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The Status of Agricultural Biotechnology and Biosafety in Romania

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Abstract. Since 2000, Romania had in place a legal Biosafety Framework with the objective of protecting human health and the environment, in accordance with the precautionary principle (Government Ordinance 49/2000). In 2000, Romania was the only country in Europe approving market release of two genetically modified (GM) crops: Roundup Ready (RR) soybean and Superior New Leaf potato. GM potato has not been commercialized. On the contrary, RR soybean was grown on thousands of hectares. Romania is one of the few European countries with favourable conditions for soybean production and, in 2006, was one of the nine countries in the world that cultivated this GM crop. As member of the European Union beginning with 2007, Romania must comply with the rules for placing on the market, traceability and labelling of genetically modified organisms (GMOs) as laid down by EU legislation. Consequently, as of 2007, Roundup Ready soybean cultivation was banned in Romania. Today, Bt-maize expressing the insecticidal protein Cry1Ab from *Bacillus thuringiensis* (Bt) in the only GM crop approved for cultivation in the EU. In 2007, Bt hybrids were grown on about 300 ha and in 2009, on about 3000 ha, especially in areas where the lepidopterean target pest caused serious infestations. In this overview, we address the current status of Romanian biosafety legislation, agricultural biotechnology research, deliberate release and commercialization of GM crops. We also present the main stakeholders and their expectations regarding the development of agricultural biotechnology in Romania.

Keywords: biotechnology, biosafety in Romania, GM crops, monitoring, stakeholders

INTRODUCTION

The first transgenic plant was cultivated for commercial purposes in 1996. In the next 12 years that have followed, the surface area cultivated with genetically modified plants has grown rapidly exceeding in 2008, 125 million hectares (James, 2008).

The world leader in genetic engineering of plants is the United States of America. http://www.aphis.usda.gov/biotechnology/status.shtml.

The first genetically modified plants cultivated on a larger area were herbicide tolerant soybean and rapeseed, insect resistant maize and cotton. In time, on the market appeared maize and cotton hybrids with stacked traits, insect resistance and herbicide tolerance. In 2005, in the United States of America, the first generation of triple stacked maize hybrids deriving from genetically modified parental lines by conventional breeding were cultivated. These stacked traits hybrids expresses resistance to certain Lepidopterian insects, resistance to Corn Root worm (*Diabrotica* sp.) and herbicide tolerance.

Currently, approximately thirty different GM events are in commercial use and an increase is expected in this number to 120 by the year 2015 (gmo-safety.eu/en/news). A report issued through the OECD (Organisation for Economic Cooperation and Development) project „a marked rise globally in the commercial use of genetically modified plants" has been

published. According to this OECD report, by 2015, GM varieties are expected to represent as much as 76 per cent of global soy production. In the case of maize and rapeseed, the number will represent 20 per cent. The OECD report also predicts that for beans, peanuts, barley, potatoes, rice and sunflower, herbicide-tolerant or insect-resistant GM varieties may be market-ready by 2015 (gmo-safety.eu/en/news).

In contrast, in the European Union, approvals are stagnating, commercial cultivation of only one genetically modified insect resistant maize event is approved. At the same time, the import for use as food and feed for more than 14 of soybean, maize, canola and sugar beet events received approval. (http://europa.eu.int/comm./food/dyna/gm_register/insex_en.cfm).

Romania agricultural land area is about 15 million ha. According to Eurostat data, Romania is the third potato growing country in Europe and is in first place regarding the area cultivated with maize. This is not the same case when it comes to yield. The growth in maize production quantity and quality may bring Romania in a leading position on the European market of agricultural foodstuffs, seed and maize derived products.

According to a statement from the Academy of Agricultural Sciences and Forestry "Gheorghe Ionescu-Sisesti", current medium level yields in agriculture is equivalent to 40% of the real potential for cropping under conditions present in our country. It is thus imperiously necessary to identify and value the possibilities for rapid growth of agricultural efficiency that represents sustainable agriculture. This paper will give an overview of GMO legislation and biosafety research in Romania. In this overview, we address the current status of Romanian biosafety legislation, agricultural biotechnology research, deliberate release and commercialization of GMP and present the main stakeholders and their expectations regarding the development of agricultural biotechnology in Romania.

