee of 74 experts from nine ministries, nine research institutes and nine universities, which aims to assess national and international applications for biosafety certification. The Committee is divided into three groups: biotech plants, animals and microorganisms, food and feed.
30. The reference here is to the old five-year plan that is now concluding, since that of the new plan, the *12th Five Year Plan on the Development of Biotech Industry* (2011-2015), has recently been approved but no detailed information is available concerning it.
31. Among the main objectives of the plan, to be highlighted: 1) the consolidation of a legal and political structure that is appropriate and able to stimulate technological innovation and dissemination of technical standards for the development of biotechnology techniques; 2) the development of new biotech products protected by intellectual property rights capable of generating total annual revenues of 1 billion RMB, and 3) the creation of about 10 biotech compa-

nies, each with a turnover exceeding 1 billion RMB, and 8 specialized industrial parks in various biotechnology applications, with a turnover of 50 billion RMB each.

32. ISAAA, May 2011.
33. These regulations are implemented by the Ministry of Agriculture through the Ministerial Decrees 8, 9 and 10 (*Measures on the Safety Evaluation Administration of Agricultural GMOs, Measures on the Safety Evaluation of Agricultural GMO Imports and Measures on Agricultural GMO Labeling Administration*) governing the approval processes for the production and domestic trade, those of import and labeling.
34. By way of example: Li, Q., K.R. Curtis, J.J. McCluskey, T.I. Wahi, *Consumer Attitudes Toward Genetically Modified Foods in Beijing-China*, in "AgBioForum," 2002.
35. *Food Biotechnology: consumer perception of food biotechnology in Asia*, AFIC, 2008.
36. 65% of the survey sample, AFIC, 2008.
37. Knowledge of issues related to sustainable food production is low and only 10% of the sample said they had heard about them before.
38. Numerous studies often cite incidents of farmers committing suicide because of failed harvests and cattle and goats that died from grazing in Bt cotton fields (Rangasamy, N., K. Elumalai, *Market Opportunities and Challenges for Agri-Biotech Products in India*, in "Agricultural Economics Research Review," 2009).
39. *Global Status of Commercialized Biotech/GM Crops*, ISAAA, 2010.
40. In October 2009, the "Genetic Engineering Appraisal Committee," after a long process of analysis and study, concluded that the Bt eggplant (Brinjal) is safe for the environment and health. However, the market entry of this variety has been blocked by the Ministry of Environment and Forests, which in February 2010 announced a moratorium on the approval process while waiting for the government's regulatory system to conduct more detailed studies on this new variety. Although so far there seem to be no further developments on this matter, India is poised to approve the first biotech crop used as food (Singh, S., *India Biotechnology - GE Plants and Animals*, GAIN Report, USDA Foreign Agricultural Service, 2010).
41. Singh, S., *India Biotechnology - GE Plants and Animals*, GAIN Report, USDA Foreign Agricultural Service, 2010.
42. Choudhary, B., K. Gaur, *Celebrating 10 Years Bt cotton in India: A Multipurpose Crop*, ISAAA, 2011.
43. *Global Status of Commercialized Biotech/GM Crops*, ISAAA, 2010.
44. According to the Cotton Advisory Board, the yield of cotton in India has declined from 554 kg/hectare in 2007-08, to 524 kg in 2008-09, to 498 kg in 2009-10 and down to 475 kg in 2010-11 (*Spurious Bt Seeds, weather Take Toll on Cotton Yields in India*, Business Standard, India 2011. We have dedicated a specific focus to this issue in the position paper *Is GMO agriculture sustainable?*).
45. Sales of Bt cotton count for 77% of the total sales of biotech companies operating in the agri-food sector (Rangasamy, N., K. Elumalai, *Market Opportunities and Challenges for Agri-Biotech Products in India*, in "Agricultural Economics Research Review," 2009).
46. Singh, S., *India Biotechnology - GE Plants and Animals*, GAIN Report, USDA Foreign Agricultural Service, 2010.
47. See Note 5, Chapter 1.
48. For example: Monsanto India Ltd., Mahyco Monsanto Biotech (India), Syngenta India, Rasi Seeds, Ankur Seeds, Nuziveedu Seeds, Prabhat Agri, JK Seeds, Nath Seeds and Indo-American Seeds (Rangasamy, N., K. Elumalai, *Market Opportunities and Challenges for Agri-Biotech Products in India*, in "Agricultural Economics Research Review," 2009).
49. For example: Avani Seeds, Nav Gujarat Seeds, Nimbkar Seeds Pvt. Ltd (see Note 5, Chapter 1).

