LAWSCI (2017) http://sciforum.net/conference/mol2net-03/lawsci-01

Biotechnology in plants genomics: a legal and bioethics overview.

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ABSTRACT
Concepts like bio-security and bioethics have been put into the test whit the rapid advance of the Biotechnology. Specifically the plant's genome manipulation is worthy to be reconsidered by the ethical and juridical point of views. Plants varieties and products obtained by these new biotechnological methods are important achievements but also can be a risk for the human health and the environment. On the other hand, a monopoly of commercial exploitation for the holder of the patent and other exclusives titles like Certificates of Vegetable Obtaining can leave out the fair access to the technological progresses. In this work we make a valuation about those aspects of Biotechnology related with the genome of the plants and their juridical protection.

Key words: Biotechnology, Genetic Engineer, Plants genome, Organisms genetically modified, Vegetable variety, obtainer, Bio-security, Bioethics.

1. PLANTS GENETIC MODIFICATION: THE RISK-BENEFIT DICHOTOMIES

The modern Biotechnology innovations regarding plants genome are presented as an alternative for solves some of climatic changes troubles. Because of the difficulties to predict long term effects of innovation in agricultural ecosystems such point of view is discussible, and the supporters of the "biotechnical agriculture" number it is comparable to their detractors.

One reason why many people are worry about biotech agriculture is the assumption, in some circles, that almost any problem of production or plague control in agriculture can be solved through genetic manipulation. From this perspective, working with the right genes will eliminate any problem, or at least make management it much easier. This idea is based on a dangerous lack of knowledge about what happens in agricultural ecosystems and is one of the reasons why Biotechnology worries so many people (1).

On the other hand, Intellectual Property recognizes rights equivalent to a patent to the obtainer's of new varieties of plants that could have come along the path of genetic manipulation. The Certificate of Plant Variety is thus established as a monopoly of exploitation rights. Thus the questions are: if the genetic modification of plants, applied essentially to agriculture, is a real alternative, why to recognize the exclusives rights of the breeder that prevents society from free consumption? And if -on the contrary- it constitutes a danger, why to protect genetic manipulation on plants?

Certainly the application of Genetic Engineering techniques in the agricultural environment has generated a debate about the advantages and risks of genetically modified plants, both for human health and for the environment. Advantage example is the obtaining more resistant to diseases and pests crops; in this way, it can avoid the use of insecticides that produce environmental problems, while preventing viruses, fungi and insects from becoming more resistant every day. It is also advantageous to achieve crops that are more resistant to adverse soil and climate factors such as heat, frost, drought, salinity or acidity. So is the improvement of the nutritional quality and the appearance of the fruits, providing them with a balanced nutritional content and a better taste and texture.

The application of genetic engineering in animals and plants for the production of drugs, industrial chemical compounds, fuels, plastics, medical products and other materials could also be understood as an advantage (8). As well as the so-called phyto-remediation, or application of certain plants for the regeneration of contaminated soils" (8).

Nonetheless the genetic modification of plants also involves risks, both for the environment and human health. Among the former, it is necessary to emphasize the uncontrollable dispersion of the offspring of the transgenic plant and the genetic contamination of genetically modified plants to others. Concern is centered mainly on the resistance gene being transferred to the herbicide, creating also resistant weeds. Another important risk to take into account lies with the extend the resistance of genetically modified plants to external agents that they want to control, such as weeds, insects, viruses and fungi. What we would be talking about is a natural inversion of the technique.

Genetic Engineering allows selecting the qualities that are desired in a plant and from there to create an unlimited number of plants whose genomes are identical to each other. The cultivation of these plants will lead, in the opinion of some authors, to the genetic uniformity of the crops, with the increasing deterioration of the biological diversity and vulnerability to diseases, pests or adverse factors of the soil and the climate that would suppose.

