Trade in *transgenic products:* a review of the *international debate*

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Transgenic products have a number of contradictory aspects. On the one hand, the genetic manipulation of plants makes it possible to develop both products which contain insecticidal toxins and can thus permit a reduction in the use of pesticides that may harm the environment, as well as foodstuffs with contents of vitamins and proteins that can improve the social indicators of the developing countries. On the other hand, however, questions have been raised about the possible effects of transgenic products on biosafety and biodiversity and the potential danger involved in consuming them, and the various actors participating in the debate on these products have widely different positions on their commercialization. The process of negotiation and subsequent approval of the Biosafety Protocol and the controversies over acceptance of the safety first principle or over the rules of the World Trade Organization (WTO) for restricting the production and commercialization of transgenics have shown up the great divergences that exist among governments.

I

Introduction

1. Background

New biotechnological research with economic applications has been taking place for several decades now. The rapid progress of biotechnology ("the genetic revolution") is often compared with the "green revolution" of the 1960s and 1970s. The new biotechnology[1] has a direct relation with biosafety and biodiversity, both of which are important tools for enabling a country to achieve economical and efficient agricultural development.

Genetic engineering techniques play a fundamental role in the progress of agricultural biotechnology and have a particularly strong impact on the inputs used in agriculture and food production. Manipulation of the existing genes allows agroindustrial enterprises to develop new varieties of crops and processed foodstuffs with a smaller consumption of energy or chemical inputs.

The use of agricultural biotechnology has given rise to great expectations, but also to uncertainty over possible risks. There is concern over its possible repercussions on human health and the environment. Even though there is no evidence so far that biotechnology makes foodstuffs any less innocuous, there is continuing mistrust in society about consuming products subjected to such techniques.

The Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". This definition covers a whole range of techniques used in agriculture and the food industry, such as DNA[2] and reproductive techniques and gene manipulation and transfer. Through their application it is possible to modify foodstuffs more quickly and precisely.

Genetic engineering techniques make it possible to alter the inherited characteristics of living organisms such as animals or plants. The individual genes are extracted from the genome of one organism and introduced into that of another, so that moving the genes also moves their features and characteristics and new substances or functions are produced. The resulting organism has a new combination of genes which is not found in nature and cannot be attained by natural means. The use of these techniques makes it possible to increase or block the amount of proteins produced by an organism which, for example, does not produce them or whose production it is desired to inhibit (OECD, 1999a).

Another application of biotechnology is the use of techniques to recombine DNA. Scientists can isolate the genes of different organisms, different species or a single species and divide or join them and add or transfer genetic material between different varieties deliberately and at will. This technique has a well-defined capacity for intervention. As the DNA is part of the nucleus of cells, the genetic information is transferred between unrelated organisms to produce a new one. Thus, with the existing technology hereditary information can cross the barriers between species (OECD, 1999a and 1999b; Grace, 1997).

Through the breaking down of biological barriers and crosses between species, transgenic foodstuffs or organisms are obtained. The new organisms with the desired genetic characteristics are a crop variety which is identical to the traditional one but now incorporates new genetic information.

2. The issues and actors in the international debate

a) *The issues*

Biotechnological applications are designed to help satisfy the growing food needs of the world's population. At the same time, however, scientists and entrepreneurs warn that scientific progress, while offering benefits to society, also presents risks and challenges of an ethical, environmental and health-related nature.

Ethical, because it is within their territories that the indigenous communities of some developing countries possess the ownership and knowledge of the genetic resources found there. These countries and communities are not taken into account, however, when

[1] Hereinafter, "biotechnology" will be used in the sense of the modern or new biotechnology.

[2] The nucleic acid chain containing the genetic material governing the development of cells and organisms.

the enterprises that possess the relevant technology share out the resulting benefits. The use of biotechnology cannot be viewed solely from the scientific standpoint, because when scientists intervene they produce genetic combinations that may transgress the laws of nature.

Environmental, because agricultural biotechnological applications raise possible risks of reducing biodiversity and affecting the biological balance. Crops - plants and organisms - can be reduced to a state of complete uniformity from the genetic standpoint. Expanding the area devoted to a single type of crop reduces the overall variety of crops and contributes to the loss of genetic diversity, especially in rural areas. There may also be a risk of developing wild species which are resistant to insecticides or to diseases and thus unbalancing the ecosystem.

Lastly, the fear that the consumption of transgenic foodstuffs may be dangerous to health is due to the fact that there is no convincing scientific evidence that such foodstuffs really are harmless. The risks involved include the transfer of toxins or allergenic compounds from one species to another, the creation of new toxins, or the appearance of unexpected allergic reactions. This is one of the ever-present issues in the present debate. The short length of time that has passed since the introduction of these products makes it difficult to deal with this problem, because of the insufficient evidence available for determining whether transgenic foodstuffs are a danger to human health or not.

The use of transgenic organisms in agricultural production has revealed improvements in some of the original characteristics, such as greater resistance to certain pesticides or herbicides and to diseases or pests (viruses, fungi, insects and parasites). Crops are now better adapted to environmental conditions –such as frosts, droughts and poor soils– which were unfavourable when using traditional techniques; they have a higher content of nutrients, vitamins, minerals or proteins; their fat content is lower; the flavour, colour or texture of foodstuffs is better, and they are easier to prepare and store.

One of the contributions of genetic modification is that it can introduce elements designed to lower the risk of infection and reduce the use of chemical products for pest control. Some experts note, however, that this resistance can also represent a threat to biological diversity, because farmers will tend to cultivate genetically uniform plant varieties or the conservation and/or use of traditional crops will be adversely affected.

Another unfavourable result is the spread in the earth of micro-organisms which can give rise to biochemical changes and affect the balance of the ecosystem. There is also the negative impact of transgenic crops on the conservation of neighbouring traditional crops, by pollinating them with genetically modified elements and passing these on to future generations of the crops. Furthermore, while biotechnology has developed new and more powerful pesticides and weedkillers which destroy pests and weeds and prevent them from affecting crop productivity, they may also endanger other plants which are desirable for conserving biodiversity (Brañes and Rey, 1999).

