CO-EXTRA

GM and non-GM supply chains: their CO-EXistence and TRAceability

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1 Summary

The aim of this study is to overview the traceability and co-existence systems and practices in European, non-EU countries in order to identify potential similarities, differences, novel good practices or approaches that could be successfully applied by the EU Member States.

The report focuses on several groups of countries. Since the study started before the last enlargement of the European Union, Bulgaria and Romania are also included in the report, as new Member States. The EU candidate countries, which have already started their negotiations with EU – Croatia, Turkey and Macedonia, were regarded separately. The traceability and co-existence issues in representatives from NIS countries – Russia and Ukraine, as well as from Western Balkans – Serbia and Bosnia and Herzegovina have been also considered.

The report provides with a detailed overview of the status of GMO releases in every country, focusing on the legislative framework that regulates the issues of modern biotechnology – as status of implementation and particularities, with emphasis on the issues with particular relevance with co-existence, traceability and labeling (summarized in Annex 1).

Conclusions on the similarities and differences, as well as the status of implementation of systems for traceability and co-existence in these countries and their practicability, when applicable, have been presented.

2 New EU Member States – Romania and Bulgaria

2.1 Romania

2.1.1 Status of GMO plantings and trade in Romania

Since 2000, Romania has pioneered the planting of biotech crops, especially soybeans. The first approval for commercial planting of GM soybeans (Glycine max. line GTS 40-3-2) tolerant to glufosinate herbicide was issued by the Romanian Biosafety Commission in accordance with the GOR Ordinance 49/2000.

In 2001, about 15,000 hectares of biotech soybeans were planted and the figure steadily climbed especially given Romania's huge weed reserve. In 2004, roughly 50,000 hectares of biotech soybeans led to record yields, while the local affiliates of US biotech companies reported unprecedented high demand for seeds for the just completed 2005 spring campaign.

In recent years, field trials were approved for a number of genetically engineered crops, including BT potato, sugar beet, and corn. In 2005, variety testing is being conducted in the national network for a herbicide-resistant corn hybrid (NK603).

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 is only one corn hybrid, tolerant to glyphosate herbicide (NK603), approved for testing on about 1 HA in the network of the State Institute for Variety Trials and Registration (ISTIS).

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.

Table of Approved Biotechnology Products in Romania (2005)

Crop	Trait Category	Applicant(s)	Event	Trait Description	Approved for
Soybeans/Glycine max.	Herbicide Tolerance	Monsanto, Pioneer	GTS 40-3-2	Glufosinate tolerant	Field Trials; commercial cultivation and processing for food and feed use
Corn/ Zea mays	Herbicide Tolerance	Pioneer	NK-603	Glufosinate tolerant	Field trials

In 2006, Romania has planted 0,1 million ha of biotech crops (Clive James, 2007).

2.1.2 Legislative framework on modern biotechnology (GMOs)

Romania had its first legislative regime on GMOs and the products thereof in 1999: the Government Ordinance 49/2000 (GO) on the obtaining, testing, use and commercialization of

genetically modified organisms resulted by the modern biotechnology techniques, and of the products resulting thereof.

The efforts of the Romanian government (GOR) to bring its regulatory capacity into line with EU rules and international agreements resulted in the passage of Law 214 of April 19, 2002, effective from May 2002, which enforces and amends GOR Ordinance 49/2000 on development, testing, use and commercialization of GMOs, as well as products derived from GMOs. The Law provides the main framework for GMOs and GMO products in Romania. Two other pieces of legislation relevant to biotech-related issues are: (1) GOR Decision 106/February 2002 on labeling food derived from GMOs, or containing genetically modified additives and (2) Minister of Agriculture's Order 462/2003, enforced since July 2003, with provisions aimed at tracing biotech products.

As a Party to the Convention on Biological Diversity (CBD), Romania signed the Cartagena Protocol on Biosafety, on 11 October, 2000. It also ratified the Protocol by the Law 59/2003 from 30 June 2003 which entered into force on 28 September 2003.

National Competent 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(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. Additionally, 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
Law 214/2002 stipulates that, the user shall submit to the National Competent Authority, prior to the utilization of any GMO, notification containing at least the information specified by Law 214 . After receiving the notification, the NCA 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 NCA will then also request specific assessments from the Ministry of Health and the National Authority for Consumer Protection (which is responsible for food and feed safety) on the impacts of such use on human health.

The NCA (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 NCA 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 with the proposed activity only after obtaining the NCA 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.

Monitoring and Enforcement
According Law 214/2002, the NCA 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 post-approval surveillance to check compliance with authorization requirements.

Violations of Law 214/2002 provisions may become infringements according to the penal law and they are punished with a fine (from approximately 250 to 2500 Euros at the current exchange rate) and/or temporary or final suspension of the activity, on a case by case basis. Specialized personnel authorized by the Ministry Agriculture, Waters, Forests and Environment, Ministry of Public Health and Family and the National Authority for Consumer Protection enforce the sanctions provided by the law. Law 214/2002 also states that if damage results from activities regulated through this law that is detrimental to human or animal health, to biological diversity or to the environment, the user is responsible for the damage. The nature and scope of the damage are to be established by a commission of experts appointed by the National Competent Authority. (GAIN report N. RO5008 Romania Biotechnology Annual 2005)

2.1.3. Labeling

According to Law 214/2002, in force until 2007, 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 NCA 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. The label shall clearly state if the genetically modified organism is present. The label bearing the inscription “This product contains genetically modified organisms” is compulsory. There is currently no law or regulation governing the use of labels such as biotech-free, non-biotech, GMO-free, or non-GMO, Law 214/2002 states that within a period of 10 years procedures for such labeling will be established.

The GOR Decision 106/February 2002 - further detailed in its accompanying Methodological Norm 7/2002 - provides more detail on the labeling methodology of foods obtained from biotechnology or containing genetically modified additives derived from GMOs.

Interestingly, this norm is narrowed to foodstuffs delivered as such to the final consumer and to processed food entirely or partially obtained from: (i) genetically modified soybean and/or (ii) genetically modified corn. “Product derived from GM Soybean” or “product derived from GM corn” must be clearly written on the label. These additional labeling requirements can be ignored if the content of biotech soybean or corn is less than 0.9 percent of total ingredients.
Legislation on requirements for labeling of foodstuffs that are based on GMO products or contain additives that have been genetically modified was fully brought in line with the EU Regulation No. 1830/2003 in March 2006, when the GOR passed the Decision 173 (enforced since June 30, 2006). To be consistent with European Union, 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 (undergone risk assessment). 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 (enforces since January 1, 2007), animal feed, if produced from GM crops, is for the first time required to be labeled as such.

2.1.4. Traceability

Tracking biotech products in Romania has become stricter and more rigorous lately from the regulatory perspective. Traceability is required as a consequence of the labeling requirements provided by Law 214/2002 and GOR Decision 106/2002, brought in line EU directives.

In July 2003, the Minister of Agriculture, Waters, Forests and Environment issued its Order 462 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/companies that cultivate biotech crops must submit two declarations to the Directorate for Agriculture and Rural Development of the Ministry of Agriculture, Waters, Forests and Environment, 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 plant, the production obtained and its destination (seed for sowing or consumption).

The regulation on traceability requires companies involved in this business, when using or handling biotech products, to submit and keep information at each stage of placing them on the market. Companies are responsible for ensuring that a tracking system is in place.

According to Law no. 266/2002, seeds can be imported only after receiving the import approval issued by the MAFRD. The commodity is packed into bags, and on the labels and accompanying documents it should be specified that the variety is genetically modified. For a clear record regarding of the seed distribution, the clients are obliged to return the empty packages to the respective companies, after the cultivation season. The MAFRD can forbid the use of a GMO variety in a certain region of the country or on the whole territory, if it is found that the respective variety is harmful for other crop varieties (i.e. outcross pollination) or it endangers the environment or human health. A genetically modified variety cannot be tested or registered if the applicant does not prove that this complies with the legal conditions regarding environment and human health protection.

Other traceability elements were also introduced in Romania through food safety legislation, namely Law no. 412/2004 for the modification and completion of Law no. 150/2004 on food safety. This law provides for checking the means by which feed traceability is carried out by all the operators and agents in the food industry. On this basis, for the year 2005, the notifications of GMO producing companies, regarding GMO imports and deliberate release into the environment for testing as well as for cultivation purposes were approved only on the following condition: the economic operators, authorized natural or legal persons operating in this field, should demonstrate the destination of the GMO seeds, up to the point of their commercialization of GMO as food or feed. At the same time, the labeling of products was imposed. The users of GMO seeds are to be informed by notifiers on the obligations they have in traceability and labeling.

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 ensures, from June 30, 2006, 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.

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 obtained yields.

2.1.5 Co-existence

Although Romania with its 0,1 million ha of GM soybean cultivation in 2006 has become one of the 14th biotech mega countries, the larger GM cultivator together with Spain on the European continent (Clive James, 2007), Romanian authorities have not developed any co-existence rules. Nonetheless, this is expected to change very soon and the EU-line to be adopted, especially given that the Ministry of Agriculture recently stated its priority to encourage organic agronomic practices.

Organic products are not restricted by CAP quotas and, being labor-intensive, are assessed to be able to absorb in the middle-term, the social shocks of an agricultural sector struggling to adapt itself to meet the new competitiveness requirements of the enlarged common market (Antofie, M-M, Baz, A, 2006).

