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Report Highlights:
Over the past year, the GOR intensified the pace of bringing its biotech regulatory capacity into line with the EU *acquis communautaire*. Despite the fact that the adoption of GMO soybeans provides Romania with a unique opportunity to produce an export crop and lower the cost of producing animal feed, the authorities decided to drastically limit its cultivation in 2006 and totally ban it upon accession, without seeking any transitory mechanism with the EU Commission in Brussels.

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I. BIOTECHNOLOGY TRADE AND PRODUCTION

Since 2000, when the first approval for commercial planting of GM soybeans (Glycine max. line GTS 40-3-2) tolerant to glyphosate herbicide was issued by the National Biosafety Commission in accordance with the GOR Ordinance 49/2000, this crop became well established in Romania, resulting in increased yields year after year. Nonetheless, as the country will be joining the European Union in January 2007, the GOR recently passed new legislation which bans commercial cultivation of biotech crops that are not approved for cultivation in the EU Member States. Despite the fact that Monsanto registered with EFSA, its application for herbicide resistant soy cultivation in October 2005, it is quite unlikely that the EU Commission will provide a resolution on this dossier soon enough to save plantings in Romania for the 2007 crop year.

In 2001, about 15,000 hectares of biotech soybeans were planted and the figure steadily climbed as farmers experienced the advantages of this new technology, especially in response to Romania's huge weed reserve. In 2005, Romanian farmers planted 85,000 hectares of Round-up Ready Soybeans and had excellent yields. For the first time since the 1989 Revolution, Romania became a net exporter of vegetable protein. The adoption of GMO soybeans provided Romania with a unique opportunity to produce an export crop and lower the cost of producing animal feed which will be critical for pig and poultry producers to compete with more heavily subsidized EU producers. In 2006, out of a total of 148,000 hectares planted in soybeans, about 118,000 hectares were with GM varieties. Growers' associations have constantly expressed high interest in this crop, which can potentially be extended on roughly 500,000 HA in Romania, given the great vegetable protein deficit both domestically and in the EU, but also because of the rapidly expanding demand for biodiesel production[1].

In 2006, variety testing is being conducted in the national network for two staked corn hybrids (herbicide-resistant and insect-resistant) as well as for 11 varieties of herbicide-resistant soybean.

II. BIOTECHNOLOGY POLICY

Over the past year, the GOR intensified the pace of bringing its regulatory capacity into line with the EU's *acquis communautaire*[2]. They must adopt, implement and enforce all the acquis to be allowed to join the EU. The main legal framework for bio-engineered products in Romania was provided by Law 214 of April 19, 2002, which became effective from May 2002, and lays down the requirements for obtaining, testing, utilization, and commercialization of GMOs, as well as products derived from GMOs. Additional pieces of legislation[3] were recently passed in accordance with the country's EU accession commitments, especially related to

[1] A positive outlook for the upcoming years is the expected increased demand for refined soy oil in bulk and for biofuel production. Although currently there is no notable biodiesel production in Romania, the anticipated 2007 EU membership will come with the common regulations of minimum domestic usage of biofuels. With the potential to increase domestic production of rapeseed and soybeans and still running an excess crush capacity, the country has increasingly captured investors' interest in this field. Industry sources indicate that Romania has the potential to produce, by 2010, up to 2 million MT of bioethanol and up to 400,000 MT of biodiesel.

[2] The entire body of European laws which includes all the treaties, regulations and directives passed by the European institutions as well as judgments laid down by the Court of Justice. The term is most often used in connection with preparations by the last 12 candidate countries to join the union.)

[3] GOR Decision 256/2006 and GOR Decision 173/2006 respectively.

traceability and labeling of food products derived from GMOs (transposing EC Regs 1829/03 and 1830/03). Other requirements which are specified in relevant legislation adopted in the past (e.g., Minister of Agriculture's Order 462/2003, effective from July 2003, with provisions aimed at tracing biotech products) continue to remain in place.

Various measures to limit and control GMOs, particularly in this pre-accession year, were adopted. Among those were the decision to introduce a discriminatory subsidization of conventional vs. transgenic soybeans; the new requirement for a buffer zone between GMOs and natural protected areas (as per Emergency Ordinance 195/2005[4]); as well as the provision for all farmers to seek approval for each individual field prior to planting GM soybeans (Minister of Agriculture's Order 237/2006).