At the same time, the cultivation of transgenic crops can cause socio-economic changes in less developed countries by displacing labour from one of its principal economic activities. In those countries, an important source of employment is the cultivation of staple crops such as maize, and the displacement of the labour force employed in this can endanger the livelihood of a considerable part of the population.

b) *The actors*

The participants in the international debate include governments, biotechnology enterprises, scientists, non-governmental organizations, farmers, consumers and environmentalists; some of them are more critical than others of the application of the new techniques. These groups are not homogeneous and display differences both among them and within the groups themselves.

There are two main currents of opinion, with opposing arguments, in the debates on the use of biotechnology. One of them, which supports the new biotechnology, is made up in particular of producers and distributors; the other group, which rejects this technology, is mainly made up of consumers and environmentalists.

Those in favour of the continued progress of the biotechnology industry emphasize that the greater output will allow consumers to obtain food at lower prices because of the lower production costs, the reduced use of production inputs and chemicals, the higher yields, and the availability of more environmentally favourable production techniques. The application of biotechnology to crops, they claim, has given these greater resistance to pests, diseases and adverse environmental conditions.

The biotechnology industry is run mainly by a small group of transnational corporations, mostly

located in industrialized countries. These enterprises develop and market products and processes and are concerned with achieving efficient production and making a profit. The high cost of biotechnological innovation means that the world seed, fertilizer and pesticide market is concentrated in only a few enterprises, which, in their campaigns in favour of transgenic products, lay great stress on the fact that only small amounts of their inputs are needed in agricultural production. The transnationals do not, however, publicize the fact that they themselves are the main producers of such agricultural inputs: they control 60% of the pesticide market and 100% of the transgenic seed market.

Distributors also gain from the advance of biotechnology, since perishable transgenic foodstuffs can be stored longer without deterioration.

Scientists do not take a united stance. They are divided between those who defend the harmlessness of transgenic foods, on the grounds that so far they have not caused any major accidents in the areas of health and the environment, and those who consider that such foods involve potential risks. As public opinion is highly sensitive to biotechnological matters, scientists must redouble their research efforts in order to arrive at an objective and impartial evaluation of their effects.

Those members of the scientific community who are in favour of biotechnology consider that the use of the new genetic techniques is an advance and that, if they are properly used, they could benefit countries by improving their crop yields, saving costs on inputs, or improving production by increasing the content of nutrients in foodstuffs. They also consider that facilitating access to markets would help developing producer countries to reduce their dependence on imported staple foods, thus enabling them to combat famines in depressed areas.

Consumers are not very well organized and, unlike the scientists, they have only confusing information on the risks and benefits of transgenic foods for health. The information they receive is incomplete, since the producing companies do not always publicize the transgenic origin of their products, thus further increasing the degree of uncertainty. They consider that they have the right to receive innocuous and good-quality foodstuffs and to know what inputs were used in their production. They demand transparency, education and true, adequate and timely information on the benefits and risks for their health. They do not always believe that the results of scientific studies are true. They are very reluctant to accept agricultural products that damage the environment. They claim that regulations are either non-existent or inappropriate, and they demand more participation from the governments responsible for regulating the production and marketing of the new products.

Advances in biotechnology help to create new foodstuffs of agricultural and agroindustrial origin, and since these are aimed at society as a whole, greater attention should be paid to consumers' complaints. Society demands that governments should detect and appraise possible health risks before allowing transgenic foodstuffs to be placed on the market.

Environmentalists are generally against the production of these foods because they consider that they represent risks for the environment and biodiversity and not enough studies have been made of the possible dangers. This group is also joined in this attitude by the non-governmental organizations, which take an active part in these debates.

The debates stress the need to carry out more careful studies of the effects that the application of genetic engineering techniques may have on human health, on the environment and on agriculture, and they emphasize that the task is how to produce more and provide real benefits to society.

The studies on the effects of incorporating biotechnological applications in the agricultural environment have centered mainly on the developed countries, especially the United States and the Western European countries. The differing interpretations on the harmlessness of transgenic products which have emerged in the developed world, however, have given rise to concerns which have spread to the developing countries in advance. With the appearance of the first transgenic products, some governments have shown more concern than others, regulating transgenic crops in experimental fields and providing information to ensure that there are no risks even before the modified products are placed on the market.

II

Production and commercialization of transgenic foodstuffs

1. World production

The surprisingly rapid growth in the area planted with transgenic crops faces agricultural producers with an enormous challenge. According to James (2000), the total area planted with such crops in the world increased from 1.7 million to nearly 40 million hectares between 1996 and 1999. The 44% increase between 1998 and 1999 was accounted for mainly by four industrialized and four developing countries.[3] The total area planted with transgenic crops in the United States came to 29 million hectares in 1999: i.e., almost 80% of the world total (table 1).

In the year 2000 this area increased once again, but more slowly. The 11% increase over the previous year was equivalent to 4.3 million hectares, of which 3.6 million (84%) corresponded to developing countries, with the remaining 0.7 million (16%) being accounted for by industrialized countries. Between 1996 and 2000, the area planted with such crops increased by a factor of 25 and the number of countries involved rose from 6 to 13. Today, these crops have spread to Australia, China, India, Malaysia and Thailand.

The United States, Canada and Argentina accounted for 98% of the total area planted with transgenic seeds in the year 2000. In that year, 100% of the area planted with such crops corresponded to soya beans, maize, cotton and canola. Of the 273 million hectares devoted to these four products in the world, 16% corresponded to modified crops (table 2).

In 2000, there were 26 million hectares of modified soya in the world: 58% of the total area planted with transgenic seeds and 19% more than in the previous year. Thus, of the 72 million hectares of soya planted in the world, 34% corresponded to the modified variety.