2.2 Bulgaria

2.2.1 Status of GMO plantings and trade in Bulgaria

Bulgaria was one of the first of the Central and East European (CEE) Countries to release genetically modified organisms (GMOs) in open field trials in accordance with its previous legislation, an interim regulation "Guideline for the dispersal of genetically modified higher plants, developed through DNA recombinant technology" has been adopted (1996) in line with the EU Directive 90/220 in place of that time. In 1998 the Bulgarian government established a Council for the Safe Use of Genetically Modified Higher Plants as required by the guideline. Members of the Council were representatives from the Ministry of Agriculture and Forests, Ministry of Environment and Waters, Ministry of Health, the Executive agency for seed production, approbation and seed control, the National service for plant protection and agrochemistry as well as representatives from the scientific community. Chairman of the Council is the Minister of Agriculture and Forests, and Executive Secretary is a prominent scientist in the field of genetic engineering. The Council was the only body to grant permits concerning GMO environmental releases (small- and large scale

field trials). Up to date, approvals for commercial planting of GMO have not been granted. (Atanassov at al., 2003).

FIELD TRIALS WITH GM CROPS IN BULGARIA

Year	Crop	Event	Trait	Notifier company	Surface (ha)
1998	Maize	PR38B22BT GLU	IR+HT	Pioneer Hi-Bred	
		PR34T14BT GLU	IR+HT	Pioneer Hi-Bred	
		PR38G17BT	IR	Pioneer Hi-Bred	
		PR36G32BT	IR	Pioneer Hi-Bred	
		PR35R58BT	IR	Pioneer Hi-Bred	
		DK 493RR	HT	Monsanto	
		DK591RR/BT	IR+HT	Monsanto	
		Furio Cb	IR	Novartis	
1999	Maize	PR37R71Bt	IR	Pioneer Hi-Bred	13 000
		PR38P06Bt	IR	Pioneer Hi-Bred	
		PR38R22Bt GLU	IR+HT	Pioneer Hi-Bred	
		PR34T14Bt GLU	IR+HT	Pioneer Hi-Bred	
		PR38G17Bt	IR	Pioneer Hi-Bred	
		PR36G32Bt	IR	Pioneer Hi-Bred	
		PR35R58Bt	IR	Pioneer Hi-Bred	
		DK493RR	HT	Monsanto	
	Potato	Super New Leaf BT	IR	Monsanto	30
2000	Maize	PR37H26GLU	HT	Pioneer Hi-Bred	19 000
		PR37R71Bt	IR	Pioneer Hi-Bred	
		PR38P06Bt	IR	Pioneer Hi-Bred	
		PR38B22BtGLU	IR+HT	Pioneer Hi-Bred	
		PR34T14BtGLU	IR+HT	Pioneer Hi-Bred	
		PR36G32Bt	IR	Pioneer Hi-Bred	
		1507Bt	IR	Pioneer Hi-Bred	

		5499Bt	IR	Pioneer Hi-Bred	
		5639Bt	IR	Pioneer Hi-Bred	
		Aw641RR	HT	Monsanto	
		DK493RR	HT	Monsanto	
	Potato	Super New Leaf BT	IR	Monsanto	3
	Sunflower	TF28	Resistance to *Sclerotinia*	Pioneer Hi-Bred	
		TF34	Resistance to *Sclerotinia*	Pioneer Hi-Bred	
2001	Maize	PR37H26GLU	HT	Pioneer Hi-Bred	6 400
		10671	IR+HT	Pioneer Hi-Bred	
		15344	IR+HT	Pioneer Hi-Bred	
		5639	IR+HT	Pioneer Hi-Bred	
		6228	IR	Pioneer Hi-Bred	
		DK440RR	HT	Monsanto	
		DK391RR	HT	Monsanto	
		DK538RR	HT	Monsanto	
		AW641RR	HT	Monsanto	
		DK493RR	HT	Monsanto	
	Tobacco	Vector 21-41	Low nicotine level	Vector Tobacco	0,3
	Potato	Super New Leaf BT	IR	Monsanto	3
2002	Maize	15344 x 1504	IR+HT	Pioneer Hi-Bred	2 200
		6275	IR+HT	Pioneer Hi-Bred	
		15344	IR+HT	Pioneer Hi-Bred	
		1507	IR+HT	Pioneer Hi-Bred	
		DK493RR	HT	Monsanto	
		AW641RR	HT	Monsanto	
2003	Maize	DK440RR (NK603)	HT	Monsanto	2 119,5
		DK391RR (NK603)	HT	Monsanto	
		DK493RR	HT	Monsanto	
		AW641RR	HT	Monsanto	

		E4497.42.1.18	IR+HT	Pioneer Hi-Bred	
		E4497.45.2.14	IR+HT	Pioneer Hi-Bred	
		E4497.45.2.16	IR+HT	Pioneer Hi-Bred	
		E4497.59.1.10	IR+HT	Pioneer Hi-Bred	
		E4497.59.1.22	IR+HT	Pioneer Hi-Bred	
		E4497.59.1.32	IR+HT	Pioneer Hi-Bred	
		E4497.52.4.3	IR+HT	Pioneer Hi-Bred	
		E4497.71.1.33	IR+HT	Pioneer Hi-Bred	
		1507 x NK603	IR+HT	Pioneer Hi-Bred	
		PR38A81	HT	Pioneer Hi-Bred	
		PR35P80	HT	Pioneer Hi-Bred	
2004	Maize	59122	IR+HT	Pioneer Hi-Bred	0,5
		NK603 x 1507	IR+HT	Pioneer Hi-Bred	
		1507 x 59122	IR+HT	Pioneer Hi-Bred	
		1507 x 59122 x NK603	IR+HT	Pioneer Hi-Bred	
		59122 x NK 603	IR+HT	Pioneer Hi-Bred	
		PR38A81	HT	Pioneer Hi-Bred	
		PR35P80	HT	Pioneer Hi-Bred	

2.2.2 Legislative framework on modern biotechnology (GMOs)

Bulgaria's first biotech regulation was developed in 1996, in a form of a Decree issued by the Ministry of Agriculture and Forestry (MAF)Ag and regulating contained use, field experiments and release into environment of crops developed by DNA modifications (Official Gazette, #70 of August 16, 1996). This regulation was based on main principles of EU Directive 90/220 EEC and provided good legislative basis for biotech laboratory research and field tests. In 2000, the regulation was slightly changed, so that the Ag Minister to chair a Bio Safety Council established based on this regulation (Official Gazette #47, June 2000). In the same year, the government submitted the first biotech draft law (harmonized with the EU Directives 2001/18 EC and 98/81 EC) to the Parliament pressured by upcoming EU accession. Due to a short period for consideration and political differences, the Law was not passed by that Parliament.

Current major biotech law called a Law on Genetically Modified Organisms (LGMO) was passed in 2005 after heated political, scientific and public debates. The original draft (proposed to the Parliament in 2003), elaborated under UNEP/GEF project "Implementation of a national biosafety framework in Bulgaria) was fully harmonised with the respective EU legislation and science –based. However, prior to final approval, Parliamentary deputies were swayed by biotech-wary scientists, along with various NGOs, to pass a much more restrictive law.

On March, 15th 2005, the Bulgarian Parliament adopted a GMO law (Official Gazette #27, March 29, 2005, effective June 1, 2005) that implements EC Directives 2001/18 on deliberate release and placing on the market of GMOs, 90/219/ EC, amended by 98/81 on contained use of GMOs and Regulation 1946/2003/EC on the transboundary movement of GMOs. It does not cover the regulation of the GM food and feed, which are addressed by the Regulation of novel food, implemented by the Ministry of Health. Due to the specific scientific matter and its potential impact on the environment and human health, this Law has been discussed for more than two years by the Parliament.

According the new law on GMO, the issuance, change or withdrawal of permits for the contained use GMO falls under the service of the Ministry of Environment and Water, while the Ministry of Agriculture and Forestry is competent for legal aspects of placing of GM products on the market, as well as for the issues of import and export of GMOs. Public discussions and initiatives for building up science-based public awareness are in the prerogatives of this Ministry.

The law prohibits the field testing, production and commercialization for a number of biotech crops: tobacco, grapevines, wheat, cotton, damask rose, vegetables and perennial fruits (art. 79, Chapter IV) and animals (§4/2, Chapter Additional Orders). Moreover, Bulgaria is perhaps the only country in the world where lab research on certain crops is also banned (§4/1, Chapter Additional Orders), namely with damask rose, grapevines and tobacco. These crops are considered by authorities as "strategic", in which Bulgaria has a unique comparative advantage. Research, including field experiments is limited to a negligible list of crops such as corn and sunflower. All biotech products and their GMO ingredients which have been rejected EU approval are also banned for deliberate release and commercialization (art 82, Chapter IV).

Nowhere in the world, including the EU-Member-States prohibitions for deliberate release of specific crops are in place but rather options for refusal for deliberate release into the environment and placing on the market after the performance of specific procedure: notification with providing a detailed dossier; checking the dossier for completeness; performance of science based risk assessment and decision upon risk-benefit of the competent national authority (which is political and may not be based only on the scientific results) and after a public debate for the introduction of the specific GM event .

Moreover, such a prohibition can easily be interpreted as confrontation with EU policy and as a technical barrier to international trade (according to the TBT- WTO- agreement) and thus, Bulgaria risks to bear severe international sanctions.

It is evident that the Bulgarian GMO Act has been strongly influenced by the spirit of restrictiveness of the EU legislative system and especially by the interference of non-governmental ecological organizations and organic farmers' associations (although the rate of organic farming in Bulgarian agriculture is less than 1% and the market of organic

products is extremely limited). It goes much beyond the EU biosafety framework by putting a ban on carrying scientific experiments with specific plant species, especially in the case, in which such species are priority for the country's economy. This automatically exclude the consideration of the benefits of the gene technology for the farmers and Bulgarian economy and with regard of the research it will hinder the developments both of applied science and the basic research in plant sciences as functional genomics, in which trans-genes are used to knock out a given gene in order to discover its function in the organism. Such research is predominantly done on tobacco, which is a model plant and the techniques of genetic transformation and regeneration are well established. A social impact of such politicizing of the GMO issue, would be a possible regress of Bulgarian life science, loss of competing ability of Bulgarian researchers and enhancing of already high brain drain.