The Biotech-related Issues Regulatory Authorities

According to Law 214/2002, the competent authorities in implementing and enforcing all activities related to the use of GMOs, and all activities concerning the deliberate release of GMOs are: (1) the Ministry for Environment and Water Management, responsible for the issuance of authorizations/permits and carrying out the post-control of all related activities (or the National Authority, NA); (2) the Ministry of Agriculture, Forests and Rural Development; (3) The Ministry of Health and Family; (4) the National Authority for Consumer Protection. Subsequently, the Veterinary and Food Safety National Authority was given a major part in the approval process as well as in the enforcement of the regulations.

The National Biosafety Commission (NBC), an independent scientific body, advises the Ministry of Environment during the decision making process on biotech policy. The NBC consists of twelve scientists with relevant backgrounds who are members of the Romanian Academy or representatives of research institutes in life sciences, agriculture or medicine.

Approval Procedures

As reported in RO5008, per Law 214/2002, the user shall submit a notification to the National Authority, prior to the utilization of any GMO. The notification must contain at least the minimum information specified by law. After receiving the notification, the NA will inform and consult with the public regarding the received notification and consult the Biosafety Commission, which will then evaluate the environmental and agricultural impact of such use. The NA will then also request specific assessments from the Ministry of Health, the National Authority for Consumer Protection and the Veterinary and Food Safety National Authority (which is responsible for food and feed safety) on the impacts of such use on human health.

The NA (the Ministry of Environment and Water Management) must respond to the notifier within a period of 90 days after receipt of the notification whether or not the received notification is in compliance with the current legislation. The notifier may be required to submit additional information. If the proposed activity does not comply with the legislation in effect, the notification is rejected. The 90-day period referred to does not include any periods of time during which the NA: (a) is awaiting further information requested from the notifier, (b) is awaiting the approval of the Biosafety Commission; (c) is conducting public hearings. If the National Authority considers that sufficient evidence has already been gathered through the previous release of certain genetically modified organisms into the environment, it can decide to apply simplified approval procedures. The notifier may proceed

[4] Subsequently amended and approved via Law 265/July 2006.

with the proposed activity only after obtaining the NA authorization, and it must observe the conditions specified in the authorization. In-country field tests are required prior to granting the commercial status to biotech crops.

Law 265/2006 specifically stipulates in Art. 54 that, effective Romania's EU accession date, cultivation and testing of genetically modified crops will strictly follow the *acquis communautaire.* Also, commercial plantings of any biotech crops that are not accepted on the territory of the EU will be forbidden in Romania when the country becomes a Member State.

Monitoring

According Law 214/2002, the NA officially issues the approval for releasing a specified genetically modified organism into the environment, while relevant departments are responsible for assessing different types of risk conduct and post-approval surveillance to ensure compliance with the authorization requirements.

The monitoring activity will follow clear procedures and will be conducted according to a plan submitted by the notifier and can be carried out for restricted use and/or after obtaining the approval for GMO release into the environment or placing it on the market. If new information appears as a result of the monitoring, this should, by default, be incorporated into future risk assessment studies. Order 838/2005 issued by the Ministry of Environment describes the Monitoring Plan, which is part of the notification dossier and includes three sections:
- Monitoring strategy
- Monitoring Methodology
- Assessment, reporting, reassessment.

Monitoring reports should be submitted by the notifier to the central authority for environmental protection as well as other bodies, who will forward them to the EU Commission and other competent authorities. The notifier is responsible for ensuring transparency in the monitoring plan results through workshops, dissemination of materials, webpage publications, and scientific and commercial publications.

The Minister of Environment and Water Management's Order 606/2005 approves the format (template) for presenting the results of the monitoring activity (by fully transposing Commission Decision no. 2003/701/EC, based on Directive no. 2001/18/EC).

Labeling

Requirements for labeling foodstuffs that are based on GMO products or contain additives that have been genetically modified were initially specified by Law 214/2002, according to which the producer is responsible for labeling biotech products placed on the market. This complies with EU legislation and regulations 1/39/98, 49/2000, and 50/2000. The notification submitted to the NA requires the applicant to provide a description of the envisaged conditions for placing the product on the market, including use, handling, and a proposal for labeling and packaging which should comply with the requirements stipulated by Law 214/2002.

Nonetheless, the national legislation on GM labeling was fully brought in line with the current EU requirements (Regulation (EC) No 1830/2003) in March 2006, when the GOR passed its Decision No. 173, taking effect on June 30, 2006. In general, these labeling regulations apply to bulk agricultural commodities such as grains and oilseeds. To be consistent with EU,

Romania adopted measures on thresholds for labeling, set at 0.9% for an adventitious presence of an authorized GM in food or feed and, 0.5% for the accidental presence of unauthorized, but scientifically acceptable GMOs. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable.

