ANALELE UNIVERSITATII DIN ORADEA Fascicula Ecotoxicologie, Zootehnie si Tehnologii de Industrie Alimentara

GENETICALLY MODIFIED ORGANISMS AND THE PRECAUTIONARY PRINCIPLE

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Abstract

On the basis of legislation governing the production and use of GMO stands precautionary principle, which requires studies on the potential environmental and public health risks associated with the use of technology or completion of an action with potential impact at these level.

Key words: Genetically modified organisms, prevention safety risks, resistance to viruses and compositional changes, EU harmonized legislation

INTRODUCTION

On the basis of legislation governing the production and use of GMO stands precautionary principle, which requires studies on the potential environmental and public health risks associated with the use of technology or completion of an action with potential impact at these levels. Principle 15 of Rio Declaration on Environment and Development states that "To protect the environment, States should adopt a cautious behavior consistent with their capabilities. Where there is danger of occurrence of serious or irreversible damage, lack of absolute scientific certainty should not be used as a reason for postponing cost-effective measures to prevent degradation of the economic environment. The need for cautious behavior is reaffirmed in the Preamble and Article 1 of the Cartagena Protocol, which specifies that "lack of scientific certainty due to insufficient information or knowledge relevant scientifically on the extent of potentially adverse effects of a living modified organism GM (OVMG) on sustainable use of biological diversity by making the import side, especially given for human health risks, should not stop the party concerned to take an appropriate decision on import OVMG in question"

RESULTS AND DISCUSSION

The first provisions on the regulation of GMOs, including GM plants and derived food have been developed by scientists, policy experts, in the mid 1980s (OECD, 1986; U.S. OSTIP, 1986), almost a decade before the first product approval biotechnology of modern, in 1995. Policies, institutions, laws and regulations have evolved over time.

The evolution was affected both science and society. Scientific progress has made possible a better understanding of the implications of food on health and resulted in the adoption of new agri-food production technologies, some of which required a regulatory oversight. Also, change the value parts of society can lead to highlighting the importance of consumer protection policies and changes in institutions and regulations. In turn, the regulation may affect both innovation and risk perception. It may distinguish between two types of GMO regulatory systems.

To regulate all GMOs, some jurisdictions have adopted specific legislation "based on the process," such as the European Union and Australia. In contrast, other regulatory systems are "based on the product, focusing on features and use the resulting product, not the genetic modification process that, for example, the United States of America and Canada.

In the early 80, United States Supreme Court ruled that genetically altered life forms can be patented. Testing and marketing of GMOs are regulated in the U.S., the five laws, nothing specific to this type of body: Federal Food, Drug, and Cosmetic Act, Federal Insecticide, Fungicide, and Rodenticides Act, Federal Plant Pest Act, Toxic Substances Control Act; Virus -Serum-toxin act. Existing laws to regulate plant pests and diseases, pesticides and food were amended resulting, in 1986, a coordinated framework for regulation of biotechnology. The regulatory framework of the GMO and derived food is down, "based on the product. (US.OSTP, 986). Three regulatory agencies assess the scientific risks to human health and the environment: U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA) and Food and Drug Administration (FDA), the cooperation of these agencies is coordinated by the Division of Regulatory Services biotechnology (Biotechnology Regulatory Services) (USRAUB, 2008). USDA regulates the importation, interstate movement, placing the fields of environmental testing and commercial introduction on "the Federal Plant Pest Act and the Plant Quarantine Act, administered by APHIS, Plant and Health Inspection Service Animal. There is no federal regulation requiring the registration of new plant varieties. Introduction of transgenic organisms in environmental regulation is based on the concept of "familiarity". Under this concept, PMG

is compared with the traditional equivalent in terms of environmental safety. A product already rated and apply the concept of “antecedent organism and the analysis is less severe”.

Environmental Protection Agency (EPA = Environmental Protection Agency) has authority to regulate GM plants that produce pesticides. These plants are regulated by similar processes to those applied pesticides. In 1986, Environmental Protection Agency (EPA = Environmental Protection Agency) approved the introduction of the commercial environment of the first genetically modified crop plants, tobacco with modified genes.

Food and Drug Administration (FDA = Food and Drug Administration) is the authority that manages the food and feed safety, including in products derived via genetic modification. FDA provisions of the Federal Food, Drug, and Cosmetic Act. In the early '90s, the FDA said that food and feed derived from GM plants are inherently dangerous ("is not inherently dangerous") and should not be regulated differently than comparable products made by traditional methods of improvement (AExcellence, 1993). In 1994, the FDA approved the marketing of the first genetically modified food, tomatoes Flavr SAVRIV. Currently, over two thirds of U.S. food products containing at least one genetically modified ingredient (GMOFFT, 2006).

In the U.S., or labeling of products containing GMOs are not mandatory, except for foods that could pose a health risk to certain subsets of the population.

Canada has a single system governing agricultural biotechnology products based on familiarity (familiar with the equivalent used for comparison), substantial equivalence (defined risk threshold) and novelty characters. "New" is not necessarily equivalent to "risk". A product may be considered new if: (1) have new/ new character / characteristic or trait / traits (herbicide resistance, insect resistance), (2) possess qualities or characteristics change (resistance to disease outside the normal variation within species), (3) is intended for uses considered new (as food or feed). Therefore, in Canada, are monitored all plants and products have been used in agriculture or food industry. Before a plant with traits in November to be used as food, animal feed or is introduced into the environment, risk assessment is required. Since 2005, he was permitted entry into the environment of 62 plants in November features: tolerance to herbicides, resistance to pest attacks, resistance to viruses and compositional changes. In the future, challenges the view that the regulation will include the interpretation of novelty, new classes of plants in November qualities (tolerance to stress, molecular culture, biofuel production), and evaluating long-term effects on non-target organisms.