Between 1999 and 2000 the total area planted with modified maize in the world went down from 11.1 million hectares to 10.3 million, so that of the 140 million hectares planted with maize in the world, 7% corresponded to the transgenic variety. The reductions in the United States and Canada were partly offset by increases in Argentina and South Africa. In the year 2000, the United States Environmental Protection Agency (EPA) warned growers of modified maize that they must reserve between 20% and 50% of their cultivated area for traditional products in order to help stop the increase in transgenic crops.

Cotton has an important place among transgenic crops: between 1999 and 2000 it increased by 1.6

TABLE 1
Selected countries: Area of transgenic crops, by country,[a] 1997-2000
(*Millions of hectares*)

	1997	1999	2000	2000/1999 (%)
United States	8.1	28.7	30.3	6
Argentina	1.4	6.7	10.0	49
Canada	1.3	4.0	3.0	-25
Australia	0.1	0.1	0.2	100
Mexico	0.1	0.1	< 0.1	0.0
Europe	...	...	...	...
Total	*11.0*	*39.9*	*44.2*	*11.0*

Source: Agrodigital, 11-05-99, Bioinfo Centre, http://www.biotechknowledge.com; reference 2781.

[a] Excluding China. Inclusion of China would increase the total area for 1997 to 12.8 million hectares.

TABLE 2
World: Area of transgenic crops, 1996-2000
(*Millions of hectares*)

Crops	1996	%	1999	%	2000	%
Tomatoes	0.1	4	...	...	...	...
Potatoes	...	...	0.1	...	...	...
Soya	0.5	18	21.6	54	25.8	58
Maize	0.3	10	11.1	28	10.3	23
Tobacco	1	35	...	...	...	...
Cotton	0.8	28	3.7	9	5.3	12
Canola	0.1	5	...	...	2.8	6
Total	*2.8*	*100*	*39.9*	*100*	*44.2*	*100*

Source: James, 2000.

[3] South Africa, Argentina, Australia, Canada, Spain, the United States, France and Mexico.

million hectares (43%). Of the 34 million hectares planted with cotton in the world, 16% correspond to transgenic cotton. The increases observed are mainly due to the larger areas planted in the United States (55% and 72% in 1999 and 2000 respectively). China also increased its area of this crop, but only moderately (10%); it was followed by Mexico, Australia, Argentina and South Africa.

China was one of the first countries to produce transgenic crops. It began in 1992, and this activity has come to occupy an important place in the country. In 1999 it planted some 750,000 hectares of such crops (mostly cotton), and it is estimated that in 2000 the total area came to 1.2 million hectares.

The situation in Europe is different, and the areas planted with transgenic crops are only small. Spain is an importer of transgenic products, especially modified maize, and it has the largest experimental plantations of genetically modified products in Europe, with over 20 experimental stations. In 1999 it was the leading producer of modified maize, with 10,000 hectares planted with this crop (0.02% of the world total). In the year 2000 the total area planted with transgenic crops went down in Europe, but two new producers entered the scene: Romania with soya and potatoes, and Bulgaria with maize.

In recent years the European Union has approved only a few experimental plantations, and only for a limited number of transgenic crops. The small number of authorizations granted by the EU, compared with the number granted by the United States, Canada and some Latin American countries, is putting the European authorities under pressure. In 1999 the United States approved 35 modified crops and the EU countries only nine, while Japan alone authorized seven.

Early in 2001, the European Parliament approved the unification of the different national regulations and authorized the fixing of deadlines and labelling standards, which suggests that it intends to put an end to the moratorium on the marketing of modified agricultural products. This new attitude could begin to bring the positions of the European countries closer to that of the United States.

2. Production in Latin America

The area planted with transgenic crops in the developing countries increased by 14% in 1997, 18% in 1999 and 24% in 2000. In the latter year, a quarter of the total world area planted with such crops corresponded to the developing countries (10.7 million hectares).

Between 1999 and 2000, the area of transgenic crops in the developing countries increased from 7.1 to 10.7 million hectares (51%), the countries which contributed most to this increase being China and Argentina, with 0.5 million and 10 million hectares respectively.

In 1998 there were two outstanding developing producers of transgenic crops: Argentina, with 15% of the total area, and Mexico, with nearly 1%. Argentina has the largest area of transgenic crops in Latin America and is the second largest producer of them at the world level, with 4.3 million hectares out of a world total of 28 million in 1998.

Soya accounts for the largest number of hectares of transgenic crops, and Argentina is the third largest producer of transgenic soya in the world. Over the last five years the area devoted to this crop has grown by 29%, while over the last ten years it has doubled, reaching 7.4 million hectares in the year 2000. Of the 4.2 million hectares by which world production of transgenic soya increased in that year, 2.7 million corresponded to Argentina and 1.5 million to the United States; in 2000 the total area planted with soya was 9.6 million hectares in Argentina and 30.2 million in the United States.

The cultivation of modified maize, for its part, increased from 5% to 20% between 1999 and 2000 in Argentina, and this growth, together with that registered in South Africa, partly offset the decline in the United States and Canada.

Mexico has one of the highest levels of biodiversity in the world, and its protection is a priority matter. It has authorized some 150 applications to release genetic organisms in fields, greenhouses and laboratories, of which 33 corresponded to maize, 28 to cotton, 15 to tomatoes, 13 to soya and 3 to wheat, among other species.

In Brazil, biotechnology is applied especially in agriculture. That country is the second largest producer of soya in the world, with an output of 30.5 million tons in the 1998-1999 period. Brazil has great biodiversity, and the government seeks to protect it by limiting or prohibiting modified crops until environmental impact studies are carried out. At the end of 2000, however, the situation seemed about to be reversed with the Ministry of Agriculture's announcement that it would permit the production of those crops for which there was a demand.

In Chile there are nearly 5,000 hectares of transgenic seed plantations, mostly run by foreign firms. Land is available for their reproduction, and there is a

possibility of increasing exports of such seeds in coming seasons. The country has been importing genetically modified seeds of maize, soya, sugar beet, canola and tomatoes since 1992 but only for reproduction and export, since their local sale is not yet allowed (Manzur, 1999). The production of transgenic foods for local consumption is not allowed, but such foods are imported without any knowledge of the origin of the inputs they contain. A high percentage of the imports of foodstuffs containing soya and maize come from Argentina and the United States, without any indication of whether they contain manipulated genes.