50. The crops being developed by the public sector include: bananas, cabbage, cassava, cauliflower, chickpeas, eggplant, rapeseed/mustard, papaya, potatoes, rice, tomatoes, watermelon and wheat. Instead, among those of interest to private companies are: cabbage, cauliflower, cotton, corn, rapeseed/mustard, rice and tomato.

51. Hautea, R.A., M. Escaler, *Plant Biotechnology in Asia*, in "AgBioForum," ISAAA, 2004.

52. See Note 6, Chapter 1.

53. *11th Five Year Plan 2007-2012*, Government of India, 2008.

54. Rangasamy, N., K. Elumalai, *Market Opportunities and Challenges for Agri-Biotech Products in India*, in "Agricultural Economics Research Review," 2009.

55. India Resource Center, 2011.

56. Public spending on R&D in agriculture between 1991 and 2003 grew at an average rate of 6.4% per year (Beintema, N., P. Adhiguru, P.S. BIRTHAL, A.K. Bawa, *Public Agricultural Research Investments: India in a Global Context*, National Center for Agricultural Economics and Policy Research, ICAR Policy Brief, 2008).

57. In 2000, spending on agricultural R&D in India amounted to \$1.3 billion; in the United States, \$4.4 billion; in Japan, \$2.5 billion; and in China, \$1.9 billion (Beintema Stads, 2008).

58. 60 million children under 5 years of age (World Bank, 2009).

59. Hautea, R.A., M. Escaler, *Plant Biotechnology in Asia*, in "AgBioForum," ISAAA, 2004.

60. See Note 5, Chapter 2.

61. Together with the Act, the related regulation already implemented should also be taken into consideration: *Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells*, 1989.

62. By way of example: *Recombinant DNA Guidelines*, 1994; *Guidelines and Standard Operating Procedures for the Conduct of Confined Field Trials*, 2008; *Guidelines for Safety Assessment of Foods derived from Genetically Engineered Plants*, 2008.

63. *National Biotechnology Development Strategy*, DBT-Ministry of Science & Technology, 2007.

64. Singh, S., *India Biotechnology – GE Plants and Animals*, GAIN Report, USDA Foreign Agricultural Service, 2010.

65. *Annual Report*, Department of Biotechnology, 2009-2010.

66. This is the case, for example, of the state of Andhra, which after numerous appeals and having received approval from the Monopolies and Restrictive Trade Practices Commission, issued a directive that requires a roof (limit) for the price of seed of all biotech companies working in the area (USDA, 2010).

67. *Food Biotechnology: Consumer perceptions of food biotechnology in Asia*, AFIC, 2008.

68. According to the AFIC study, 66% of the population demonstrates confidence in the quality and safety of foods derived from genetically modified products.

69. According to the AFIC study, 70% of the population declared that agri-food biotechnologies will be able to bring real benefits to themselves and their families over the next 5 years.

70. Singh, S., *India Biotechnology – GE Plants and Animals*, GAIN Report, USDA Foreign Agricultural Service, 2010.

71. Vandana Shiva (Dehra Dunh, November 5, 1952), a political activist and environmentalist, has fought to change paradigms and practices in agriculture and food; she has also been dealing with matters of intellectual property rights, biodiversity, biotechnology, bioethics, genetic engineering and more. In 1993, she received the Right Livelihood Award. She is one of the principal leaders of the "International Forum on Globalization."

72. "Many farmers have been led to believe that they would get rich by buying the new seeds,

which would increase production. Those who let themselves be convinced discovered that they had to buy the seeds again every year – the seeds do not breed and they have a 'suicidal' gene, which is proof that they are against nature – at a price three times higher than traditional seeds. So they were in debt up to their necks. Result: 200,000 suicides in 10 years" ("La Stampa", 4/3/2010).

73. *Global Status of Commercialized Biotech/GM Crops*, ISAAA, 2010.

74. Also regarding the cultivated areas, over the last decade there has been a process of the "soying" of the country, with a high growth rate of land planted with soya.

75. Bisang, R. et al., *The Political Economy of Biotechnology in Argentina* Prometeo, Perugia, 2005.

76. Biotechnology in Argentina, *Knowledge + Innovation to Meet Global Market Needs*, Sector Profile, ProsperAr, 2009.

77. Falling into this category are: seeds and plants, food components and inocula (ProsperAr, 2009).

78. Revenues from exports of biotech products amounted to more than 80 million US\$ (ProsperAr, 2009).

79. About 80% of enterprises in the biotechnology sector are small-medium local businesses (ProsperAr 2009).

80. *Market Review: Plant Biotechnology in Argentina*, Agrival SA, 2007.