The regulation does not require labeling of products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

According to GOR Decision 256/2006 (effective from January 1, 2007), animal feed, if produced from GM crops, is for the first time required to be labeled.

Traceability

Similarly to labeling, regulatory framework for tracking biotech products in Romania was updated to reflect the latest EU provisions. According to GOR Decision 173/2006 (transposing 2003/1830/EC), appropriate labeling throughout the marketing chain will, from June 30, 2006, ensure full traceability in Romania. The responsibility lies with the Veterinary and Food Safety National Authority, in close cooperation with the other biotech regulatory authorities. Under these rules for traceability, companies involved in this business must transmit and retain information about products that contain or are produced from GMOs at each stage of placing them on the market. Information concerning the presence of GMOs must be transmitted throughout the commercial chain and must be kept for five years. The regulation covers all products, including food and feed, containing or derived from GMOs that received a national authorization, e.g. GM seeds, GM grain (soybeans), oil etc.

In the case of GMOs intended for deliberate release into the environment, business operators must transmit specified information on the identity of the individual GMO(s) a product contains.

For GMOs intended for food, feed or for processing, operators may either transmit the specified information or transmit a declaration that the product shall only be used as food or feed or for processing together with the identity of the GMO(s) from which the product was derived.

In the case of food and feed produced from GMOs, operators at each link of the chain must inform the next link that the product is produced from GMO(s).

Additional traceability elements are provided in the Ministry of Agriculture's Order 462 from July 2003, which requires all farmers using seeds for biotech crops to report the area planted with such seeds and the yields obtained. More specifically, all individuals or companies that cultivate biotech crops must submit two declarations/templates to the field offices of the Ministry of Agriculture, Forests and Rural Development (MAFRD); the first one within 10 days after sowing is completed, while the second one within 10 days after harvest. The first declaration must describe the name of the crop, area cultivated, and the origin of the seed (whether acquired via procurement or own production). The second declaration must include the name of the crop, the production obtained and its destination (seed for sowing or consumption). In parallel, the seed producing companies are required to submit to MAFRD information referring to the client identification data, the amount of seed sold and from which variety and biological category.

As biotech soybean plantings become forbidden in Romania upon the country's EU accession (scheduled for 2007), the Ministry of Agriculture together with the control corps of the Ministry of Environment (that is, the Environmental Guard) and the Veterinary and Food Safety National Authority are currently involved in making sure that no seed for sowing of this crop is being produced during the current crop year. The use of saved seed is also banned from 2006, as per MAFRD's Order 237/2006. This Order (passed in April 2006) consists of a set of measures meant to drastically restrict the area planted in GMOs, including through setting up a minimum size of a field to be planted to biotech crops (2 HA), reportedly to facilitate traceability. Also, each farmer should seek authorization from the county office of MAFRD for each plot intended to be cultivated with GM crops. The issuance of such an authorization is subject to all other regulations in place (e.g., the observance of the separation distance between GM fields and the so-called "national protected areas", as per Law 265/2006). The county office of MAFRD subsequently submits to the Central Authority information for the preparation of a National Registry of Biotech Growers, containing identification data for each farmer.

As for trans-boundary movements of GMOs, according to Law 266/2002, seeds can be imported only after the importing company receives an approval issued by the MAFRD. The commodity must be packed into bags and labeled accordingly; both labels and accompanying documents should specify that the variety is genetically modified. After the cultivation season, the clients should return empty packages to the selling companies, for a clear record of the seed distribution.

Enforcement

Various GOR agencies play different roles in enforcing the current legislation related to the national biosafety system. The country is current making an effort to bring them together in a functional biosafety inspection body. At the same time, by the end of 2006, a national reference laboratory (according to ISO 17025) will become operational and perform tests along the production and marketing chain.

Main responsibilities in carrying out inspection and control activities lie with:

1. The Ministry of Environment and Water Management – via its National Environmental Guard (NEG). As NEG is in charge of enforcing the whole package of environmental protection legislation (via inspection and control). Current recommendations from the EU Commission are that Romania should develop a GMO inspection body specialized in sampling and conducting specialized inspections.