ROMANIAN BIOSAFETY FRAMEWORK

Romania adopted its initial legislation on bio-engineered products in 2000 (Government Ordinance 49/2000). All activities with GMOs were regulated: contained use of genetically modified micro-organisms; deliberate release into the environment for any other purposes than placing on the market; placing on the market of GMOs as or in products and import/export operations with GMOs as or in products. According to that regulation, Competent Authority was Ministry of Environment but the National Biosafety Commission (NBC), composing of representatives of relevant regulatory agencies, and also comprising members of public research institutions, had a major role in the decision making process. Moreover, the presence of scientific representatives in the NBC helped lead to a science based approach. Among the first biotech crops approved under the biotech GO 49/2000 were Roundup Ready soybean and Superior NewLeaf potato, products approved for commercial cultivation at national level. Law 214/2002 approving Ordinance 49/2000, stipulated that the Biosafety Commission became the scientific authority with a consultative role. Under these new circumstances, decisions regarding environmental release of bioengineered crops (either for commercial cultivation or experimental purposes), although requiring the scientific opinion from the Biosafety Commission, would be more susceptible to political climatic. According to that law, Ministry of Environment and Water Management was Competent Authority approving all the activities with GMO, including environmental release of bioengineered crops (either for commercial cultivation or experimental purposes) based on scientific consent of a scientific advisory committee and the consent of Ministry of Agriculture, Forests and Rural Development, Ministry of Health and Family, National Authority for Consumer Protection.

To date, biotech Romanian legislation is harmonised with EU legislation. Romania has transposed Directive 2001/18 into Romanian regulatory framework adopting law 247/

2009 for regulating activities involving deliberate release and placing on the market of GMOs. According to this law decisions regarding deliberate release for experimental purposes of genetically engineered plants are taken at national level. National Environmental Protection Agency (NEPA) which is subordinated to Ministry of Environment and Sustainable Development (MESD), is the Competent Authority responsible for authorisations regarding the import into the country and deliberate release into the environment of living GMOs.

The National Environmental Guard (NEG) is the specialized body, which operates under the Ministry of Environment, responsible with the effective enforcement of the Romanian environment legislation. The NEG controls the cultivation of GM plants and checks if GM plants are cultivated in forbidden areas such as the natural protected areas. In order to obtain an approval for the activities regulated at the national level, Ministry of Agriculture, Forests and Rural Development, Ministry of Public Health and Family and Ministry of Education, Research and Innovation has to give their consent. Biosafety Commission is scientific authority with advisory role.

Romania signed the Cartagena Protocol on Biosafety on the 11th of October 2000 and ratified it by Law 59/2003 (11 March, 2003). The Protocol entered into force on the 28th of September, 2003.1946

Since 2006, Regulations (EC) No. 1830/2003 and No.1829/2003 of the European Parliament and the Council have been transposed (Government Decisions 256/2006 and 173/2006). Competent Authority for food and feed is the National Sanitary Veterinary and Food Safety Authority. The National Authority for Consumers Protection (NACP) is a central public administration body that has responsibilities in the labelling control, at retailers, of foodstuffs made of or containing GMOs.

AGRICULTURAL BIOTECHNOLOGY RESEARCH

In Romania, research regarding modern plant biotechnology was ongoing in universities and public research institutes. The main objectives of research undertaken in public institutions using transgenic plants was the study of chimerical gene expression involved in embryogenesis (Badea et al., 2002, 2006-2007), the evaluation of transformation ability of Romanian potato varieties and the stability of transgenic expression in vegetative descendants (Badea et al., 2000; Franțescu et al., 2003; Badea et al., 2004), economical and agronomical impact of the cultivation of products resulting from modern biotechnology in Romania (Badea and Otiman, 2006; Otiman et al., 2008) or the impact of GMO soybean on the Romanian market (Sisea, et al., 2008).