In addition to the above law, current Bulgarian biotech legislation covers special provisions in the Food Law and three biotech implementing regulations: Regulation for GMO contained use (Decree #211, Official Gazette #81, October 11, 2005), Regulation for GMO deliberate release (Decree 212, Official Gazette #81, October 11, 205); and Regulation for food labeling (Decree #136 of July 19, 2000 for labeling requirements and placing of foods on the market, Official Gazette #62/ 2000).

The Food Law introduced the term "new foods or food ingredients" (art. 4a) as such containing of consisting of GMOs; and such produced from GMOs but not containing them. It regulates their placing on the market (art. 19) after a permission issued the Minister of Health. It also regulates imports and trade of new food and food ingredients (art. 24a).

Issues such as placing on the market of pharmaceutical products in the human medicine and veterinary drugs, which consist or contain GMOs or a combination of GMOs are regulated in the Law for Medicines and Drug Stores; and the Law for Veterinary Medical Activity. (Alexandrova et al. 2005)

2.2.3. Enforcement

Both the Ministry of Environment and Health had to establish bio safety commissions to deal with biotech issues (with organisms and foods, respectively). Such commissions were formed only in late 2006. The Ministry of Environment had to establish and maintain an information system "Clearing House on Biosafety" as required by the Cartagena protocol. As of December 2006, such clearing house has not been established.

The GMO Act requires for quantitative and qualitative lab testing for presence or absence of GMOs to be made at labs appointed by the Minister of Environment and accredited by the Bulgarian Accreditation Agency under standard EN ISO/IES 17025.

Local laboratory infrastructure is still developing and places a challenge for biotech research and legislation implementation. There are a few local labs able to make analysis of biotech products, as follows:

- AgroBioInstitute lab – this is the major biotech research lab which received accreditation to EN 45001 in 2002 and it is in process of obtaining accreditation to ISO 9000. At present, the capacity for testing is about 160 samples per day, for qualitative testing only, no RT-PCR testing.
- Private SGS lab in Varna – accredited in 2005, uses RT PCR. The lab is destined mainly for trade purposes and is analyzing grains, oilseeds, feedstuffs and has the capacity to perform biotech foods tests as well.

- One lab in Sofia for biotech foods under the Ministry of Health. This lab makes tests of foods and supports biotech foods imports/exports control for food safety purposes. The lab is in process of accreditation.

2.2.4. Labelling and traceability

The threshold for labelling of genetically modified organisms is 0.5% (art.73 LGMO), and for the biotech foods – 0.9% (art.24 b of the labelling regulation).

Labelling of GMOs should contain the following minimum amount of information (art. 73. LGMO):

- the trade/commercial name of the product;
- the statement "This product contains genetically modified organisms". This labelling requirement is not valid for those products which have adventitious and technical traces of GMO which are officially approved for commercialization and which are in quantities below the threshold (art.45).
- the name of the GMO;
- name and address of the company responsible for releasing the product to the market – producer, importer or distributor;
- information how to access the public register.

Current regulation about labelling of biotech foods under the Food Law (Decree #136/2000 published in Official Gazette #62, 2000 and following revisions, the last one in Official Gazette #20, 2006) requires, if known, the products containing modified corn and soybean products to be labelled (art.6/4).

The regulation calls for the following labelling requirements for biotech foods (art. 24 and art. 24a):

- information about each characteristic or quality of food as content, nutritional value, effect and purpose of the food, which makes the new food or the food ingredient not equivalent to already existent conventional food;
- information about the presence of substances which are not present in the existent equivalent foods and which may have effects on the health of certain population groups;
- information about the presence of a substance which does not exist in the available equivalent food and which may be an ethical problem for the consumers.

The label should contain the following provisions:

1. the words "genetically modified" or "produced from genetically modified" and the name of the organism;
2. the words "contains genetically modified ….the name of the organism.. or the words "contains ..the name of the organism… produced from genetically modified organism". This text is to be included in the list of substances.
3. the words "genetically modified" or "produced from genetically modified organism" have to be clearly written on the label when there is no list of substances;

2.2.5 Co-existence

2.2.5.1 Provisions with respect to co-existence in the GMO Act

The Bulgarian GMO Act, in force since 1 July 2005 and discussed for more than two years by the Parliament, has been strongly influenced by non-governmental ecological organizations and organic farmers' associations (although the rate of organic farming in Bulgarian agriculture is less than 1% and the market of organic products is extremely limited). With relevance to co-existence, it goes much beyond the EU biosafety framework

and particularly the EC recommendation on guidelines for co-existence as of July 2003 that states “No form of agriculture, be it conventional, organic or agriculture using genetically modified organisms (GMOs), should be excluded in the European Union”, by putting a ban on:

• carrying on research that involves genetic modification with specific plant species: tobacco, vine, and oil rose;
• deliberate release into environment and placing on the market of tobacco, vine, cotton, damask rose, wheat, and all vegetable and orchard crops
• applying GMO-based farming “if organic farming is practiced on an adjoining field” (art.52/2)
• the deliberate release of any GMOs into the areas included in the National Ecological

Network, as well as into the adjoining areas within a zone of 30 kilometers around any such areas. This requirement is particularly onerous given the country’s small size and the fact that only approximately 35 percent of land in Bulgaria is arable. The upcoming approval of new protected territories under EU “Natura 2000” program expected to be passed soon by the Parliament will further complicate the implementation of this requirement.

The GMO Law provides for public registers of permits for deliberate release of GMOs into environment and register of the areas wherein the deliberate release of GMOs is authorized. The GMO farmer is to inform the Ministry of Agriculture and Forestry of the location and size of the areas planted. The obligation to respect respective isolation distances (provided by the Law) is onus to the GMO grower. As an example, the distances found to assure sufficient level of protection to the conventional and organic fields planted with non-modified crops of the same species are for maize, soybean and rape 800, 20, and 400m, respectively. As a comparison, field trials with GM maize have been performed in the period of 1998-2004 on overall 428,005 ha in different landscape regions in Bulgaria. The distance between the GMO and the conventional fields was 50 m when the conventional fields were not used for seed production. The adventitious presence of GMOs in the non-transgenic fields was found to be under 0.5% (Atanassov *et al.*, 2003). The isolation distance for maize adopted by the GMO Act however, exceeds the scientifically approved one (50m) 40 times and thus, practically makes co-existence impossible.

One of the core questions with direct relevance to co-existence is how to comply with the threshold of 0.9% of adventitious presence of GMOs in conventional production systems. The economic studies performed so far have shown as well, that co-existence at the 0.9% level for certain crops is possible but with different costs and needs for changing farming practices. Interestingly it has been found out that organics farms, as they already operate rules of segregation and traceability, will support less additional costs than conventional non-GM farms to achieve the 0.9% threshold (Bock *et al.* 2002; Rieger *et al.* 2002; Ramsley *et al.*2003; Brookes & Barfoot, 2003a,b). According to Bulgarian GMO Act, the threshold of adventitious or technically unavoidable admixture is 0.5%.

Bulgarian legislation, including the Ordinance on organic farming N.22/2001 does however not provide any definition of the notion of “GMO free” organic production. The above mentioned studies demonstrated also that apart from the inherent biological inability to obtain 100% pure crops, zero tolerance thresholds, when technically achievable, would be very expensive. It is therefore recommendable that a common threshold of above 0.5% for liability of GMO farmers independently on the production system they might affect, to be adopted in Bulgaria. In addition, amendments in the GMO Act have to be envisaged in order to ensure co-existence and thus to comply with the EC policy in this line. Such amendments should include provisions for science-based case-by-case risk assessment; adoption of realistic isolation distances and realistic liability and redress regime (according to the present GMO

Act the GMO farmer may be finable with up to 500 000 Euro in case of causing adventitious GMO presence in organic production) among others. Possibility of establishment of fund with the participation of all farmers' groups, which would serve the issue of liability and redress, is also to be considered. (Alexandrova and Atanassov, 2005)

2.2.5.2 Co-existence policy

By request of the Bulgarian Parliament, a working group under the auspices of the Ministry of Agriculture and Forests has been convened to elaborate a national policy for the co-existence of conventional, organic and GM crops. The paper, revealing the strategic view for the next 5-10 years of scientists and ministry officers actively working in the field of conventional agriculture, organic farming or biotechnology, is based on economical, political, geographic, biological, social &ethical factors and was prepared in February 2004. It consists of recommendations given in accordance with several groups of economically important crops. The basic concept in this document is that the conventional agriculture shall keep being the main production system for the staple crops like wheat, rye, barley, rice and almost all vegetables. Together with the principal role of the conventional methods for the crops maize and potato, some steps towards commercialization of legal GM varieties can be envisaged. At the same time, t he local conventional breeding in maize and potato should receive stronger governmental/public support. For all fruits, with particular emphasis on small fruits as well as for the emblematic Bulgarian crops of oil rose and grapes a priority should be given to the organic farming with view of further consumer niche on the European market.

3 EU candidate countries

3.1 Croatia

3.1.1 Status of GMO planting and trade in Croatia

In Croatia there are no commercially produced biotech crops neither biotech crops under development.

Croatia is not importing biotech crops/products because there are no laws or acts outlining the registration process for biotech crops/products for market release.