Uruguay and Paraguay take a cautious stance in this respect. In 2001 the Ministry of Stockraising, Agriculture and Fisheries of Uruguay authorized the experimental planting of transgenic products, but not their sale. In Paraguay, consideration is being given to an application to allow Argentina and the United States to introduce transgenic soya and maize seeds, but so far the country is considered to be free of transgenics (The Biotechnology Knowledge Center, 1999a and 1999b).

Costa Rica has a rich diversity of biological resources and uses biotechnological means to conserve them. It is estimated to possess 5% of the biodiversity existing in the entire world (Brañes and Rey, 1999). The use of pesticides on banana, coffee and rice plantations trebled between 1993 and 1996, causing health problems for workers and contamination of land, water and animals.

3. Trade

Between 1995 and 1998, world sales of transgenic crops soared from US$ 84 million to nearly US$ 2.3 billion, and in 1999 they amounted to US$ 3 billion (Krattiger, 1999), while they are expected to reach US$ 20 billion by 2010 (James, 1999). The most important market is for seeds, followed by microbiological agricultural inputs. There is a growing trade in new types of fruit and vegetables marketed directly by the companies that develop them (Jaffé and Infante, 1996).

Authorizations for the marketing of transgenic products include such items as soya, canola, cotton and potatoes. The countries which market the largest quantities of modified foods are the United States, Canada and Australia, together with some Latin American countries such as Argentina and Mexico. The marketing of such products has got off to a slow start in Europe, where the sale of only 18 transgenic products has been authorized between 1992 and 1998.

The United States leads the way in the use of genetic engineering in the production of modified soya, maize, wheat and cotton for export. It accounts for nearly 90% of the world trade in transgenic soya and maize. In transgenic soya alone it exports 40% to Europe. It exported some 9 million tons of modified and unmodified soya in 1998 (*The Economist*, 1999).

United States exports of modified maize to the European Union went down from 2.7 million tons in 1995/96 to only 100,000 tons in 1997/98 because of the mistrust of EU consumers over possible effects on health.

Japan imports transgenic foods, mainly from the United States. It currently imports 29 varieties of seven crops: maize, soya, colza, potatoes, cotton, tomatoes and sugar beet (Programa Chile Sustentable, 1999).

Free trade is menaced by national regulations such as production and import controls, limitations on access or sales, or direct prohibitions of entry into markets. There is an ever-present danger that food safety regulations will be adopted in response to the pressures of consumers and defenders of the environment.

The increase in opposition to the consumption of transgenic foods has affected the destinations of Argentina's soya exports. In 1999, 40% of the seeds and some 60% of soya pellets went to Europe, but since then they have gone to countries where consumers are not opposed to the consumption of such foods, such as India, China and some Latin American countries.

Other Latin American countries have expressed a desire for well-defined guidelines on trade in foodstuffs obtained through biogenetic applications, because they are aware that they have an asset –biodiversity– which they want to conserve. They are also producers of various organic products (fruit and vegetables) which have a better chance of acceptance than transgenics.

It is not expected that the production and marketing of transgenic foods can be stopped. On the contrary, some new ones will come on the market soon, now with incorporated vaccines. This could endanger the foreign exchange income from exports of traditional foods if developing countries, including some from Latin America, replace some products with others that are similar but are obtained through *in vitro* techniques using transgenic organisms.

III

The Protocol on Biosafety and the WTO rules

1. The Protocol on Biosafety

a) *Background*

From the very beginning the application of biotechnology to agricultural crops and foodstuffs has given rise to a debate on their impact on agriculture, the environment and human health. It is therefore not surprising that the scientific, socioeconomic and environmental issues connected with biological and biotechnological resources come up frequently in the main forums of negotiation.

Environmental concerns were expressed at the Earth Summit (Rio de Janeiro, 1992) and were given concrete form in the Rio Declaration on Environment and Development, in Agenda 21, and in the Convention on Biological Diversity (CBD). The negotiations on the Protocol on Biological Diversity began in 1996, and six meetings have been held, the first at Aarhus, Denmark, and the latest, in February 2000, at Montreal, Canada.

The CBD lays down that the countries must consider the form and need for a Protocol to regulate procedures regarding the transfer, handling and use of transgenic organisms which could have harmful effects on biodiversity and its components. The aim was to create an international juridical framework for the application of measures to ensure complete safety or at least minimal risks so that this technological advance will not affect biodiversity, already threatened today by over-exploitation of resources and degradation of ecosystems, through the danger of homogenizing crops.

The European Union countries have defined standards, domestic laws and EU-wide laws concerning human health and the environment. They included in them regulations on agricultural production, and within them rules on transgenic foods, whether for experimental purposes or commercialization, in order to avoid negative repercussions on themselves and other States.

At the same time, the difficulty of harmonizing the different national interests, regardless of whether countries are EU members or not, has meant that biodiversity has ceased to be the common property of the human race and has become instead the property of States, which have now been given responsibility for preserving it. As a result, it was decided that States also had territorial responsibilities in regulating their domestic standards.

In 1999 the Ministers of the Environment of the EU tried to check the spread of transgenic organisms and adopted a "policy declaration" which was seen as a *de facto* moratorium on new crops and authorizations for their commercialization, to remain in force until research findings were more conclusive. This decision causes conflicts with the United States and with companies producing transgenic foods, and could give rise to complaints to the WTO.

By including the safety-first principle in the Protocol, the European Union can block the sowing of seeds containing modified genes or prohibit their importation on the grounds of doubts or lack of sufficient information. The Ministers of France, Greece, Italy, Denmark and Luxembourg defend the moratorium on the introduction of new crops. Countries with a more favourable attitude to the marketing of such products are Germany, Spain, the Netherlands and the United Kingdom, although Germany and Spain, which have only incipient markets in this respect, did not oppose the moratorium. Moreover, some countries do not wish to lose the chance of doing business with the main vendors of biotechnology and its products, nor do they wish to face possible sanctions applied by the WTO.