Ministry of Education, Research and Innovation and the Romanian Academies have not elaborated yet any strategy in the field of modern biotechnology research. A few research projects regarding GMOs were financed by National Authority for Scientific Research through the National Plan for Research Development and Innovation (2007-2013) (www.ansc.ro) and CNCSIS have financed one of the moderns GMO lab through the Knowledge Base Platform for Biotechnology at USAMV Cluj-Napoca (www.usamvcluj.ro)

Under National Program „Research Excellence" Module IV, some Agricultural Universities were financed for the organisation and accreditation of laboratories for detection and quantification of GMOs (http://www.cnmp.ro/ceex/comp). A GMO laboratory is on the way to be accredited at Research Institute in Ştefăneşti and another two are in function in Bucharest. Only three laboratories are members and have signed the agreement with the European Network of GMO laboratories (http://engl.jrc.ec.europa.eu/designated.htm).

Currently, in Romania, only two GM crops were obtained with the potential for market release: plum resistant to *Plum pox viruses* and two Romanian potato varieties resistant to Colorado beetle attack. Redsec and Coval varieties belonging to Târgul Secuiesc Research Station have been genetically modified. Field trials with selected lines have not yet been approved (Badea et al., 2004; Badea et al., 2008).

STATUS OF DELIBERATE RELEASE OF GM CROPS

Since 2000, the Ministry of Environment/National Authority for Environment Protection has received more than 30 applications for deliberate release of agricultural genetically engineered organisms. Two domestic applicants (an agricultural university and an agricultural research institution) and four foreign companies were not equally treated. Only applications submitted by foreign companies and the application for field release of transgenic plum (domestic research station) have been approved. By the year 2009, 3 species of transgenic plants including *Glycine max* (40-3-2 event), *Zea mays* and *Prunus domestica* were approved for deliberate releases for field trial purposes. As mentioned above, deliberate release of *Solanum tuberosum* romanian varieties resistant to Colorado Beetle atack did not receive consent from Ministry of Agriculture.

Transgenic clones of *Prunus domestica* transformed with the *Plum pox virus* coat protein gene (PPV-CP) were evaluated for Sharca resistance under high infection pressure in natural field conditions in Romania. The clone named „HoneySweet" showed resistance to PPV (Zagrai et al., 2008)

Currently in Romania, field trials with second generation of corn hybrids with stacked genes belonging to Monsanto, Pioneer and Syngenta companies are being carried out.

STATUS OF COMMERCIALIZATION OF GM CROPS

In 2000, Romania started to commercialize transgenic crops and two approvals for cultivation were granted: Roundup Ready (RR) soybean and Superior NewLeaf potato (expired in 2002). While the NewLeaf potato never wasmarketed, beginning with the same year, the area dedicated to GM soy expanded constantly, peaking in 2006 (the eighth year of use of this technology) at 137 thousand Ha (Otiman et al., 2008). Large areas with RR soybean were cultivated in regions most appropriate for this crop: Danube Plain (Călăraşi, Ialomița, Brăila, Galați), Dobrogea (Constanța), Banat (Timiş, Arad). In the Romanian Official Catalogue 14 varieties were registered (3 Pioneer variesties and 11 Monsanto varieties). In 2006, 6 varieties from maturity groups 00, 0, I and II were marketed (one belonging Pioneer and 5 to Monsanto). Officially, certified seeds were used but Romanian farmers illegally used uncertified seed.

The specific cultivation, management and harvesting techniques used for RR soybean are identical to those used for non-genetically modified soybean, with the exception of the herbicide regime. In Romania, according to the results of a survey conducted by Monsanto Company, most of the farmers indicated that economic efficiency was mainly due to the adoption RR technology (www.askbmi.com).