3.1.2 Legislative framework on modern biotechnology (GMOs)

The Law on Consumer Protection was the first biotech-related law to be passed. It was published in the government gazette, number 96/03 on June 10, 2003, after being approved on May 29, 2003. Its relevance lies in the fact that it outlines the legal requirements for the clear labeling of biotech products. The highest penalty for violating this Law by misleadingly marketing products includes fines for the manufacturer or trader in the range of 6350 euros to 13 000 euros and fines for each responsible employee in the range of 400 euros to 635 euros.

The Food Act governs the possible import, licensing and labeling of any foods/feed containing GMOs. The Food Act was approved by Parliament on July 14, 2003 and published in government gazette number 117 on July 23, 2003. This law outlines many regulations that would enable biotech products to enter the market and be labeled. However, the regulations have not yet been passed, so the labeling threshold is governed by the Government Ordinance on GMO Levels in Products under which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO passed on December 3, 2004. Company penalties for violating the "novel food" provisions of the Food Law concerning placing novel food on the market or labeling are from 13 000 euros to 65000 euros, with each responsible individual fined from 635 to 130 euros.

Until recently, the Law on Protection of Nature was the overarching law for biotechnology issues, but it was replaced on May 20, 2005 by a separate piece of legislation entitled the Law on Genetically Modified Organisms (Law on GMOs). The Law on Genetically Modified Organisms (Governmental Gazette 70/2005) together with the Food Act (and forthcoming future regulations) regulate the importation, transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed, and seed). This Law established a testing and licensing regime that is so restrictive that it constitutes a de facto ban. The highest penalties for breaching the provisions of this Law range from 63500 to 130 000 euros for the responsible company and from 1300 to 10 000 euros for the responsible employee in the company.

National Competent Authorities
Ministry of Science, Education and Sport

– According to the GMO Law, is responsible for limited-contained use of GMOs
Ministry of Health and Social Welfare
– According to the Food Act responsible for all the issues regarding food and foodstuff containing biotechnology content

– According to the GMO Law, the umbrella ministry and coordinating body for all biotechnology issues
Ministry of Culture (Environment Protection Department)
– According to the GMO Law, responsible for the intentional introduction of GMOs to the environment
– According to the Food Act is responsible for also giving its consent for approving foods that contain live GMOs
Ministry of Agriculture, Forestry and Water Management
– According to the Food Act responsible for all the issues regarding feed containing biotech content and cooperates with the Ministry of Health on some other novel food related issues such as labeling
– According to the GMO Law responsibilities for feed and animal food; reproduction material in agriculture, forestry and veterinary medicine; drugs in veterinary medicine and pesticides; is also responsible for giving its consent for the intentional release of biotech products into the environment

The GMO Law requires also the establishment of a Council for GMOs with the specific task of assisting Governmental bodies to apply the Law. The Council has 17 members appointed by the Government of Croatia based on nominations from the pertinent Ministries. Council membership lasts for four years. The Council's work is independent and public. According to the Law, the Council's tasks include: tracking gene technology development and usage; tracking scientific breakthroughs and giving opinion and incentives for usage of gene technology and GMOs; giving opinions on social, ethical, technical, scientific and other conditions of GMO use; advising responsible institutions on GMO and gene technology issues; informing the public on GMO and gene technology development and also giving viewpoints and opinions.

The GMO Law also calls for establishing a Board for Limited Usage of GMOs with 11 members made up of scientists from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental protection, and occupational protection. In addition, the GMO Law requires establishing a board for the introduction of biotech products into the environment and consisting of nine scientists from the fields of: genetics, ecology, nature protection, and environment protection, agriculture, forestry, veterinary medicine, biochemistry, molecular biology, microbiology, and medicine. The tasks of these boards include: giving opinions on biotech usage in terms of legal procedures as outlined by the GMO Law, giving opinions and proposals for preparing other legislation on GMO usage, giving opinions and proposals to responsible ministries on biotech usage issues and other expert work as outlined by the GMO Law and related regulations. According to the law, these two boards should report to the GMO Council once a year.

The Food Act calls for the establishment of the Croatian Food Agency, which already began its work in 2004. The Agency work consists of conducting scientific and professional business regarding food/feed safety and hygiene that is to analyze risks regarding food/feed safety. Apart from that the Food Agency is also required to: develop guide books for good production practices and the application of the HACCP system and on good laboratory practices; offer scientific opinion regarding human nutrition, animal feed and other issues regarding the health and well-being of animals, as well as plant health; cooperate with international institutions and organizations that deal with food and nutrition issues.

At the moment Croatia clearly sees its future as a "niche market for healthy food" and Croatian officials see little need to implement a procedure to allow GM seed imports given a lack of agricultural demand for biotech products to combat drought, pests, or soil problems.

Government officials acknowledge the legal obligation to open their agricultural market to foreign imports and openly acknowledge that Croatia is positioning itself as a GMO-free, “healthy” tourist destination. Also the Croatian public is generally very negative towards biotech products.

Croatia signed and ratified the Cartagena Biosafety Protocol. Officially there is no trade of biotech products, especially not with seeds. However, at present it is hard to tell whether or not the Biosafety Protocol is being applied and working in practice. (GAIN report N. HR5008 Croatia Biotechnology New Law on genetically modified organisms GMOs 2005, USDA FAS GAIN report N. HR5009 Croatia Biotechnology Annual Report 2005, USDA FAS)

3.1.3 Labeling and traceability

No biotech crops have been approved for food or feed use in Croatia, but there is a 0.9% threshold level for some GMOs in food and feed. Under the Food Act (special ordinance from 2004), the threshold for biotech content in food depends upon whether or not the product has previously been tested and licensed in the EU. If the product has been approved by an EU member state, it does not need to be labeled for sale on the Croatian market-provided separate tests within Croatia confirm the product contains less than 0.9% biotech content. However, if the biotech content is above 0.9%, the product has to be labeled. The biotech threshold level drops to 0.0% for products that have not yet been approved by an EU member. The same goes for feed.

Food and feed containing agricultural biotechnology products must be labeled according to the Food Act, the Law on GMOs, and the Consumer Protection Law.

Excerpt from the Food Act:

The Declaration or Labeling of Novel Foods
Article 57
1) Novel foods placed on the market of the Republic of Croatia, apart from the general declaration or indication requirements from Article 42 of this Act, must also contain on the declaration additional special information to keep the consumers informed about all the characteristics and features by which the novel food or its ingredient no longer corresponds to the existing food or food ingredient.
2) In that case the declaration must contain information about the changed characteristics or features including the method used to get that indication or characteristic.
3) The food and food ingredients containing or consisting of GMOs, must have a visible indication that it contains or consists of GMOs including the term GMO.
4) The indication must clearly state "genetically modified organisms" or contain the sentence "This product contains genetically modified organisms."
5) The food and food ingredients originating from GMOs but not containing them must have a visible indication that they originate from GMOs.
The requirements regarding the declaration of novel food shall be provided for by an enforced regulation by the Minister of Health in accordance with the Minister of Agriculture and Forestry.
Declaration and Indication of Feed Containing or Consisting of GMOs
Article 86
1) Feed and feed ingredients containing or consisting of GMOs marketed in the Republic of Croatia, among the general declaration or indication requirements from Article 52 of this Act must contain on the declaration, packaging and accompanying documentation a visible indication that it contains or consists of GMOs and which GMO or its contents it contains.
2) The indication must clearly state the following" this product contains a genetically modified organism."
3) More detailed requirements regarding feed and feed ingredients declaration containing or consisting of GMOs shall be provided for by an enforced regulation by the Minister of Agriculture and Forestry.

The specific regulation with requirements for the declaration for novel foods/feed is still nonexistent, so nobody labels their product as such. However, products have been withdrawn from the market if it was established that they contain biotech components that were not labeled. However, companies would be reluctant to label anyway because of a possible consumer boycott. Therefore, they will rather avoid manufacturing products that contain biotech components.
Labeling requirements were established by different legislation and for many reasons including consumer health/safety concerns and consumers' right to know. (GAIN report N. HR4006 2004)

3.1.4 Co-existence

The GMO Law forbids planting of biotechnology crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco tourism, and in protected areas (i.e. as defined as protection impact zones with previously enlisted zones). In addition, biotech crop plantings for reproduction are allowed only in areas that are suggested by the Ministries of Agriculture and Culture and approved by the Croatian Government in a special ordinance.

3.2 The former Yugoslav Republic of Macedonia

3.2.1 Status of GMO planting and trade in Macedonia

There are no commercial plantings of GM crops in Macedonia.

3.2.2 Legislative framework on modern biotechnology (GMOs)

Republic of Macedonia is in the initial phase of establishing the statutory and administrative system that will regulate the mechanism for decision making for safety transport, handling and use of GMOs. Although Macedonia is a Party to the Cartagena Protocol on Biosafety, there is no Law for monitoring and GMO inspection of food, feed and seed, for deliberate release and their placing on the market. The need for the adjustment of the regulations regarding biosafety with EU regulations has provoked the initiation of drafting of a GMO Law. The draft GMO law will be based on already existing legislations in the agricultural and health sectors and will be harmonized with the horizontal legislation for the use of GMOs or GM products. The draft covers the contained use of GMOs, the deliberate release into the environment and the placing on the market of GMOs, as well as the transboundary movement and will transpose Directives 90/219 EEC, 98/81/EC; 2001/18/EC and Cartagena Protocol on Biosafety.

The draft Law will not cover pharmaceutical products, which are regulated by the Law for medicines and medical tools (Ministry of Health); the food and the alimentary ingredients-regulated by the Law for safety of food and products that are in contact with food (Ministry of Health); and transportation – regulated with the decision for accession of republic of Macedonia to the European settlement for international transport of dangerous substances in passenger traffic (ministry of transport and connections).