In the United States, in order to put a transgenic agricultural food product on the market it is necessary to comply with procedures laid down by three Federal agencies: the U.S. Department of Agriculture, the Food and Drugs Administration, and the Environmental Protection Agency. Responsibility in health matters lies with the National Institute of Health and a division of the Department of Agriculture which supervises food safety.

Some of the developing countries are in favour of regulating trade in transgenic foods on the grounds that little is known about their effects on health and the environment. They are worried that in the future dependence on imported biotechnology will be added to their already high degree of subordination to foreign scientific knowledge and outside management of new technology. Acceptance of an international law

regulating cross-border trade could avoid their land being used as testing grounds for such crops and thus obviate possible environmental risks.

b) *Positions and negotiations in the debate*

The negotiations in Cartagena and Montreal were difficult, and countries with diametrically opposed positions had to give way in their demands in order for the Protocol on Biosafety to be adopted. The discussions were continued in other international forums with different actors, including representatives of consumers and environmentalists.

Biotechnology has raised the value of genetic resources and made it advisable to establish international regulatory frameworks. The Convention on Biological Diversity called upon States to consider the possible forms of an international instrument to regulate the use of the new techniques. The Protocol on Biosafety, which is an international instrument, only covers the cross-border movement of products and asks its signatory States to complement it with national legislation.

The difficulties in arriving at a consensus caused the countries to form groups according to their interests and opinions. Five such negotiating groups were formed: i) the Miami Group, made up of the United States, Canada, Australia, Argentina, Uruguay and Chile; ii) the European Union countries; iii) the Compromise Group; iv) countries with a high level of biodiversity, such as Switzerland, Norway, New Zealand, Mexico, Japan and South Korea; and v) the Like-Minded Group, made up of developing countries such as China and countries from Africa, Asia, Latin America and the Caribbean, excepting those already mentioned earlier.

The negotiations began with matters connected with biodiversity and the safety of human health and the environment and continued with the evaluation of risks in the handling, use and transport of transgenic products, socioeconomic implications, responsibility for damage or accidents, institutional capacity, and the exchange of information. With time, trade-related aspects were also dealt with, such as cross-border movements, the safety-first principle, labelling, and the relation with other international agreements, especially with the WTO in the Sanitary and Phytosanitary Measures (SPM) and Technical Barriers to Trade (TBT) agreements.

In the position of the EU countries and a number of developing countries, the Protocol on Biosafety was linked with agreements on the environment. It was feared that controls on transgenic foods would become a dead letter and that trade-related measures would take precedence over environmental and sanitary measures, so the members of this group sought to balance environmental measures with trade-related measures and make the former complementary to those of the WTO.

The European Union countries considered that it was necessary to weigh risks under the safety-first principle on the basis of scientifically proven evidence. That principle, which is not regulated by international law, does not allow the circulation of foodstuffs unless it is known for certain that they do not have any adverse effects on health or the environment. The countries which are in favour of international rules reject the importation of transgenic foodstuffs unless they have passed the risk evaluation tests carried out by national and EU authorities. The European Commission does not permit unilateral prohibition of a crop unless there is new evidence that it is harmful.

The members of the European Union have striven to achieve a common position and set of rules on modified organisms, as they have been obliged to regulate the liberation of such organisms (for sale, experiments or trade) in their territories. The stricter European rules, compared with the absence of suitable legislation in other markets, has led EU companies with biotechnological interests to experiment in unregulated markets, or else in their own markets, but with prior authorization. The differing opinions of governments on the effects of the different national standards of food safety make it difficult to advance in the negotiations.

In the year 2000, the European Commission did an about-turn in its position on the moratorium existing since 1998 on authorizations for new transgenic products: it now admits that such a moratorium is an illegal and unjustified measure which must be lifted, and it plans to adopt some new proposals, but in return for medium- or long-term licences the biotechnology companies must accept stricter rules which include risk evaluation, labelling and closer controls over trade.

The Miami Group countries prevented the approval of a regulatory framework which would prevent the free trading of transgenic foodstuffs and derivates thereof.[4] The Group was worried that the safety-first principle could be used as a legal barrier to trade even when there

[4] As it has not ratified the Convention on Biological Diversity, the United States does not have voting rights in the negotiations on the Protocol.

was no sound scientific evidence to back it up. The Group was also reluctant to include labelling in the Protocol, although this is an essential element in the safety-first approach to commercialization. The United States position is that only those transgenic foods which are substantially different from traditional ones warrant regulation. Otherwise, they say, the European Union could take advantage of the situation to demand that all modified foods are labelled to show the genetic origin of the product: the WTO trade regime should therefore prevail over the Protocol on Biosafety (Kerr, 1999).

The negotiations to define rules on trade in transgenic foodstuffs failed at the Cartagena meeting in 1999. Some countries feared that the WTO rules would come into conflict with those of the Protocol, since they saw that the environmentalist group was not fully familiar with the international trade rules. If the Protocol were accepted, the international movement of transgenic foodstuffs could be limited for human, plant or animal health reasons or for alleged damage to the environment. That should not be allowed to create barriers to agricultural trade or to weaken the Sanitary and Phytosanitary Measures Agreement.

Early in the year 2000, the Miami Group prevented other governments from demanding prior authorization for imports for re-export. The negotiations ground to a halt, and a year later, at Montreal, the Miami Group and the European Union gave way on their initial positions and assumed a compromise position. 135 States voted in favour of the Protocol, which, when ratified, will be added to other environmental treaties for regulating trade.

c) *The Protocol and its significance*

A distinction may usefully be made between two cases of introduction of transgenic organisms into the environment: one is their incorporation into cultivation (seeds, for example), while the other is their incorporation into the processing and consumption of human or animal food (grains, for example). This distinction will make it easier to understand certain aspects of some of the principles included in the Protocol.