Beginning with 2007, Roundup Ready soybean cultivation was banned. With no access to RR technology, the area cultivated has started to decline in 2007, reaching 113 thousand ha, while in 2009 only 63,000 ha were planted with this crop (MADR). This is equivalent to about 70% reduction in only three years. Romania has become a net importer of vegetable protein, similar to the European Union itself. The EU imports about three quarters

of its total soybean supply, mainly from the USA, Argentina and Brazil, countries in which mainly RR soybean is cultivated. At the national economy's level, hard currency losses (as a result of increased imports) are estimated to exceed millions of Euros per year (Otiman et al., 2008; Dinu and Alecu, 2009).

The growing of GM herbicide tolerant soybean in Romania has resulted in substantially greater net farm income gains per hectare than any of the other country using the technology (until the GM herbicide tolerant soybean technology became available, weed infestation levels, particularly weeds difficult to control such as Johnson grass have been very high in Romania because of low levels farm income, abandonment of land and very low levels of weed control (Brookes, 2008)).

As like all EU Member States, Romania may grow the only crop approved for import and cultivation in EU, MON810 maize. The total area planted in 2009 with GM maize (MON 810 event) has been about 3000 ha. The following GM maize hybrids have been cultivated: DKC 4442YG, DKC 5784YG, DKC 5018YG, DKC 3946YG, DKC 3421YG, DKC 6451YG, PR36R11, listed in the common catalogue of varieties of agriculture plant species (27th complete edition, OJ C 279 A, 20 November 2008).

STATUS OF GMO BIOSAFETY RESEARCH

- Environmental monitoring of glyphosate-tolerant soybean

According to EU Directive 2001/18/EC, post-market monitoring (PMM) for commercial GMP cultivation must be implemented, in order to detect and prevent adverse effects on human health and the environment. However, no general PMM strategies for GMP cultivation have been established so far. Sanvido et al., (2005) presents a conceptual framework for the design of environmental PMM for GMP cultivation based on current EU legislation and common risk analysis procedures.

In Romania, Ministry of Environment and Water Management (MEWM) Order no 838/2005 approved the guidelines regarding the application of Annex 12.2 Monitoring Plan, belonging to Law 214/2002 regarding the regime for obtaining, testing, use and commercialization of genetically modified organisms obtained through modern biotechnology techniques and also of the products resulting thereof. These guidelines are complying with Decision 2002/811/EC for the application of Annex VII of Directive 2001/18/EC regarding the deliberate release into the environment of GMO.

According to biotech law, post-marketing monitoring has the objectives to confirm the conclusions of the environmental risk assessment and to identify unanticipated adverse effects.

Risk analysis of GM Roundup Ready soybean was based mainly on the following elements: soybean is not sexually compatible with any indigenous or introduced wild plant species present in Europe (OECD, 2001); soybean is a self-pollinated species, propagated commercially by seed, cross pollination is usually less than one percent (OECD, 2001); soybean cannot survive without human assistance and is not capable of surviving as a weed; soybean possess few of the characteristics of plants that are weeds (Baker, 1974). In Romania, GM soybean will be commercially grown in pre-existing agro-ecological environments, and the direct and indirect ecological effects of the Roundup Ready technology would likely to be broadly similar to those resulting from conventional chemical spraying. In Romania, *Glycine max* is not found outside of cultivation and until now hybridization between soybean and other spontaneous or cultivated leguminous species is not known to occur. Additionally, in Romania, biology of the soybean have been also studied (Ţopa, 1957; Ciocîrlan, 1990; Popescu and Sanda 1998).

Monitoring of Roundup Ready soybean in Romania was carried out by Universities and Research Institutes, in good collaboration with the private sectors that have received authorizations. In order to confirm some conclusions of the environmental risk assessment submitted by the applicants, field experiments (case-specific monitoring) were undertaken for evaluating the impact of RR *versus* conventional technology on the soil microorganisms, arthropod fauna and weed population. Results of these monitoring activities of RR soybean crops in Romania have been published (Badea et al., 2005; 2006). A general surveillance was conducted, during the period 2002-2004, farmers cultivating RR soybean being asked questions regarding plant behaviour in new agro-ecosystem. Responses were considered indicators for soybean behaviour related to invasiveness, persistence, rate and/or mode of reproduction, dissemination, survivability, etc. The conclusion of monitoring activities: the environmental risk of utilisation of RR soybean technology can be regarded as negligible.