At present, the Law on Food Safety and Safety of products and Materials in Contact with food (Official Gazette of RM No.54/02) contains some definitions with relation to GM foods that state:

“the food that contains or consists of GMOs, produced by GMOs, is called food produced by innovative technologies and is not available for public use yet.”

and

“the food of plant origin and plant food products whose seed material was genetically inserted is considered as unsafe food, and its production and trade is prohibited”.

The latter sets actually moratorium on the use of GM food in Macedonia.

The laboratory of Biochemistry and Molecular Biology at the University St. st. Cyril and Methodius, Skopje has the capacity to perform PCR based, both qualitative and quantitative, GMO testing.

Co-existence

No rules for co-existence have been adopted so far, since there are no plantings or trade with GMOs or GM products in the country.

3.3 Turkey

Turkey does not currently produce biotechnology crops. No new crops are expected to be introduced for cultivation in the near future, since the biosafety regulations will need to be passed before applications for field crop trials will be accepted. Between 1998 and 2000, there were limited field trials of corn, cotton and potatoes. After 2000, trials were halted on the basis that there was inadequate legislation to regulate the technology, and the Government of Turkey has not released any results from those field trials.

All policy related to agricultural biotechnology is coordinated by the Ministry of Agriculture and Rural Affairs (MARA). Since MARA has been given authority over biotechnology, there is little or no participation from the Ministry of Health or Environment outside of previously existing interagency biosafety committees. Within MARA, the General Directorate of Research and Development (TAGEM) has had primary responsibility for participation in the Biosafety Protocol meetings and workshops and the drafting of the biosafety regulations. As a result, bureaucratic expertise in the field of agricultural biotechnology is quite limited.

The review of the draft Biosafety Law has slowed somewhat due to the appointment of the new Minister. Previously, the Ministry of Agriculture has sent the draft Law to all related ministries, universities, and organizations for their comments. Comments have been submitted, however the steering committee appears to be disbanded with the appointment of the new Minister of Agriculture. Once the draft law leaves the Ministry of Agriculture, it will be sent to the Prime Ministry to be sent to the Parliament. At the parliament, several committees, including agricultural committee and health committee, will review the draft and make changes, if needed. After completion of the work with these committees, the law will be sent to the General Assembly of the Parliament and wait for its turn to be discussed and adopted.

Even though the desired time for the law to be adopted is by the end of the year, many sources do not believe that this can be accomplished. In order to implement the law, (which is a framework law), the GOT will need to prepare and publish related regulations within the following twelve-month period after it is adopted and published in the Official Gazette. Thus, the implementation does not seem possible before 2008.

Technically, there is currently no legislation regulating the import of agricultural biotech products for food, processing or feed. In other words, there are no restrictions. That said, there have been problems importing products that have been labeled ‘as containing GMOs’.

There are no labeling requirements for foods or feeds, however, if it is labeled, it will likely be rejected at customs on the basis that a lack of regulations on biotech products is grounds for refusing them. No products are approved for release in the environment (planting) since the regulations permitting field trials were withdrawn in 2000 (GAIN report, Turkey 2005)

4 NIS countries representatives – Russia and Ukraine

4.1 Russia

4.1.1 Status of GMO planting and trade in Russia

At present Russia officially does not produce any biotechnology crop commercially. Only two biotechnology potato varieties, Bt potato Russet Burbank NL (Monsanto) and Bt potato Superior NL (Monsanto), have undergone all field tests, including tests on biosafety, and received the biosafety registration in 2002 for 5 years. However, obstacles from legislative and administrative origin (Article 50 "Protection of Environment from Negative Biological Impact" of the Federal Law on the Protection of Environment, 2002; restructuring in the Ministry of Agriculture) these two biotech potato varieties have not been included in the Register and cannot be used commercially. The biosafety registration of these varieties expires in 2007.

Approvals for food and feed use of imported varieties and products

Crop	Applicant	Year and period of registration		
		For Food Use	For Feed Use	Biosafety approval
Bt potato Russet Burbank NL	Monsanto	2002, ext. 2003 - 2008		2002-2007
Bt Potato Superior NL	Monsanto	2002, ext. 2003 - 2008		2002-2007
Roundup Ready® corn GA 21	Monsanto	2000, ext. 2004 - 2009	2003 -2008	
Bt corn	Monsanto	2000,	2003 -2008	
MON 810		ext. 2003 -2008		
Roundup Ready® corn	Monsanto	2002 – 2007	2003 -2008	
NK 603				
Bt corn	Monsanto	2003 -2008	2003 -2008	
MON 863				
Corn Bt 11	Syngenta Seeds	2003 -2008		
Glyphosate-resistant,	S.A.			
Insect Resistant				
LL Corn T25	Bayer Crop Science	2001 -2007	Submitted	
Glyphosate-resistant			2004,	
			expected	
			2005	
Roundup Ready®	Monsanto	1999,	2003 -2008	
soybeans		ext. 2002 -2007		
40-3-2				
Liberty Link®	Bayer Crop	2002 -2007		
Soybeans A2704-12	Sciences			
Glyphosate-resistant				
Liberty Link®	Bayer Crop	2002 -2007		
Soybeans A5547-127,	Sciences			
Glyphosate-resistant				
Roundup Ready®	Monsanto/Syngenta	2001 -2006		

sugar beet #77				
Sugar derived from	Monsanto/Syngenta	2001 -2006		
Roundup Ready®				
sugar beet #77				
Rice LL62,	Bayer Crop	2003 -2008		

4.1.2 Legislative framework on modern biotechnology (GMOs)

By 2002 Russia had adopted several laws that directly and indirectly influence agricultural biotechnology, including the framework Law "On Sanitary and Epidemiological Well-Being of the Population" of 1999 as amended in 2001, 2003 and 2004; the Federal Law "On the State Regulation in the Sphere of Genetic Engineering Activities "and the Federal Law "On Protection of the Environment". These laws did not specify the criteria, methods and directions of development of agricultural and food biotechnology.

The regulatory basis for testing, examining and registration of GMO events, food products and feeds was developed based on these laws by different ministries and was put in force by a number of resolutions of the Russian Government and by ministerial decrees issued by 2003. However, in 2003 - 2004 the following drastic legislative changes actually stopped for more than a year any further development of agricultural biotechnology in Russia. First, the government administrative reform of 2004 liquidated all previously existing registration bodies, and along with reorganization of all ministries and agencies their previous orders and regulations lost force.

Second, the Federal "Law on Technical Regulation" of December 2002, which went into force in July 2003, revised principles of standardization, and mandated that in 10 years Russian safety requirements, would be adjusted to international patterns. Instead of numerous standards a few basic technical regulations should regulate and guarantee the safety of humans, animals, and the environment in Russia. The process of drafting basic technical regulations started in 2004 and will continue through 2007. (GAIN report Russian Federation Report 2004)

In November 2004 the government of the Russian Federation approved a program of development of technical regulations. Of the total seventy-four technical regulations that will create the framework for safety of humans, animals and environment in Russia, two concern biotech crops: "Requirements for the Biological Safety and Harmlessness of Genetically Modified Plants" and "Requirements for the safety of food products that have been produced from raw materials that are from genetically modified plants or animals". The federal bodies participating in the development of the draft are the Ministry of Agriculture, Ministry of Health and Social Development, and Ministry of Industry and Energy.

The Interagency Commission for Genetic Engineering is the main policymaking and regulatory body for genetic engineering in Russia. The Minister of Education and Science serves as chair.

The Commission will participate in the development of government policy for genetic engineering and biotechnology, will coordinate government regulatory activity in the field of genetic engineering and biotechnology, and will "coordinate issues of implementation and further development of the licensing-and-information system for genetic engineering and biotechnology including the issues related to the improvement of Russian law for biotechnology and development of scientific bases for the assessment and management of potential risks related to biotechnology".

The commission does not approve or register new biotech events, but develops strategy and policy for registration and in this sense remains the main decision making and permitting body on biotechnology in the Russian Federation.

If the authorities of the Interagency Commission remain the same as its predecessor's, then all initiatives and undertakings in the field of bioengineering in the Russian Federation, starting from imports of samples for field trials, and extending to laboratory testing and registration of events and products, will be authorized by the commission in writing with the signature of its several members, with the authorization prepared based on the minutes of the meetings of the Commission. These authorities are not specified in the commission's bylaws, but are implied.

Registration for Food Use
All imported food products may contain only registered biotech events. On July 1, 1999 the Russian Ministry of Health implemented a regulation outlining the procedures required to register food products derived from genetically modified sources. It applies to all foodstuffs sold through retail chains, whether imported or produced domestically. In the previous Government the Ministry of Health was responsible for registration of events and biotechnology products for food consumption. Food safety (food risk assessment) tests of these events and products (separately) were conducted in the Nutrition Institute of the Academy of Medical Sciences, with results going through the office of the Chief Sanitary Physician of the Russian Federation for his approval before the event or product was finally registered and approved by the Ministry of Health.

The new system remains almost identical – the new events and products undergo food risk assessment tests and are examined in the Institute of Nutrition, but approval and registration is now given directly by the new service, Rospotrebnadzor, headed by the Chief Sanitary Physician of the Russian Federation. The general registration procedures require interested parties to submit an application accompanied by required, supporting scientific documentation and samples. Review of the data and samples will determine if further testing is required or if a registration certificate can be issued based on the submitted information. All data and technical information must be submitted in the Russian language.