Regulatory system in China and is considering the product, but attention and economic interests posed by the application.

In the European Union, considering that genetic modification is a new process and especially appreciated that existing legislation is insufficient. New legislation was drafted, "based on the process, which has changed from its appearance in 1990. Directive 90/220/EEC (European Commission, 1990), which entered into force in 1991, which govern the introduction of GMOs into the environment (Part B, placing the environment for experimental purposes, the C-market) was revised in substantial and repeated, and finally was replaced by Directive 2001/18/EC (European Commission, 2001), which entered into force on October 17, 2002. Under this Directive, the approval period is limited to ten years and for certain product categories, the applicant must submit a plan for monitoring post-marketing.

Regulatory bodies involved in EU Member States competent authorities and the European Commission. European Commission's role has been strengthened by the publication of EC regulation 178/2002, called the General Law of the food, setting out general principles of food law and establishing the European Food Safety Authority (European Food Safety Authority - EFSA) (European Commission, 2002). General principles of EU food law:

• risk analysis by the scientific assessment by EFSA; •EU approval procedure;

• protect and inform consumers through comprehensive labeling scheme;

• provisions for traceability - meaning the ability to determine the origin and understand the distribution of food and food ingredients;

• the precautionary principle in cases of significant uncertainty in risk assessment.

General food law establishes a single decision procedure for all products to be approved at EU level, such as food additives, pesticide residues in food, novel foods and genetically modified organisms. Moreover, the new law clarifies the responsibilities of all legal entities involved in food production and regulation in the EU, describing the general requirements of food safety that are required both Member States and operators. Under the authorization procedure at European level:

European Commission (Directorate for Health and Consumer Protection and Environment Directorate) manages the review process and make proposals based on risk assessment and other broader considerations that may influence policy option;

Regulatory Committee, composed of representatives of authorities of Member States, decides whether to approve the Commission proposal by a majority voting system (232 votes out of 321, representing 62% of the

population), if the decision is not consistent with the Commission or if not issued any opinion, the matter is passed to the Council of Ministers;

Council of Ministers may approve or reject the Commission proposal by qualified majority of Member States to support its position. If rejected, the Commission must prepare a new proposal. If the Council of Ministers decides within three months or if not met a qualified majority that it opposes the proposal emphasize that the Commission will adopt the proposal.

In June 2003, the Council of Ministers adopted two new regulations for specific food and feed derived from genetically modified organisms. Regulation (EC) 1829/2003 provides the legal basis for the approval procedure for GMOs, as specified in the General Law of the food. The safety of food derived from genetically modified organisms is evaluated by the Scientific Panel on GMOs of the EFSA. The Group assesses and issues related to animal health and the environment, according to the principle of "one door - one key". Regulation (EC) 1830/2003 provides the legal basis for the traceability and labeling of genetically modified organisms and traceability of food and feed derived. Meat, milk or eggs from animals fed with GM feed or treated with GM medicinal products should not be labeled. All foods are or contain GMOs, produced from GMOs or containing ingredients produced from GMOs must be labeled even if no longer contain detectable traces of GMOs. Traceability rules require all operators to transmit and retain information on GM products in order to identify both the supplier and purchaser of the product. GM varieties approved in the EU for the accidental presence allowed is 0.9%. Above this level all products must be labeled. For varieties that have received a positive risk assessment, but not yet approved, the presence of random is 0.5%. A list of these varieties is available at http://ec.europa.eu/food/food/ Biotechnology / gmfood / events_en.pdf.

May be differences between Member States on implementation of EU harmonized legislation. It may be temporary exemptions or exceptions and, in some cases, there is room for interpretation of this legislation or in different Member States can be made different interpretations of issues not covered in detail at EU level.

In cases where EU legislation is found to be still incomplete or omitted regulate a given matter, the laws of Member States. The result: the application of different rules in different Member States.

Under the directive 2001/18/ECC, a notifier who intends to market a GMO must submit an application to the competent authority which shall include a risk assessment. Principles for environmental risk assessment (ERM) are provided in Annex II to Directive 2001/18/ECC. In 2002, the European Commission issued "recommendations" to supplement Annex II,

detailing the principles, elements and methodology of risk assessment (2002/623/EC) Annex III to Directive 2001/18/ECC comment on the information required to be based on risk assessment . "Seed law" demands that genetically modified varieties to be authorized under Directive 2001/18/EEC. Evaluation of environmental risk associated with placing, completed under Directive 2001/18/EEC is compulsory and if the varieties derived from conventional methods of improving the line of origin of transgenic plants. If they are used to produce food, the variety must be authorized under regulations 1829 / 2003/EC and 1830/2003/EC, before being included in the common catalog.

CONCLUSIONS

The precautionary principle requires studies on the potential environmental and public health risks associated with the use of technology or completion of an action with potential impact at these levels. Principle 15 of Rio Declaration on Environment and Development states that "To protect the environment, States should adopt a cautious behavior consistent with their capabilities.

Lack of scientific certainty due to insufficient information or knowledge relevant scientifically on the extent of potentially adverse effects of a living modified organism GM (OVMG) on sustainable use of biological diversity by making the import side, especially given for human health risks, should not stop the party concerned to take an appropriate decision on import OVMG in question.

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