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Bulgaria: GMPs and the Law Become European

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Bulgaria joined the European Union on 1 January 2007. In 2004, following a parliamentary bill, the reaction by an NGO coalition led to the adoption of an Act that greatly shrank the scope of possibility for the introduction of commercial and experimental GMPs. But will this quasi-moratorium last much longer vis-à-vis the European Commission?

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The use of biotechnologies in agriculture in Bulgaria goes back to the early 1990s. Bulgaria was not yet under the thumb of European Community regulations and was a field of experimentation for seed companies. These latter relied on the national research laboratories, which were searching for new sources of funding after the fall of the Communist regime. Much of the information presented here consists of excerpts of interviews and of declarations by the administration or by researchers, upon which the organisations EcoSouthWest and ANPED later based their report *"Bulgaria: The Corporate European Playground for Genetically Engineered Food and Agriculture"* published in May 2000[1]. Given the confidential nature of the information related to GMPs before 2004, it was sometimes difficult for these NGOs to obtain official confirmations.

The 1990s: free rein in experiments

From 1991, a tobacco plant with genes for resistance to viruses and bacteria as well as a transgenic alfafa plant were being experimentally grown in Kostinbrod by the Institute of Genetic Engineering (IGE). In 1999, a GM potato resistant to potato beetles was field tested for the first time, on 30 ha in 2000, then on 3 hectares in 2001. Sunflower and tobacco crops were also found. According to the Eco-SouthWest report, several interviews and newspaper articles of that time mentioned trials of other crops, including Monsanto and Novartis herbicide-resistant wheat varieties, as well as a Monsanto Bt potato[2]. Nevertheless, the same report states that, according to the members of the Biosecurity Council of that time, only authorisations for experimental crops had been granted to Round Up-resistant maize of Monsanto and to Liberty Link maize of Pioneer, but not to the insect-resistant Bt varieties. In 2000, some Bulgarian scientists declared that the most convincing progress concerned tobacco and had to do with the characteristics of resistance to the *"mosaic virus"*, bacterial and fun-

The new reality of Bulgarian agriculture

In the 1990s, after the end of 40 years of Communist monopoly, Bulgarian agriculture went through a profound breakdown and a growing decline within the national economy. In 2004, this sector covered 11% of GDP and employed 25% of the working population[1]. In 2003, the agricultural land used represented 5,326,000 ha, or 48% of the country, including 60% arable land and nearly 8% temporarily non-cultivated[2]. Agriculture has become a sector based on individual property as well as on private cooperatives and private businesses: 98% of agricultural land now has the status of private property. About 770,000 farms manage 3.4 hectares, or about 4.4 ha per farm; however, these figures do not give a clear picture of a reality of extremes. Subsistence agriculture plays a buffer role in low salaries in the rural environment[3]. More than 1.5 million households (i.e., 51.5% Bulgarian households) cultivate land and raise livestock, on an average surface area of 0.64 ha. On the other side, a small number of individuals or cooperative businesses, mostly cereal producers, occupy the bulk of agricultural land.

At the same time, the sector of highly added value specialised productions (small fruits, medicinal and aromatic herbs, roses for making essential oil) is developing in order to better match an export market, and this in particular in organic farming.

1. www.mzgar.government.bg
2. www.mzgar.government.bg/MZ_eng/OfficialDocuments/Agry'_report/Agry_report_2004.htm
3. National Human Development Report 2003 - Rural Regions, Overcoming Development Disparities, UNDP, page 22

gal diseases, characteristics of resistance to extreme temperatures, and tolerance to herbicides and heavy metals. At that time, they declared that other GMPs had been perfected, including alfalfa, tomato, grapevine, barley, maize, potato, carnation, and apple[3].

Field trials were then authorised by the Council for the Safe Use of Genetically Modified Higher Plants, established on the basis of 1996 regulations[4]. Presided over by the Minister of Agriculture and an Executive Secretary, Prof. Atanassov – also Director of the IGE – this Council was, before 2004, in charge of issuing authorisations to field crops for commercial and research purposes. However, the registers containing the information on the authorisations granted and details about the GMPs put into question were considered highly confidential and were not made public. The Council could, independently of the government, grant authorisations for field trials, for commercial crops and for import and export of GM plants as well as of GM seeds and other plant material. Registration of GM crops was updated but remained and still remains unavailable to the public. Whoever belonged to this Council signed a confidentiality clause. Prof. Atanassov, a key figure in this institutional scene as secretary of this Council, simultaneously carried out work with Monsanto and Pioneer, within the IGE, of which he is still the director.