Registration is initially valid for three years, but renewals may be issued for five years. Under the supervision of the Chief Sanitary Physician of the Russian Federation, a system of monitoring of food products in the trade system has been developed in order to detect biotechnology events. In June-September 2002, the first attempt to monitor content of products of biotechnology in food products were made in Moscow. Since that time, more examinations have been conducted to make sure only properly registered products are on grocery store shelves.

Registration for Feed Use
Registration for feed use has been discontinued along with liquidation of the Expert Council for this registration at the Ministry of Agriculture in the course of administrative reform.

The procedure for registration is likely to be the same as before: the applicant will submit the same package of materials as for the food registration, then after everything is examined the event and product will be approved for feed use, and a registration certificate issued.

Registering lines of genetically modified whole grains and oilseeds (corn and soybeans) for feed has been a much more difficult process than registering of meal, because a Biosafety Certificate from the Ministry of Industry, Science and Technology was required as both corn

and soybeans “remain reproductive”. It is not quite clear what the new procedure for registration of GMO feeds and GMO grain for feed will be.

4.1.3 Policy on Co-existence

There are no commercialized biotechnology crops in Russia. Tests are done on the isolated and strictly controlled fields in the research institutes. On sample plots in these institutes and laboratories researchers are studying co-existence, but this is all at the laboratory level. One of the arguments of opponents of biotech crops is that in Russia it is not possible (or will be too expensive) to provide for necessary isolation of GMO and non-GMO crops.

4.1.4 Labeling and traceability

At the end of 2004 the Russian Federation Committee on Standards and Metrology published standards to be used for food labeling in Russia (National Standard of the Russian Federation GOST R 51074-2003 “Food Products. Information for Consumers. General requirements,” 2004). These labeling standards apply to both domestically produced and imported food products, and are presumed to have gone into effect officially on July 1, 2005. Many food processing companies have announced that they started using these standards in January 2005.

The requirement for labeling products of biotechnology is one of most controversial in the new standard. The standard stipulates, “Information on genetically modified food products, food products manufactured of genetically modified products, or food products containing components from genetically modified sources is mandatory. For food products containing components from genetically modified sources, the information is indicated if content of such components is higher than the rate set by a regulatory legal act (technical regulations). Consumer information on food products manufactured of genetically modified sources or containing genetically modified sources shall be stated on the label in the form of the following inscriptions: ‘genetically modified … (product name) …,’ or ‘… (product name) manufactured of genetically modified sources’, or ‘… (product name) contains ingredients manufactured of genetically modified sources’. Information on use of genetically modified sources shall not be stated for products that do not contain protein (DNA) obtained from genetically modified sources.”

On December 20, 2004, Russian President signed “Amendments to the Law of the Russian Federation “On Protection of Consumer Rights”. The new edition of the Law adds “information on the presence in food products of components from genetically modified sources” to the mandatory information about the main consumer characteristics of food products. In accordance with the new edition of the Federal Law “On Protection of Consumer Rights”, the information about any commodity (work, service) shall start with the “Name of technical regulation or name of other document certifying the conformity of commodity in accordance with the law of the Russian Federation on technical regulation” (Article 10 “Information about commodities (works, services)", item 2). Unfortunately, however, the regulatory act (technical regulation) setting the threshold for declaring presence of genetically modified sources in food products has not yet developed. In the meantime, the Chief Sanitary Physician of the Russian Federation decreased the threshold from nonlabeled presence of biotechnology-based raw material in food products from 5 percent to 0.9 percent by his Order of April 6, 2004. The Order was not registered by the Russian Ministry of Justice, and does not have force outside the authority of the agency of the Chief Sanitary Physician, which is now the “Federal Service for Surveillance in the Sphere of Protection of Consumers’ Rights and Well-being of People” (Rospotrebnadzor) at the Ministry of Health and Social Development.

In addition, testing procedures have not yet been validated, except of two methods. Trade in soybean products was affected most of all by these decisions. Corn and soybean traders believe that if the 0.9 percent GMO labeling requirement is included in the technical regulation, all food products processed from imported corn and soybeans will have to be labeled. Given the present anti- GMO publicity campaign of Greenpeace and other "eNGOs, this labeling will affect competitiveness of products of and thus affects the most transparent (i.e., law-abiding) food producers.

The 0.9 labeling threshold for GMO content remains in the draft of the technical regulation "Requirements for the safety of food products that have been produced from raw materials that are from genetically modified plants or animals". In part this is motivated by a desire to harmonize with European Union regulations in the belief that Russian can become an exporter of "organic" foods to the European Union.
Consumer labeling of feed is not required.

Russia has not signed or ratified the Biosafety Protocol. The Russian Customs Service is not aware of and does not require any document on the conformity of the shipped samples with the Biosafety Protocol.

Attitude of the public towards the products of agricultural biotechnology
The Russian consumer is presently aware of agricultural biotechnology, and largely in a negative light due to a combination of widespread yellow journalism and fear campaigns orchestrated by scaremongering anti-biotechnology NGOs. As a result the imposition of labeling requirements, particularly of products, which may have an adventitious presence, is causing some retailers and many processors to shy away from products and ingredients that may contain products of biotechnology.

Moscow, the biggest consumer market in Russia, has been affected by these fears to the greatest extent, as "organic food" finds more and more supporters among the richest strata of Moscow citizens, who determine the Moscow food market preferences. Several sausage processors heavily dependent on extenders have begun to advertise their products as "GMOfree" in order to attract customers. The Moscow City Government also pursues an anti-biotechnology policy, and in March 2005 established the Coordination Council on Safety of Food Products Derived from GMO, significantly influenced by the NGO "National Association for Genetic Safety," and gave this Council the authority to monitor presence of GMO in food products. The National Association for Genetic Safety, although it does not have any legal authority, goes as far as calling for criminal liability for those producers who voluntary or involuntary mask the presence of GMO in their food products.

Provincial politicians have also warned their citizens to avoid U.S. products, including U.S. poultry mean, which they claim are "carriers" of genetically modified material since the birds are fed meal from bioengineered soybeans and corn. Belgorod oblast Governor Yevgeniy Savchenko has declared his province a GMO-free zone and publicly vowed to prohibit application of agricultural biotechnology there, while calling for a total ban on imports of products of biotechnology.

At the regulatory level, the inability for all practical purposes to register seeds for planting of biotechnology varieties has closed the market to seeds of bioengineered strains (GAIN report Russian Federation 2005)
.

4.2. Ukraine

4.1.5 Status of GMO planting and trade in Ukraine

Ukraine has a number of biotechnology policy issues that impact trade. Lack of legislation that would establish a biosafety regulatory framework hinders registration of biotech crops and it also impacts the development of traceability and co-existence policies in the country. Unclear food labeling regulations for genetically modified organisms and the great degree of latitude exercised by various regulatory officials at the border are also a part of the problem. Uncertainty over implementation of the Cartagena Protocol would discourage imports of bulk agricultural commodities.

The Ukrainian government (GOU) authorized field trials of biotech crops along with an environmental and food safety assessment in 1998. Insect resistant (Bt) potatoes and herbicide tolerant sugar beets, corn and rapeseed underwent full-scale field trials in 1998-2000. None have received final approval since Ukraine has no system in place for approving GM crop varieties. There have been no new applications for registration of biotech crops since then because of uncertainty over the length of the approval process and uncertainty over the final result. So far Ukraine has no functional biosafety regulatory framework. Draft legislation that would delegate regulatory authority to relevant GOU agencies has been pending final approval by the Ukrainian Parliament since November 2002.

Genetically Modified Crops That Went Through Field Trials in Ukraine

Trait	Crop	Number of varieties	Applicant	Year of application	Status
BT (insect resistance)	Potatoes	3	Monsanto	1997	Pending
Glyphosinate tolerance (Liberty Link)	Sugar beets	1	Syngenta/ Monsanto	1998	Pending
BT (insect resistance)	Corn	1	Syngenta	1998	Pending
Glyphosinate tolerance (Liberty Link)	Rapeseed	1	Bayer	1998	N/A
Glyphosate tolerance (Roundup)	Corn	1	Monsanto	1998	Pending

Ukraine has not approved a single biotechnology crop for commercial production despite having received five applications in 1997-1999. Therefore, authorities claim that Ukraine's agriculture remains GMO-free. A weak regulatory system, the lack of field surveillance programs and laboratory capacities, however, leave doubt to Ukraine's GMO free status.

The Ukrainian Veterinary Service tried to use the issue of "genetically modified feeds" used in poultry feed in the United States as a reason to block trade in poultry meat in 2002. This issue was discussed and eliminated during negotiations between the USDA and the State Department of Veterinary Medicine of the Ministry of Agricultural Policy of Ukraine in March 2003.

In September 2000, a joint order from the Ministry of Agricultural Policy of Ukraine and the Ukrainian Academy of Agricultural Sciences (UAAS) prohibited the importation of honey and bee products that were byproducts of “bees fed with GMO-containing feeds”. Although scientific justifications that support this measure do not exist, the order remains in effect.
This order points to one of the major weaknesses of the Ukrainian regulatory system – involvement of non-regulatory agencies in the decision making process.

Ukraine imported products valued at 29 million euros in 2005 that could contain GMOs.
The first three largest suppliers of these products are Brazil, the Netherlands, and United States respectively.

4.1.6 Legislative framework on modern biotechnology (GMOs)

Ukraine is in the process of developing its national biosafety regulatory system. Currently, there is no legislation in place to regulate environmental, food or feed safety assessments of GMOs. The country, however, developed legislation to require GMO food labeling, signed the Cartagena protocol and has provisional procedures for biotech crop registration.
In response to the first application to register a biotech crop, the Cabinet of Ministers of Ukraine approved provisional procedures for testing GM crops in 1998 and authorized the State Service on Protection of Plant Variety Rights under the Ministry of Agricultural Policy of Ukraine to coordinate this process. The Interagency Biosafety Commission under the Ministry of Science and Education of Ukraine reviewed the initial application from the companies and conducted an environmental risk assessment. Five GM crops underwent field trials in 1997-2000 and although having received positive risk assessment, non was commercialized due to political reasons.