This lays down that each country can adopt its own regulations on transgenic foodstuffs, and those regulations may be more demanding than those of the Protocol itself, but they must be notified to the other countries. In order to share that information, the Advance Informed Agreement (AIA) mechanism was set up and forms a key element of the Protocol.

The AIA is merely a prior control before authorization is given for human consumption of modified foods in importing countries: i.e., it is a notification between countries. This Agreement requires an authorization from the importing country before the first cross-border movement of the transgenic organism in question. This allows information to be obtained about countries which reject transgenic foods. The application of the AIA also makes possible an evaluation of risks and possible adverse effects and, if the latter are present, denial of access based on scientific evidence, in order to avoid unjustified trade barriers.

The AIA makes possible restrictions on the trading but not on the cultivation of transgenics. As from 2002, exports –mainly made by the United States, Canada and Argentina– must obtain a prior permit from the importing country and notify it to a United Nations regulatory body.

This is where the first responsibility of the exporting country arises, which must notify its intention to export the goods, and that of the importing country, which must develop and announce its regulations. The exporter can opt between a national regulatory system consistent with the Protocol or a system regulated by the Protocol itself. The AIA allows the importing country to veto the application even if scientific evidence is submitted by the exporting country (Cosbey and Burgiel, 2000).

In the case of transgenic organisms destined for processing and consumption, the AIA is not mandatory. Through its risk evaluation the importer can request additional information, accept access with or without conditions, prohibit entry or extend the time limit for the entry of the modified organism. Although the AIA does not cover agroindustrial products whose production processes have involved some transgenic organism, this is a consumer and environmental protection element when solid scientific evidence is lacking.

The Protocol includes the safety-first principle, in order to protect the environment from the reduction of biodiversity and to protect the health of consumers. Regulation of cross-border movements of transgenic agricultural foodstuffs obviates environment and health risks. Other biosafety aspects must be covered by national laws.

The safety-first principle is a government option for rejecting access without being penalized at the international level. It allows the country to receive the information on use and safety required when transgenic organisms are introduced into the environment and requires notification among the countries when

applying the AIA. It also allows the application of restrictions and the requirement for guarantees for trade in transgenics on the grounds of insufficient scientific evidence and the assumption that there may be a risk to biodiversity or human health.

The safety-first principle was achieved through the mutual support existing between environmental and trade instruments, without the former being subordinated to multilateral trade agreements. Biological diversity and food safety do not prevail over the WTO rules, and vice versa. The Cartagena Protocol is based on the safety-first principle and the WTO rules on scientific evidence.

The Protocol must not affect the rights and obligations of governments under other international agreements (of the WTO or any other nature). With regard to trade, it does not mean any change in the rights and obligations entered into under an international agreement, including the SPM and TBT agreements. The controls on trade in transgenic products permitted under the safety-first principle reverse the burden of proof, in that stricter controls can be applied if there is no certain scientific proof that the products are free of risk.

When an activity is begun it must be shown that its effects are harmless to the environment; otherwise, those effects are subject to controls and can lead the country concerned to impose higher standards than those provided for in other international agreements, as a sovereign right. The European Commission considers that every member of the WTO has the right to establish the level of protection it sees fit, especially as regards the environment and human health. The United States, however, rejects the view that the European Union's safety-first principle should be accepted as a legitimate trade barrier, arguing that the question must be settled by having recourse to science, which is not yet capable of assuring that transgenic products will be safe in the future.

2. The WTO rules

One of the functions of the WTO is to settle trade disputes among its members. With regard to the safety of modified foodstuffs, it offers some principles that can be used when countries are faced with different interpretations of how to protect consumers.

Although the members of the WTO have not given it a mandate to develop food safety standards, it does have rules to prevent members from using unnecessary and unjustified trade barriers. These rules are to be found in the SPM, TBT and Trade-related Intellectual Property agreements and in the exceptions to GATT, article XX b) and g).[5]

Under article XX of GATT, countries have the right to establish their own environmental and food safety rules. Measures adopted under this right, however, must be consistent with the principles of GATT: absence of discrimination between nations and national treatment once an import enters the national market. In the case of a biotechnological product, however, some actors argue that the production process is an important element also. If the rules on trade include production processes, using the exceptions in article XX of GATT, the justification for the latter should be scientifically proved, otherwise an amendment to that article would be needed (ECLAC, 1998).

There is no commitment in the WTO regulating trade in transgenic products, nor are there any international rules governing their trade according to their method of production. The rules on international trade deal with trade in goods and not the production process, unless the latter affects safety and endangers the natural resource in question or human and animal health.

There are arguments both for and against the desirability of amending article XX of GATT to permit the application of trade measures to production processes. This is a point which will have to be discussed and settled in future negotiations, as also the question of whether the Protocol should include only transgenic micro-organisms or should also cover production processes which use biotechnological techniques in some part of the production chain.

National regulations can lead to discrepancies among the parties. Those countries which consider that a product obtained by traditional production methods and one obtained through the use of biotechnology are basically similar insist that the WTO agreements are adequate for settling differences. Those which consider that they are different products because the production process is different, however, complain of the lack of regulation of trade in biotechnological products.

The idea of annexing the Protocol to the WTO agreements was defended by the Miami Group, which respects the agreements of that organization. The Group proposes that differences on trade in transgenic products should be settled within the WTO, not through special agreements. This matter is down for discussion at the next round of negotiations of the organization (WTO, 1999).

[5] This allows governments to adopt trade measures which are necessary in order to protect human, animal or plant health and to ensure the conservation of exhaustible natural resources.

Other countries use the safety-first principle to justify protectionist measures. The European Union has asked the WTO to clarify the use of that principle and to extend its application to the whole framework of the organization. It argues that transgenic products represent a new technology which justifies the use of the principle, because the prevention of possible risks and the preservation of the environment should come above trade liberalization. Crops incorporating modified genes are seen by the EU members as a potential source of danger.