2. The Ministry of Agriculture, Forests and Rural Development. There are several directorates with official inspection and control capacity related to GMOs: *the Inspection Directorate* (entitled to check the observance of good agronomic practices); *the National Inspection for Seed Quality* (the authority for seed and reproductive material quality control and certification as well as monitoring and accrediting business operators involved in activities related to seed); *the County General Directorates for Agriculture and Rural Development* (with roles in authorizing local GMO plantings and in gathering information about biotech farmers, subsequently transmitted to the Central Authority); *the State Institute for Variety Trials and Registration* (Romanian acronym ISTIS), that investigates from the technical point of view the varieties for which requests have been made to be registered in the Variety Register and the Official Variety Catalogue.

A similar recommendation has been made by the EU experts for the establishment of a specialized GMO inspection body within MAFRD, for all activities pertaining from this Ministry's role in the national biosafety system.

3. The Ministry of Health has developed inspection procedures for GMO food (as per Minister's Order 861/2003) for the 42 county directorates (including country's Capital, Bucharest). Until recently (when the labeling legislation took effect) this Ministry was not, in fact, able to perform inspection activities related to GMOs.

4. The Veterinary and Food Safety National Authority (VFSNA). With respect to GMOs, VFSNA is involved in (i) endorsing approvals for GM products from the perspective of assessing potential risks to human and animal health; (ii) exerting control regarding the enforcement of food and feed traceability requirements. Except for the Central Authority, other subordinated bodies are involved in the inspection and control process: Institute of Hygiene and Public Health; Institute of Animal Health and Diagnosis; Institute for Biological Products and Veterinary Drugs; as well as 42 Veterinary and Food Safety county-directorates.

5. The National Authority for Consumer Protection, which checks on the enforcement of food product labeling requirements in order to ensure that correct, complete and accurate information is provided to consumers.

Testing

Prior to being accepted for commercial cultivation and use (food, processing and feed), any transgenic variety should be first approved for experimental environmental release (field trials). Currently, there are two staked gene corn hybrids (tolerant to glyphosate herbicide and resistant to *ostrinia nubilalis*) approved for testing in the network of the State Institute for Variety Trials and Registration (ISTIS). There are also trials for 5 varieties of herbicide-resistant soybean varieties as well as screening (pre-testing) of another 6 varieties of biotech soybean.

Commercially approved transformation events are being reauthorized for testing every year, even in the particular case of hybrid/variety registration tests carried out by the State Institute for Variety Trials and Registration. The required paperwork of the notifier is extremely time-consuming in this respect, as the NA calls for all regulatory agencies' re-issuance of approvals, including the ones with multiyear validity (e.g., Ministry of Health's case).

Table of Approved Biotechnology Products in Romania (2006)

Crop	Trait Category	Applicant(s)	Event	Trait Description	Approved for
Soybeans/Glycine max.	Herbicide Tolerance	Monsanto, Pioneer	GTS 40-3-2	Glyphosate tolerant	Field Trials; commercial cultivation and processing for food and feed use
Corn/ Zea mays	Staked genes	Pioneer	DAS-01507-	Glyphosate tolerant and	Field trials

	(Herbicide Tolerance and Insect Resistance)		1*MON-00603-6	resistant to *ostrinia nubilalis*	
Corn/ Zea mays	Staked genes (Herbicide Tolerance and Insect Resistance)	Pioneer	NK-603*MON-810	Glyphosate tolerant and resistant to *ostrinia nubilalis*	Field trials
Soybeans/Glycine max.	Herbicide Tolerance	Monsanto, Pioneer		Glyphosate tolerant	Field trials

Co-existence

As of this writing, the relevant Romanian authorities (the Ministry of Agriculture and the Ministry of Environment) have not developed actual co-existence rules.

Nonetheless, rudimentary coexistence elements were developed by GOR Emergency Ordinance 195/2005, according to which GM crops are forbidden to be planted within a buffer zone around the "national protected areas" (on a 15 KM radius). Since the only transgenic crop currently approved for commercial cultivation in Romania is soybean (a self-pollinated crop), this highly controversial and arbitrary requirement generated long disputes within the Romanian Parliament when EO 195 was submitted for approval. Finally, according to Law 265/2006 which approves and amends EO 195/2005, it was decided that the separation distance between national protected areas and GMO fields should be jointly established, on a scientific basis, by the Ministry of Agriculture and the Ministry of Environment.

At present, the Ministry of Agriculture is preparing co-existence legislation, in line with the EC directions.

Rules Governing the Movement and International Trade of Transgenic Products

Romania is signatory to the Cartagena Protocol on Biosafety, in accordance with the Ratification Law 59/March 2003. Although the Protocol requires an exporting country to seek consent from an importing country only prior to the first shipment (first trans-boundary movement) of a living modified organism (LMO) intended for intentional introduction into the environment, the Romanian national legislation exceeds this framework and requires companies to adhere to complete biotech product importation procedures (as described below) for every shipment of biotech seeds entering Romania for planting. This represents a real challenge facing local subsidiaries of U.S. biotech companies, forced every year to notify separately **each import of a commercially approved transformation event**.