81. Stads, G.J., A.M. Ruiz, G. De Greef, *Argentina*, ASTI Country Brief, 44, 2010.

82. *Full Time Equivalent*.

83. See Note 18, Chapter 2.

84. ProsperAr, 2009.

85. To be mentioned are: the CONICET Research Institutes, Institute of Genetic Engineering and Molecular Biology (INGEBI), Center for Studies on Photosynthesis and Biochemistry (CEFOBI), the INTA's Castelar Biotechnology Institute, the Universities of Buenos Aires, Cordoba, La Plata, Mendoza, Rosario, San Martin and Tucumán. The local businesses that are particularly important include Indear and the agricultural division of Bio Sidus.

86. Argentina is the country with the highest number of active researchers in Latin America (3.4/1 000 active). See, ProsperAr, 2009.

87. *Market Review: Plant Biotechnology in Argentina*, Agrival SA, 2007.

88. Based on data collected during a survey in 2000 by the ISNAR on institutions and research organizations in Latin America, it was found that Argentina, even then, was the country with the highest number of applications of biotechnology, genetic engineering, micropropagation and different techniques of molecular markers (*Market Review: Plant Biotechnology in Argentina*, Agrival SA, 2007).

89. San Luis, *Arcor and Georgalos Foods* (ProsperAr, 2009).

90. Instituto Nacional de Semillas (National Seed Institute).

91. Comisión Nacional Asesora de Biotecnología Agropecuaria (National Advisory Committee on Agricultural Biotechnology).

92. Servicio Nacional de Sanidad y Calidad Agropecuaria (National Service of Health and Agricultural Quality).

93. National Direction of Agricultural Food Markets.

94. Instituto Nacional de Semillas (National Seed Institute).

95. The food sector accounts for 52% of export revenues and employs 37% of the workforce in the country (*2005-2015 Agricultural Biotechnology Development Strategic Plan*, Ministry of Economy and Production, Department of Agriculture, Livestock, Fisheries and Production).

96. The current guidelines for labeling provides for the evaluation of the characteristics of the final product without investigating the production process.

97. See Note 10, Chapter 2.

98. The regulation of the intellectual property rights in Argentina, unique and characteristic of the country, is based on the law with the UPOV-78, which protects the right of the farmers to conserve and replant seeds and they are also exempted from more detailed explanations on their use of them.

99. After several incidents of illegal trade of RR soybean varieties developed by Monsanto, and the equally numerous unsuccessful appeals to the Argentine judicial system that the level of control for the remuneration of royalties be raised so that a patent could be granted to the plant species developed, Monsanto has announced that the new RR soybean varieties will be introduced in 2011 only in Brazil and Paraguay. Furthermore, in 2005 legal actions were once again undertaken by Monsanto also in Europe against soya shipments by ship that were not authorized. In this case, however, the outcome was not successful.

100. *2005-2015 Agricultural Biotechnology Development Strategic Plan*, Ministry of Economy and Production, Department of Agriculture, Livestock, Fisheries and Production.

101. The main exponents of the various activities related to biotechnology in Argentina were asked to participate at 12 thematic round tables for the preparation of the Plan, in order to make their expert contributions and promote a more rapid acceptance of the contents presented in it.

102. Mergen, D., *Argentina Biotechnology – 2010 Annual Biotechnology Report*, GAIN Report, USDA Foreign Agricultural Service, 2010.

103. See Note 3, Chapter 2.

104. Secretariat of Agriculture, Livestock, Fisheries and Food.

105. *United Nations Environment Program – Global Environment Facility*.

106. 64% of the people interviewed said they had heard about biotechnology in agriculture, but were confused and unsure about its exact meaning (USDA Foreign Agricultural Service, 2010).

107. 94% of the population expressed the wish that the Government would provide more precise information on the risks and benefits associated with the use of biotechnology in the agri-food sector (GAIN Report, USDA Foreign Agricultural Service, 2010).

108. On the subject, there are already both institutional and informal initiatives, and in this respect it should be mentioned that, in 2004, the Government of Argentina placed “Biotechnology” as a compulsory subject in schools. Teachers themselves, however, not having any detailed knowledge on the subject, were not able at first to put into practice the teaching and thereby implement the government’s decision. The national association of nonprofit biotechnology, Argenbio, therefore worked voluntarily for the organization of a training course and for the reference of the educational material, which was then offered free of charge to schools across the country. Today, more than 10,000 teachers have attended the appropriate training course and the number continues to grow (GAIN Report, USDA Foreign Agricultural Service, 2010).