So far, the WTO has condemned the European Union's prohibition of the importation of meat treated with hormones, the Australian ban on Pacific salmon, and Japan's requirement that a variety of fruit should be subjected to tests because there is no scientific evidence that its consumption is harmless. These two factors –solid scientific evidence or, in its absence, the application of the safety-first principle– cause tensions in the trade negotiations.

New restrictions on trade can cause friction with the multilateral trade system. According to the WTO, the SPM and TBT agreements provide the necessary basic guidelines for negotiating regulations on trade and labelling, but when these agreements were signed, in 1994, the question of transgenic products was not under negotiation. The two agreements in question seek to regulate trade restrictions arising from the indiscriminate use of technical measures to safeguard human health, the environment and national interests, as well as to harmonize national food quality standards.

a) *The Agreement on Sanitary and Phytosanitary Measures (SPM)*

This Agreement, signed at the Uruguay Round, regulates the application of sanitary and phytosanitary measures. It applies to all measures for the protection of human health that could directly or indirectly affect international trade. It refers to regulations on the harmlessness of foodstuffs and allows governments to impose temporary internal and international measures if such harmlessness and the sanitary control of animals and plants are not assured.

The SPM Agreement allows governments to regulate trade by applying national measures which are stricter than international standards. In order to do so they must scientifically prove that the international standards provide less sanitary protection and must carry out a risk evaluation; otherwise, there could be a flood of sanitary and phytosanitary measures which would impede trade flows (WTO, 1996).

There are important differences between the SPM Agreement and the Protocol on Biosafety. One difference is in respect of risk. The Agreement recognizes that a level of risk exists, but does not stipulate what constitutes a risk, and it promotes systematic risk evaluations, but does not say how to manage them; in order to apply the proper level of risk governments review similar cases in other countries. In contrast, the Protocol indicates what a risk is and how to manage it, and in the absence of a scientific basis it allows the use of the safety-first principle for prohibiting or restricting an import.

The SPM Agreement allows the adoption of provisional measures when the scientific evidence is insufficient, whereas the safety-first principle is relatively more restrictive for consumers. The Protocol permits the importer to request the exporter to carry out a risk evaluation in order to take decisions, whereas the Agreement determines in advance what constitutes a risk and how to calculate it (Cosbey and Burgiel, 2000).

On the basis of new scientific information, the Protocol permits importers to review and change a decision on the cross-border movement of transgenic products, whereas the measures of the SPM agreement are more ambiguous. Under the WTO, the rules do not judge whether there is suitable scientific evidence or what constitutes the best evidence in respect of a transgenic foodstuff. At the request of the WTO itself, this function has been transferred to the Codex Alimentarius Commission, which is trying to formulate general rules on the harmlessness of foodstuffs, to control biotechnological foodstuffs and to develop voluntary international food standards to be submitted to governments for their acceptance and use in the application of the SPM and TBT Agreements.

The rules prepared by the Codex Alimentarius Commission should make it possible to judge whether national rules inhibit international trade flows. If the national regulations are not fully justified in accordance with the international rules of the Codex, the dispute must be settled by the WTO.

b) *Agreement on Technical Barriers to Trade (TBT)*

The TBT Agreement incorporates the technical rules of national standards and regulations, regulates food quality requirements and obligations not covered by the Agreement, and includes technical prescriptions resulting from measures on food safety, inspection and labelling.

In accordance with the rights and obligations laid down in the TBT Agreement, countries can impose

technical standards with legitimate intentions, provided that the requisites thus demanded do not constitute barriers to cross-border trade which are more restrictive than is necessary in order to comply with the objectives pursued. Among the contributions of the Agreement are the establishment of international principles for the elimination of unjustified trade barriers, avoidance of the creation of new obstacles, provision of elements for the development of international standards, and the possibility of raising national standards to international levels.

The Agreement does not give a clear and precise definition of the meaning of international standards for transgenic foods, nor does it provide for the equitable distribution of national needs. The scant information available means that the standards only reflect the measures of a few countries. The Protocol on Biosafety should give a precise definition of standards at both the national and international levels.

The Codex Alimentarius Commission is considering the advisability of adopting an international standard for the labelling of transgenic foods, based on substantial equivalence: i.e., whether a transgenic organism is substantially equivalent to the original foodstuff. The labelling requirements would seek to ensure that the chosen standards support the right of consumers to be informed and given a free choice, to know what a foodstuff contains, and to be informed of the inputs used in the production process. However, this would require that the life cycle of the foodstuff be kept constantly in view, which is no easy task. Moreover, even if it were possible to follow up every stage of the production process, not all countries would be in a position to comply with that requirement.

The United States FDA does not support special labelling and argues that, if there is no scientific certainty that the incorporation of a transgenic product alters the composition of a foodstuff and represents a danger to health, special labelling should not be obligatory. It does not reject voluntary labelling, but it does not wish to establish a compulsory distinction between a transgenic and an original foodstuff unless there is a substantial difference between them. In some countries, trade problems have arisen due to domestic pressures to use labels as a condition for access to the market.

The Protocol does not aim to physically separate genetically modified products from the rest. The differences over labelling have been partly solved because the United States has yielded to the European Union's pressures that labelling should be compulsory. This is just the starting point for the reconciliation of interests and the beginning of a new stage in the negotiations. Compulsory labelling is also a matter of concern for Brazil and Argentina. The Canadian Government is analysing whether it should introduce new regulations in this respect, since its position is similar to that of the United States. In Japan, special labelling has been obligatory since April 2000.

The European Commission does not consider special labelling to be necessary, but the European Parliament does demand complete information in order to differentiate between products and considers that more drastic measures should be taken to regulate transgenic crops. Some countries of the European Union, in contrast, give priority attention to biotechnology, the introduction of new transgenic foods on the market, the storage and shelf life of products, or a responsible approach to food safety.

The main exports of transgenic products from the United States to EU countries consist of wheat, cotton and soya: precisely those products over which there are differences. For the United States, these do not raise any health risks. However, some European companies have stopped using them as inputs in their production processes because they are afraid they may contain modified organisms.