Romanian national legislation (Law 214/2002) provides that the following information must be presented to the competent national authority (i.e., Ministry of Environment) in notifications concerning documented authorization every time import/export activities of genetically modified organisms are to be performed:

a) Name, address and contact info of the exporter.
b) Name, address and contact info of the importer.

c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
d) Intended date or dates of the trans-boundary movement, if known.
e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
f) Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
j) Quantity or volume of the living modified organism to be transferred.
k) A previous and existing risk assessment report.
l) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.
m) Regulatory status of the living modified organism within the State of export and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
o) A declaration that the above-mentioned information is factually correct.

Trade Barriers

Commercialization of herbicide resistant soybean in Romania is currently hindered by technical barriers related to the manner in which the Romanian authorities implement the Cartagena Protocol (see section on Rules Governing the Movement and International Trade of Transgenic Products) as well as an excessive interpretation of the traceability concept. Regarding the latter, the NA conditions the release of the annual approval for commercial cultivation to the notifying seed companies by receiving the list of locations where transgenic soy seeds will be planted which is difficult to present given the large number of disperse growers throughout Romania.

Intellectual Property Rights

Although this aspect is regulated in Romania via a number of laws and Government Decisions (Law 285/2004 on copyright and connected rights, GD 1424/2003 for approving the National Strategy in Intellectual Property Rights, GD on the Organization of the State Office for Inventions and Trademarks, etc.), the company that was issued the initial approval for importation for commercial planting of the GM soybeans (Glycine max. line GTS 40-3-2) tolerant to glufosinate herbicide in 2002 does not collect royalties, because it did not register the patent in the first year when the technology was introduced into Romania.

III. MARKETING ISSUES

Lately, NGOs representing organic farmers and environmentalists intensified their efforts in lobbying the government and influencing public opinion through sensational newspaper headlines. Such articles are purely misleading, deliberately failing to specify that herbicide resistant soybeans are not "banned" in EU, they simply have not yet been approved because the seed companies only recently applied for inclusion into the EU catalogue.

Nevertheless, consumers' hostility towards bioengineered food remains superficial and the general public in Romania is rather inclined to trust scientific arguments.

IV. CAPACITY BUILDING AND OUTREACH

USAID, with technical assistance from FAS, is continuing its efforts to help Romania explore ways of coming into the EU with a viable biotech industry and support farmers who can produce and sell their products in an EU-compliant system. There are many arguments for this:

- Romania has a competitive advantage in the production of field crops such as soybeans and corn and therefore has more to gain than western European countries.
- Europe has a vegetable protein deficit and Romania can be a net exporter in this area.
- New member states to the European Union will not receive the same subsidy levels as existing members. New production technologies are key to being competitive.
- Biotech is based on science, is highly tested and regulated, and has the potential to increase farm incomes around the world. More and more countries are adopting GMO technologies and Romania has the opportunity to be a leader within Europe.

During FY2006, six Romanian young scientists were trained in U.S. universities on biotech-related issues, under the USDA Borlaug Program.

A logical continuation of the biotech outreach initiative which began in March 2005, FAS and the State Department have been involved over the past year in activities meant to help both the authorities and private sector to successfully contribute to a transparent, science-based national scientific framework in Romania.

A first initiative consisted of a series of workshops in Romania, between October 11-14, 2005, with the aim to present the role of modern biotechnology in agriculture as well as the EU regulatory system which Romania will soon have to comply with. This road-show targeted various audiences: GOR, farmers and processors, researchers, and media representatives. There were major themes addressed in the presentations including: an overview of the adoption of agricultural biotech, U.S. vs. EU biotech regulations, and the implementation of the Biosafety Protocol worldwide.

In March 2006, Prof. Charles Hanrahan of the US Congressional Library met with members of the Romanian Legislative, to Present to Members of Parliament the benefits of biotechnology, how the U.S. regulates biotech crops, as well information on the U.S. – EU biotech debate. The speaker also delivered a presentation in front of some 25 representatives of the scientific community at the Romanian Academy of Agriculture and Forestry Science. Prof. Hanrahan's balanced, objective stance was highly appreciated by those present. A press conference closed the speaker's highly appreciated trip to Romania.

RELEVANT REFERENCES

The Ministry of Agriculture, Forests and Rural Development
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