With regard to human health, the risks of the use of Genetic Engineering have been valued in the food sector. In this sense, two possibilities are contemplated, organisms that can be used as food and have undergone Genetic Engineering, and organisms that contain an ingredient derived from a genetically modified organism or that have taken place using enzymes or other similar products in their elaboration (9-17). The concern has focused especially about the allergy cause of these foods. In this case, the consumer would be harmed if the composition of the food is not properly reported on the labels. There is talk, then, of an allergic effect produced by the toxicity of some of these foods. Another issue worth noting in terms of the risks to human health is communication to the resident bacteria in humans of antibiotic resistance. The concern is that resistance to bacteria from the human body, making us invulnerable to certain antibiotics.

2. SOME PRINCIPLES APPLICABLE TO PLANTS GENETIC MODIFICATION

The search for an appropriate balance between the potential risks and benefits of genetically modified organisms, in order to avoid any harmful effects on human health or the environment, calls for the application of certain principles relating to the conservation and sustainable development. Such is the case of the "precautionary principle" and the "development principle".

As has been stated in the Biosafety Protocol of Cartagena, the concept of precaution recognizes that the determination of the level of acceptable risk rests in scientists, expressly stating that "lack of scientific knowledge or scientific consensus will not necessarily be understood as indicators of such level of risk, risk or existence of acceptable risk (9-17). This principle should therefore be kept in mind when scientific information is not sufficient, inconclusive or uncertain, and when there are indications of possible effects on the environment and plant, animal or human health which may be potentially dangerous and incompatible with the chosen protection level (18-22).

The United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992, established this principle at firth time, and the signatory countries assumed the duty to apply it when there could be a danger of a serious or irreversible damage for the environment. However, it was in the Bio-security Cartagena Protocol, signed in January 2000, where the true role of this principle was confirmed in the field of modern biotechnology. This Protocol, whose main objective is to ensure that the movement of genetically modified organisms from one country to another is carried out safely for the environment and human health, incorporates this principle in Articles 10.6

and 11.8, leaving the importing party with the decision about whether the conditions of importation, as well as prohibit importation, request additional information or delay such decision. Mostly when appreciates the lack of scientific knowledge about the effects of genetic modification on a living organism on human health or the environment, and to avoid or reduce these adverse effects (9-17).
However, in many countries and contexts other principles are considered relevant, which are increasingly accepted in law and are part of Biotechnology and Intellectual Property policies. Among them, we can find the principle of "sustainable development". Most Latin American developing countries claim that it is not possible to apply the precautionary principle as an unwavering rule, but must be analyzed in conjunction with other options as education, information, Recycling, polluting production, rights management and adaptation management (18-22).

3. BIO-SECURITY, ETHICS AND BIOETHICS IN PLANTS GENOMICS.

With the development of Biotechnology, there is a need to create norms and mechanisms capable of preventing and controlling the impact and negative effects of the research, production, release and introduction of new species and genetically modified products, which may undermine the integrity of the environmental, technological, socio-economic and cultural aspects, also on food safety and the quality of life of human beings.
In these sense, biosecurity is associated with concepts such as "risk", "benefit", "effectiveness", "diffusion or dispersion"; As well as the "environmental effect of transgenic organisms". And for the analysis of the risks of products derived from modern biotechnology, we must take into account ethical values and alternative forms in technological development that can lead to the same result.
Bioethics can now be defined as the "analysis of ethical issues arising in Biology and Medicine, especially those produced by human activity in society through Biotechnology" (30); Being also known as the ethics of biosecurity. An ethical behavior in Biosafety must revolve according to the economic sector when the biotechnological advances are applied.

4. CONCLUSIONS

Resultants products of genetic modification in plants can arise benefits as same as risks. The balance is necessary; as well as the setting in practice of political socio-economic not ruled by the mercantilist vision of many of the holders of Intellectual Property rights on this products, but for the willingness of governments to make the benefits of modern biotechnology reach everyone. The combination of the precautionary and the sustainable development principles will ensure the necessary balance. The consumer of such products should be offered the option of choosing between those genetically modified or those of an organic nature, unmodified. Intellectual Property offers the possibility of *sui generis* protection for genetically modified plants, different from patent protection and the rights of the holder of plant varieties. Therefore it is left to the will of the States to establish policies of intellectual property more rigid or more flexible, as well as to define in the hands of who will be such Intellectual Property rights.

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