European environmentalists continue to fear that in the long run there will be negative effects on the environment. They argue that consumers are being deprived of information on potential risks and consider that governments should require all transgenic foods to be specially labelled. They claim that the rejection of compulsory labelling by some biotechnology industries shows that they have no confidence in their own products.

Generally speaking, national and international legislation on the control of transgenic organisms is still sparse. Demands to the government by consumer groups and non-governmental organizations for sure and effective control of the foodstuffs offered on the market are stronger in many developed countries than in the developing countries. In this respect, there are proposals for the establishment of a governmental body with suitable technical and economic capacity for reviewing food imports and verifying the truth of the information printed on their packages.

V

Final considerations

Modern biotechnology should be seen as a complement to and not a substitute for traditional agricultural techniques. Its use involves human intervention to move genes between different species. The current uncertainty about consuming a transgenic foodstuff or a hybrid –which is also the result of genetic modification, but within the same species– applies to the former but not to the latter.

Biotechnology is simply a tool for solving some agricultural problems. Its possible environmental, sanitary and socioeconomic risks have caused concern within society. The risks to human health are more generally shared and similar among countries, but the environmental risks need to be studied case by case because the effects of applying this new tool –both positive and negative– vary from one situation to another.

These techniques offer possible solutions for current problems such as developing agriculture and the food industry and satisfying the nutritional needs of a growing population. This can be achieved, at least in part, if a new generation of food crops incorporating new characteristics and providing advantages over traditional similar foods can be successfully introduced.

In order to decide whether it is beneficial or not to put a transgenic foodstuff on the market, it is necessary to provide the public with more information on the advantages and biological safety of consuming it. Active participation by consumers in the corresponding debates and their guidance with information that can be readily understood by them would reduce uncertainty in this respect, but the lack of finance for establishing the necessary information networks makes communication difficult, especially in the developing countries.

The absence of rules on biotechnological foods in international trade gave rise to a series of rounds of negotiations which finally ended when the countries with opposing positions gave way. The approval of the Protocol on Biosafety showed that when the parties gave way on their positions trade interests were balanced with environmental concerns.

The Protocol requires countries to adopt domestic legislation, develop a juridical framework applicable to biotechnology, evaluate the risks of adaptation, determine the level of protection desired, and ensure the existence of national institutions capable of carrying out the relevant tasks. The dynamic development of science, the national standards and regulations established and the level of risk involved, however, make it necessary for the institutions to formulate new regulations and make constant revisions of existing ones in order to supplement and expand the rules designed to ensure the safety of consumers.

The developing countries also need capacity for adaptation, implementation, dissemination and innovation in a sector which is accessible but of high technology. They therefore need research institutions which will not only fulfill their own objectives but will also carry out the function of bringing investors and creators of technology closer to consumers.

Biotechnological development benefits producers, directly satisfies consumers' needs and involves both benefits and risks for the agricultural sector. In order to attain food security, however, it would be desirable for the developing countries, and especially their resource-poor farmers, to derive more benefits from advances in biotechnology, to have greater access to sources of genetic resources and public finance, and to receive the fruits of a better dialogue between the public and private sectors (FAO, 2000).

The confidence of consumers in the institutions which recommend standards is increasingly important for the decisions they take. Lack of transparency and clarity of the rules adopted and delays in taking suitable measures to deal with problems as they arise are elements that militate against this.

The different views regarding transgenic products are a source of concern. For the United States, only the final product and not the production process can be the subject of regulation; for the European Union, in contrast, both the final product and the production process should be subject to regulation. The tendency to regulate the production process is a source of dispute, since such regulation is not accepted by the WTO.

The SPM and TBT Agreements provide lines along which countries can guide their regulations on the basis of science and settle their differences at the bilateral level, avoiding the need to bring them before the WTO. They also make it possible to harmonize the different national regulatory systems and labelling requirements,

but they do not provide a solution if the conflict is based on ethical considerations, without scientific evidence to justify demanding special labels. This may make necessary the revision of both agreements and lead to further negotiations in the WTO.

The approval of the Protocol does not eliminate the possibility of future problems, but it does indicate that the arguments for and against the use of the new techniques are gradually beginning to draw closer to each other. Steps have begun to be taken towards convergence between the different positions which, on the one hand, promise more plentiful food and, on the other, fear the possible effects of the consumption of transgenic products on health and the environment. This does not mean that the debate is over, however, since some countries consider that the Protocol is insufficient and want to continue research in order to achieve safer trade in biotechnological products.

The question of new agricultural products is under discussion in international forums and repeatedly turns up in negotiations. The trade disputes over labelling and the different national regulations do nothing to reduce the uncertainty. Labels do not say what genes are incorporated in products; the uncertainty over the risks involved in the consumption of modified products will very likely continue, and it will be necessary to negotiate over what information should be included in order to give greater transparency. The uncertainty over the consumption of such products could be reduced if the wording of labels is precise, free of any form of manipulation, simple and balanced.

An element which helps to keep the debate alive is the fact that the Latin American countries possess great biodiversity, which currently provides large profits that go mainly into the pockets of the transnational corporations, without the countries of the region receiving the share that corresponds to them for giving access to the genetic inputs in question. The question of sharing out the profits has not been settled, and it does not seem that an easy solution can be reached in the short term. So far, the arguments usually stress the concerns of the countries that make the greatest use of biotechnology, neglecting the concerns and interests of the developing countries.

Finally, it cannot be concluded *a priori* that a foodstuff should be classed as harmful or beneficial, good or bad, deleterious or harmless simply because it is transgenic. Every new foodstuff must be subjected to exhaustive analysis before it is placed on the market. It is essential that the risks and benefits of each of the transgenic organisms involved and their repercussions on national ecosystems should be dispassionately evaluated and the conclusions passed on to society. This will pave the way for further progress in the creation of transgenic foods which are healthy and environmentally friendly.

(Original: Spanish)

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