109. Regarding this, see: Simpson, A.J.G. *et al.*, *The Genome Sequence of the Plant Pathogen Xylella Fastidiosa*, in “Nature,” 406, pp. 151-57, 2000 (The Xylella Fastidiosa Consortium of the Organization for Nucleotide Sequencing and Analysis, São Paulo, Brazil); Brazil’s biotech boom, in “Nature,” 466, Issue n. 7304, 15 July 2010.

110. CREMAQ, PIAUÍ, *The Miracle of the Cerrado. Brazil Has Revolutionized its own Farms. Can it Do the same for Others?*, in “The Economist,” Aug 26th 2010.

111. *Global Status of Commercialized Biotech/GM Crops*, ISAAA, 2010.

112. An expert from EMBRAPA we interviewed for the preparation of this document has pointed out, in the case of soybeans, there are programs dedicated to improving the traditional soybean that go hand in hand with programs to improve the genetically modified soybean; there are also similar programs for other products and other crops, such as rice. EMBRAPA tends to

try to carry out parallel programs to improve the techniques and both non-GM and GM crops, for its role as a public company, which must – in essence – offer both options to local producers. In general, the focus of EMBRAPA in the development of non-GM plants is no less than that given to transgenic variants.

113. For an in-depth discussion of the points of interest related to research in Brazil in the field of agricultural biotechnology, also see: *State of the Brazil’s Plant Genetic Resources* (2009), a report elaborated by EMBRAPA and the FAO as a supporting document for the preparation of the *Second Report on the State of the World’s Plant Genetic Resources for Food and Agriculture; Generation, Adaptation and Adoption of Appropriate Biotechnologies in the Latin America and the Caribbean Region: Concrete Actions for the Near Future*, a background paper for the ABDC-10 FAO Conference, 2010; Ruane, J., A. Sonnino, *The Role of Biotechnology in Exploring and Protecting Agricultural Genetic Resources*, FAO, 2006; Stands, G.J. N. Beintema, *Public Agricultural Research in Latin America and the Caribbean*, ASTI-IFPRI-IDB Synthesis Report, March 2009; *Agriculture for Development. World Development Report 2008*, World Bank, pp. 158-179, 2008; Da Silveira, J.M., I. Carvalho Borges, *An Overview of the Current State of Agriculture Biotechnology in Brazil*, University of Campinas, Kennedy School of Government, 2005; *Tropical Agriculture: Brazil building the future*, EMBRAPA, 2007; Cardoso Costa, M.G., A. Xavier, W. Campos Otoni, *Horticultural Biotechnology in Brazil*, *International Society for Horticultural Science*, November 2006.

114. One of the experts of EMBRAPA we interviewed for the preparation of this document stated that important agreements are currently being defined with China for access to China’s wild soybean, that seems able to resist some diseases of the plant in an optimal way, which is very important for the Brazilian agricultural context. The agreements should lead to the use of this wild variation in the development of breeding programs aimed at the selection of Brazilian variants of soybean resistant to local biotic stresses.

115. In relation to public policy and regulation in Brazil, also see: Beintema, N., F. Avila, C. Fachini, *Country Note on Brazil: New Developments in the Organization and Funding of Public Agricultural Research*, ASTI-IFPRI, October 2010; Da Silveira, J.M., I. Carvalho Borges, *An overview of the Current State of Agriculture Biotechnology in Brazil*, University of Campinas, Kennedy School of Government, 2005; Carvalho Borges, I., J.M. Da Silveira, M. Fonseca, *The Building of an International Regulatory Framework to Agricultural Biotechnology*, 2010; *Revista de política agrícola. Journal of Agricultural Policy published by the Secretariat of Agricultural Policy – Ministry of Agriculture, Livestock and Food Supply*, Year XIX – Special Edition for Mapa’s 150th Anniversary, July 2010.

116. In regard to this, an expert of EMBRAPA we interviewed for the preparation of this document pointed out – through the foundations on a regional level – that EMBRAPA creates partnerships aimed at supporting part of the financing needed for technology transfer related to the new varieties of plants (both transgenic and non-GMO).

117. Consider, in this regard, the recent agreement signed between EMBRAPA and Syngenta on the joint development of innovative solutions in reference to corn, cotton and soybeans.

118. With regard to this, also see: Marques, R., C. Gonçalves Neto, *The Brazilian System of Innovation in Biotechnology: A Preliminary Study*, in “Journal of Technology Management & Innovation,” 2007.

CONCLUSIONS

1. More than 80% of the area cultivated with GMOs sees the use of seeds that have traits of tolerance to herbicides.

2. It should, however, be noted that transgenic traits specifically designed to optimize the yield of biofuels are not commercially available.