- GM maize.

Since 1998, commercialization of the GM maize was approved in EU with a requirement for post-market monitoring and compliance with co-existence regulatory norms. Since 2007, as Member State, Romanian farmers cultivated the only event approved for import and cultivation in EU, MON810 maize.

Before 2007, field trials aimed at registration of RR maize hybrids (NK603) and Bt maize hybrids (MON810) have been approved. Biosafety studies were carried out to investigate the effects of conventional and Roundup Ready technology on the fauna in cultivation fields. No adverse effects of conventional and Roundup Ready technology on worms (Roşca, 2003) and on non-target organism were registered (Badea et al., 2006).

For maize events notified by different applicants for deliberate release in the last three years, the environmental data regarding the fate of the Bt proteins in the agroecosystems and the effects of Bt maize on the non-target organisms presented by companies were based on studies done in other countries. For this reason, the Biosafety Comission required a case-specific monitoring program to be performed in representative production areas to detect possible adverse environmental effects. Some of the preliminary results were published (Grozea et al., 2009).

RELEVANT STAKEHOLDER

- Farmers and farmers associations.

Growing RR soybean, the Romanian farmers realized the benefit of a biotech product and are open to the agriculture biotechnology. Losing a very profitable technology, the farmers understood that they have to be involved more active in co-existence political promotion. Consequently, in 2008 they have been more active involved when MESD tried to ban the cultivation of MON810 maize without consulted the farmer associations. The Romanian farmers hope that in the near future will be possible to cultivate again RR soybean. Expectations are high that farmer associations continued pleading for access to leading edge technology in their dialog with the political factors, determining those to base their decisions on socio-economic aspects when the products are considered safe for market release by the competent authorities at EU level. They joined to scientific community in the debates on the importanse to compare the socio-economic consequences of adopting a technology with the potential consequences of not adopting that technology (socio-economic impact can differ between Member State).

- **Industry association**

AGROBIOTECHROM is a professional body of agricultural biotechnology developers and users from Romania. The Association has the character of an independent, non-governmental, non-profit, non-political organization, with legal personality, governed by the internal and international laws in effect. In order to achieve the undertaken purpose, the Association establishes the following objectives:

1. it supports the development and creation of a coherent, stable and predictable legal frame in the field of biotechnology, by performing/supporting actions regarding the simplification of procedures, maintenance of constructive dialogue with the competent authorities and any other organization, association or company, involved in the process of regulation, implementation and supervision of the biotechnological applications;
2. it supports the increase of the general public's degree of knowledge of the benefits of biotechnology in healthcare, agriculture and industry;
3. it supports and actively promotes the interests and results of the Romanian researchers in the field of biotechnology and of the universities and research institutes that have ongoing or completed projects;
4. it militates for the increase of the use of biotechnology in Romania.

The Association, likewise another 25 national associations, is a member of EuropaBio, the EU Association of bio-industries.

CONCLUSIONS

Romania harmonized biotech legislations with EU legislation. The experience of Romania with RR soybean revealed that it is important to compare the socio-economic consequences of adopting a technology with the potential consequences of not adopting or banning that technology. The Romanian farmers hope that in the near future will be possible to cultivate again RR soybean and other GM crops useful for Romanian agriculture. Although Romanian researchers obtained plum and potato GM lines with the potential for commercialisation, these will never reach to market if the EU do not change policy in the field of modern biotechnology

Up to date in EU, although the biological and biosafety research on GM major crop plants were both intensively and extensively carried out, and many events are imported for processing and food and feed utilisation, only one maize event was approved for commercialization. This policy is thought to bring about enormous effects to the agricultural production of Romania in the future.

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