The current regulatory process for approval of biotech crops in Ukraine is very cumbersome. It is based on mandatory registration procedures designed for conventional plant varieties. However, a GM plant variety is required to go through a more rigid registration process than a conventional variety.

The Draft Law of Ukraine “On the State Biosafety System for Developing, Testing and Usage of Genetically Modified Organisms”, which was prepared to address the legislative vacuum, passed the first reading in the Ukrainian Parliament in November 2002. The Law has been pending final approval by Parliament since then. According to the proposed legislation, regulatory responsibilities will be divided amongst the Ministries of Education and Science (MES), Environment and Natural Resources (MENR), Health Care (MHC), Agricultural Policy (MAP) and a special regulatory agency - Interagency Commission on Biosafety (ICB). Once the law is adopted, these regulatory agencies will develop implementing regulations.

Ukraine has not approved any GM crop for food, processing or feed as there are no applicable regulations governing food or feed safety assessment of GMOs.

Ukraine ratified the Protocol on Biosafety to the Convention on Biological Diversity on September 12, 2002 (the Cartagena Protocol). Ratification of the Protocol has not resulted in the development and implementation of a comprehensive biotechnology regulatory framework in Ukraine. The Ministry of Environment and Nature Protection of Ukraine is expected to take the lead in the implementation of the Cartagena Protocol. The Ministry has undergone several reorganizations in the past few years. Diverging interests from other GOU agencies have also been a stumbling block to the development and implementation of Biosafety Legislation. It is unclear, at this point, how the new Ukrainian government will implement the requirements of the Protocol.

It is not yet clear how the Ukrainian regulatory system will treat “stacked” biotechnology events (plants that combine two already approved traits, such as herbicide tolerance and insect resistance). The biotech event will require only one registration with the Interagency Biosafety Commission in accordance with the yet-to-be-approved draft biosafety legislation.
However, agricultural authorities in charge of plant variety rights protection will most likely require a separate registration for each new variety that contains a new trait. (GAIN report Ukraine 2005)

4.2.1. Co-existence

The domestic organic farming industry is just beginning to develop; therefore, there are no official or industry organic standards at this point. Some Ukrainian farms were certified as organic by EU-based institutions. Peaceful coexistence between organic and biotech crops in Ukraine is unlikely. Organic soybean producers in Ukraine have already called for a ban on GM crop plantings.

4.2.2. Labeling

While there are no labeling requirements applicable to GM feed stuffs, Ukraine’s current GMO labeling rules represent one of the major uncertainties for food importers. Food products that contain GMOs were not regulated prior to October 24, 2002, the date when the Parliament of Ukraine incorporated changes into the Law of Ukraine On Food Safety. The legislation included food products that contain “genetically modified components” to the category of new food products along with newly developed foods, products that have not been imported before, products that contain new components/ingredients and products that were produced using new technology. A separate line on the presence of GMOs in food products was included to the list of mandatory information to be provided on the label. It appears that any quantity of GMOs must be labeled according to the Law.
This legislation was adopted to reflect the consumers’ “right to know” because the GOU does not conduct food safety risk assessments for GMOs at this point. The current labeling legislation is unclear on label language, placement or threshold. The implementing regulations entitled “On Approving Rules of Retail Trade in Food Products” adapted by the Ministry of Economy of Ukraine on July 23, 2003 did not clarify these issues. The regulations simply prohibited the sale of domestically produced and imported consumer packaged food products that do not have an “easy to comprehend” label. Unofficial tests of consumer–ready products conducted by Ukrainian labs revealed a presence of GM components in some products readily offered for sale in Ukraine. So far, the domestic food industry and food importers are not labeling GM products due to the lack of clarity in the requirements (GAIN report Ukraine 2006).
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5. Western Balkan countries – Serbia and Bosnia and Herzegovina

5.1. Serbia

5.1.1. Status of GMO planting and trade in Serbia

Serbia currently does not produce any biotechnology crops for commercial use.
The 2001 Federal Law on GMO currently applied at the Republic's level in Serbia is allowing research and commercial use of biotech products under a strict supervision of the state. Permits for research work, contained use and marketing of GMO materials can be obtained by meeting the state regulatory requirements.

At present, the only application approved in Serbia is for commercial import of soybean meal produced from Roundup Ready (RR) soybeans. RR soybeans for crushing or other commercial use are not allowed for import. Serbia has a constant deficit of soybean meal and annually imports around 120,000 MT of soybean meal, mostly from Argentina and Brazil. No other biotechnology crops or products have been approved in Serbia. At border posts, official inspectors carry out surveillance for possible introductions of GM crops and products. In 2003, the Ministry of Agriculture identified and destroyed approximately 1,000 individual plots of transgenic (i.e., glyphosate tolerant) soybeans, which were illegally imported and sowed at local farms.

5.1.2. Legislative framework on modern biotechnology (GMOs)

Serbia and Montenegro apply the same Law on Genetically Modified Organisms adopted in 2001 in addition to five rulebooks issued in 2002 and 2003. The implementation of the law has been designed to follow the regulations of the European Union and is in accordance with EU directives 90/220 and 90/219. These five rulebooks are:

- Rulebook on "Commercial release of 'GMOs' or products derived from GMO crops", No.1245/1 issued November 13, 2002
- Rulebook on "Contained use of genetically modified organisms", No.1244/1 issued November 13, 2002
- Rulebook on "Deliberate release of biotech products into the environment", No.1246/1 issued November 13, 2002
- Rulebook on "Regulation on the content and data of products derived from GMOs", No. 1669/1 issued December 15, 2002
- Rulebook on "Labeling of genetically modified products", No.16/18 issued February 27, 2003

Serbian officials are currently working on revising the existing law and rulebooks on GMO.
The current law will be expanded, while the number of rulebooks will be increased and will be written in accordance with EU Regulations EC 1829/2003, 1830/2003, 1946/2003 for regulating the labeling, traceability and trade of GMO products and products derived from GMOs.

5.1.3. Traceability and Labeling

Currently, Serbia is not implementing any traceability system for the products of agricultural biotechnology, but a new rulebook on traceability will be in accordance with EU Regulation 1829/2003 and 1830/2003. The lack of resources is the main factor holding Serbia back from full implementation such a traceability system.

Labeling of food products is currently the responsibility of the Republic's Ministry of Health in Serbia. In February 2003, labeling regulations were issued by the Federal Ministry of Internal

Trade and Economy but were never enforced due to the lack of authority and staff. The Federal Ministry of Internal Trade and Economy was abolished at the end of 2003. According to labeling regulations, all retail food labels on products with GMO content (0.9 percent minimum) must include a yellow triangle, framed with a red border and containing the English letters “GMO” (in black). A new rulebook on labeling is expected to be in accordance with EU Regulation 1829/2003 and 1830/2003. The main purpose of the new labeling regulation is fully to inform consumers about the product GMO contents and leave them the choice to decide.

There are some provisions with regard to the handling and transport of GMOs as a part of the traceability system in the rulebook on “Contained use of genetically modified organisms”.
“ The packages used for keeping and transportation must satisfy the following requirements:
- It is safe from uncontrolled GMO release (emission);
- All constituent parts of the packaging must comply with manipulation requirements, and that they cannot be damaged in transportation;
- Labeling must provide the following data: name and address of the producer, or a representative of the foreign producer, including logo, contents of the packaging, name, date of production, and expiry date, with a clearly visible label "genetically modified organism".

Destroying empty packaging used for holding a GMO shall be carried out by the end user, by known physical and chemical means”.

Imports of soybeans, soy meal and corn (and byproducts) are tested for biotech content at the border. Republic border inspectors sample every shipment and these samples are sent to one of three authorized laboratories for testing: Institute for Molecular Biology and Genetic Engineering (Belgrade), Corn Research Institute in Zemun Polje (Belgrade) and the Institute for Field and Vegetable Crops (Novi Sad). Detection of genetic modifications is PCR based.

Some Serbian soybeans crushing plants have entered long-term contracts with EU buyers to export non-GMO soybeans and products. This is the main reason why Serbia has a very strict field control system in order to prevent any illegal planting of GM seeds and preserve its image as a non-GMO crop producer. Serbian officials are likely to follow the EU lead in most GMO issues, thus any future market development for biotech events will mainly depend, to large extent, on EU decisions on growing and trading of transgenic crops (GAIN report N. Serbia 2005).

5.2. Bosnia and Herzegovina

There are no GM crops that have been approved for food, processing, and feed; no field-testing of biotechnology crops; and no policy on coexistence for GM and non-GM crops (including organic agriculture).

There is no specific law that addresses the production of GMO crops in the country yet. The Law on Seeds and Seedlings (Official Gazette # 3/05) only mentions that biotech seeds and seedlings have to be labeled, while all other products are to be regulated by a separate law on GMO products that does not yet exist.

The new Food Law adopted in November 2004 (Official Gazette # 50/04) generally regulates import and marketing of biotech food products. According to the law provisions, GM food products are considered “novel foods” and are mentioned as the following categories:

- Food and food ingredients which contain genetically modified organisms or are composed of such and

- Food and food ingredients, excluding food additives (aromas and enzymes), produced from the GMO, but which do not contain any GMOs;

According to the provisions of this Law, to market any novel food for the first time in Bosnia and Herzegovina, the applicant must obtain a permit from the B&H Food Agency, based on previously obtained scientific opinions and approvals of relevant bodies (most likely the Entity agricultural ministries and institutes, the Entity ministries of health and trade and the State Veterinary Office, depending on product type). The Council of Ministers, based on the suggestion of the Food Agency, shall, within the period of 18 months following the day of entering into force of this Law, adopt the regulations pursuant to the import and marketing of novel foods/GMOs (GAIN report Bosnia-Hercegovina 2003).

The permits for placing novel foods on the market and feed containing or consisting of GM products shall not be issued until the adoption of the implementing regulations, meaning that the import and marketing of biotech foods in Bosnia and Herzegovina is forbidden until regulations are put in place. The Food Law also does not regulate the labeling of GM products, and it will be most likely set by the regulations that will follow. Since the policy of the country is oriented towards accession to the EU in the near future, it is expected that the country will follow the EU guidelines in drafting those implementing regulations. The Food Law also regulates the prohibition of novel food marketing if there are any scientific discrepancies regarding the harmful effect of novel foods on people's health, especially food and food ingredients containing genetically modified organisms or consisting of them (that is, if based on a scientific risk assessment, a product is established as harmful to the health, and in the case of lacking relevant scientific information and knowledge about the possible extent of the negative consequences to human life and health, the product is deemed harmful).

The Law on Consumers protection (Official Gazette #17/02) that was adopted in June 2002 but not fully implemented yet states that biotech products have to be labeled.
However, it does not go into details (the Entity Ministries of Trade are responsible for labeling issues).

The main political factor that influences regulatory decisions related to the agricultural biotechnology is the country's goal to join the European Union integration. In 2003, the European Commission (EC) approved a feasibility study assessing the readiness of Bosnia and Herzegovina to begin negotiations for a Stabilization and Association Agreement (SAA) on the condition that the country makes significant progress in some priority areas, one of which was food safety. As a result, the country has been continuously adopting laws and regulations in line with those of the EU. So far significant progress has been made, but progress to date is insufficient to start with a SAA (GAIN Bosnia-Hercegovina 2006).

Bosnia and Herzegovina is not a party to the Cartagena Protocol on Biosafety.

6. Final remarks and conclusions

As a general observation, it should be recognized that the studied countries are at very different stage of implementation of traceability and co-existence measures and systems, as they have different approaches to the regulation of GMOs and implementation of respective international treaties, e.g. Cartagena protocol on Biosafety under the Convention of Biological Diversity (CBD).

There is a great variation in terms of experience with GMO plantings and use as imports among the nine studied countries in Europe. While Turkey, Croatia, Macedonia and Bosnia and Herzegovina have neither commercial plantings, field trials or approvals for imports as food and feed, Russia and Serbia have approved event/s for imports but not for commercial cultivation. No biotechnology crops were approved for placing in the market in Bulgaria and Ukraine, although there were multiyear-large field trials with GM maize (Bulgaria), and GM oilseed rape, maize and potato (Ukraine). In contrast with all other studied countries in the region, Romania has largest experience with the use of GM soybean as commercial cultivation since 2000. With its 0,1 million ha of herbicide tolerant GM soybean in 2006, Romania is among the largest GM producers in Europe (together with Spain). Since 2007, after the country's accession to EU, the cultivation of RR soybean is forbidden as non-approved for the EU market.

The legislative system to regulate GMOs and GM food and feed in the countries, included in the report also shows variability, mostly depending on the political orientation of the country towards accession to EU or/and binding to international treaties (Cartagena protocol on Biosafety).

The EU accession process acted as powerful enhancer to the new Member States (Bulgaria and Romania) and in a lower degree Croatia, to harmonize their legislation with the relevant EU regulations and directives on deliberate release and placing on the market of GMOs, GM food and feed regulations, labelling and traceability and transboundary movement of GMOs.

It is likely that Turkey, Macedonia and to certain extent Ukraine and Bosnia and Herzegovina would follow the EU legislative model although for the moment they prefer to postpone the enforcement of a domestic legislation. All these countries however, except Bosnia and Herzegovina, are also Parties to the Cartagena Protocol on Biosafety and in case of transboundary movement they can apply the procedures foreseen under the Protocol.

The regulatory system for GMOs and GM food and feed in Russia differs from the EU model. The approval of GMOs is based on a registration of the GM event after safety assessment by the National Nutrition Institute. The Federal Law on GMOs however, is too general and for its implementation needs to be clarified by ordinances, which are in a draft stage.

Five of the nine studied countries, namely Bulgaria, Croatia, Romania, Russia and Serbia have developed and enacted GMO legislation, from which only one is functioning (Romania). The GMO Acts in Croatia and, especially, Bulgaria are very restrictive to extent, which would not allow co-existence of GM and organic crops. For the period of drafting its GMO Act, Macedonia has put a ban on the use of GMOs in the country.

Co-existence, although discussed by the community at large in the studied countries, is not a subject of legal regulation. Most of the countries, especially the new EU member states and the candidate countries announced their orientation towards the organic farming since they foresee a potential market niche on the EU market.

Although Romania has greater experience with large commercial plantings of GM crop (RR soybean), Bulgaria was the only studied country that has developed co-existence policy, based on practical approaches and taking into account the immediate and long term needs and priorities of the country ‘s agriculture.

All countries with GMO legislation in place have followed the EU model of mandatory labelling as a part of the traceability system, which, in most cases, implies a threshold of 0,9 % of adventitious presence of GMOs. There are some variations though, e.g. in Bulgaria this threshold is 0,5 % for GMOs and 0,9% of GM food- and feedstuffs. In some most of the countries there is 0% for the non-approved GM events (especially when non- approved in EU). In Russia and in Ukraine, although there is a legal requirement for labelling of GM food, there is a lack of secondary legislation, which would clarify the thresholds and other details. The both countries do not require labelling for GM feedstuffs.

Romania, as the only commercial grower of GMOs in the region has the unique expertise in implementing traceability measures in practice, e.g.:

-farmers to report the area and yield of GM seeds;
-companies to take record on every step of the placing on the market;
-stricter seed distribution record;
-the companies should declare the destination of the GM seeds along the chain before the import.

Some of these measures however, were difficult to implement and have met the strong objections from the distributor company’s side, who voiced their concerns that a planning for every potential sell of GM seeds is not realistic and puts barriers to the trade.

The other studied countries, sustain of experimenting with domestic models to ensure full traceability either because of lack of experience with placing on the market of GM products and thus, because there is no immediate need of traceability, or because the development of such models would bring unacceptable financial burden. It is likely that these countries are willing to follow a successful model, developed elsewhere (particularly in EU), if proven as such, and adapt it to their domestic conditions.

A general feature of the traceability system in the studied countries is the lack of experience, lack of holistic approach in building such a system, which implies enforcement problems. These problems, however, are not correlated with the capacity in the countries to perform analyses on the detection of GMOs, since the tests are often the end point of the enforcement of the traceability measures (incl. documentary traceability and involvement of different agencies and inspectorates).

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Annex **1**

	Romania	Bulgaria	Russia	Ukraine	Turkey	Croatia	Macedonia	Serbia	Bosnia and Herzegovina
Status of GMO planting, trade	0,1 million ha GM soybean in 2006	No commercialization, field trials with GM maize until 2004	No commercial plantings, field trials with GM soybean, maize, potato	No commercial plantings, field trials with GM oilseed rape, maize, potato	No commercial plantings, no field trials	No commercial plantings, no field trials	No commercial plantings, no field trials	RR soybean for feed allowed for import; no commercialization	No commercial plantings, no field trials
GMO domestic legislation	Yes, in line with EU	Yes, mostly in line with EU, with exception of bans on many of the GM crop species and for release in national protected areas and 30 km around them	Federal law enforced but too general	Draft law for discussions in the Parliament since 2002	draft	Yes, contains bans for deliberate release into environment in national protected areas	Draft, transposing 90/219/EEC98/81/EC, 2001/18EC	Federal law on GMOs enforced, decision for further harmonization with EU regulations and directives.	no
Secondary legislation (ordinances)	yes	yes	2 draft regulations	no	no	yes	no	yes	no

Co-existence policy	no	Yes, not completed	no	no	no	no	no	no	no
Labeling	Mandatory required over the threshold of 0,9 %	Mandatory required over the threshold of 0,9 % for GM foodstuffs and 0,5% for GMOs	Mandatory by law, excluding products thereof, threshold should be established in ordinance (status-draft); non-binding requirement of a threshold 0,9% since 2004. No labeling for feedstuffs.	Mandatory for foodstuffs, label and threshold – unclear (it may require labeling of any quantity of GMOs). No labeling for feedstuffs.	No labeling requirements since no law has been adopted; 0 % tolerance at the borders if the product is initially labeled.	Mandatory required over the threshold of 0,9 % for GM food- and feedstuffs if they were approved in EU. 0% for non-approved events in EU	Not yet	Mandatory required over the threshold of 0,9 %, not enforced	Mandatory labeling of GM seeds; mo threshold specified, labeling for GM foodstuffs envisaged
Traceability	In line with EU, additional obligations: -farmers to report the area and	In line with EU	Not implemented yet at federal level, some retailers promote	Not yet	Not yet	Declaration, packaging and accompanying documentation	Not yet	Not implemented yet	Not yet

	yield of GM seeds; - companies to take record on every step of the placing on the market; -stricter seed distribution record; -the companies should declare the destination of the GM seeds along the chain before the import		"GMO free" products			envisaged by law, details should be provided in an ordinance (not yet enforced)			
Cartagena Protocol status	party	party	Non party	party	party	party	party	party	Non party
GMO testing capacity	yes	yes	yes	yes	yes	yes	yes	yes	no