Mysterious commercial crops

With regards to commercial crops, from 1998 an official piece of information revealed that three companies - Monsanto, Pioneer and Novartis - had submitted an authorisation application to commercialise transgenic maize that was either tolerant to an herbicide (Round Up or Basta), or resistant to corn borer (maize Bt) or a combination of the two characteristics. Even if it has not been established whether these companies obtained these authorisations, we can suppose that it was the case, since the catalogues of the seed companies offered GM maize varieties from 1999 and 2000. The seed companies then signed contracts with local distributors that sold the seeds again directly to farmers. For example, during the seed production season of 2000, the seed distributor Panacea, in the Sevlievo region, had a contract with the firms Monsanto and Pioneer. The maize Roundup Ready was sold to farmers at 702 euros for a set containing about 450,000 seeds as well as 30 litres of Round Up. According to the dealer, there was no restriction regarding the quantity that the farmers could purchase and plant[5].

According to Svetla Nikolova of Agrolink, an organisation that promotes organic agriculture, the commercial authorisations granted at the end of the 1990s by the Council for the Safe Use of Genetically Modified Higher Plants to seed companies for the sale of seeds and GMP crops were conditional upon the companies undertaking to purchase and sell off productions abroad or to destroy the harvest, with no a guarantee of a written trace of this obligation. Furthermore, GM maize harvests were sold off for animal feed, as reported by EcoSouthWest and ANPED, following an interview with Mityu Mitev, a farmer at the cooperative farm *"ZPPK Edinstvo"* in Bogatevo, near Sevlievo. This latter states that he purchased Monsanto Roundup Ready maize seeds in 1999 from the distributor Panacea and planted them on 30 hectares, without any contract having been signed. The entire harvest was sold off as fodder in three ways: a third went back to the distributor to be resold, another third was used directly on the cooperative, and the last third was sold elsewhere.

But, from 1999 to 2003 and according to the official statistics, we can observe a decline in land cultivated with GM maize, dropping from 13,000 ha in 1999 to 2195 ha in 2003[6]. Several factors can explain this phenomenon, but commercial pressure may have played out the same way as for the Belgium company Amylum, based in Razgrad. Its European partners having refused to purchase starch produced from GM maize, this company had to review its policy of supply from producers. The same phenomenon occurred with tobacco crops, which are concentrated in the Rhodopes region. In 1997, Philip Morris,

The broad outlines of the 2005 Act

Authorisation for release in the environment

The Council for the Safe Use of Genetically Modified Higher Plants is replaced by an Advisory Commission on GMPs in charge of giving opinions on all the procedures for granting, modifying or withdrawing authorisations administered by the Ministries of the Environment (MEW) and of Agriculture (MAF). The petitioner must provide an assessment of the risks on the environment and on human health. The study must include a study on the effects of the GM crops on the biogeochemistry of soils and an assessment of the potentially allergy-causing or toxic elements of the GMP concerned. If the scientific results come to show noxious effects on the environment and/or on human health, emergency procedures would be set up quickly, with retroactive effect, for withdrawing the crops or products put on the market. The petitioner must provide a map of the farm, locating the experimental fields as well as the neighbouring crops and their nature. After reception of the Commission's opinion, public consultation and consultation of the MAF, the MEW accepts or rejects the authorisation request, within a period of 90 days after reception. For these two authorisation procedures, as well as for that concerning handling in closed environments, the Ministries are in charge of charging a tax when the authorisation request is registered, without specification as to the future use of these funds.

Commercialisation of products entirely or partially containing GMPs

For non-food GMPs, these authorisation requests are the responsibility of the MAF. The authorisation procedure is modelled on that of release into the environment. If a finished product contains more than 0.5% of GMPs, labelling indicating the presence of GMPs is mandatory. This threshold concerns all the commercial productions not covered by the Food Act and thus also applies to seeds and fodder. This Act thus concerns crops for commercial and research purposes, for putting on the market as well as for transport and for export and import of GMPs. After the Commission's opinions are given, the decision is up to the MEW and MAF only. The Act does not deal with GMPs after harvest, when it comes to products that are defined as food according to the Food Act.

For these *"food"* GMPs (human and animal food), this Food Act gives obligations for labelling for a quantity of transgenic products higher than 0.9%: *"special labelling must include [...] the quantity and nature of GMP the product contains [...]"* It also establishes a commission on new foods and GM foods in order to subject the foods stemming from GMPs to risk evaluation procedures and, if needs be, grants them an authorisation. The authorisations are valid 10 years and must appear in an Internet state gazette updated by the Ministry of Health.

Public information

The decisions of the Commission are made public. Public consultation is then held for a period of 45 days for the authorisations for field crops and for putting them on the market. The public can have access to a summary of the technical reports. The results of this consultation are published in one national daily newspaper and on the Internet. The Commission's decisions, the authorisation request procedures as well as the results of the risk evaluation studies and activities reports are also public. Authorisations for deliberate release, the installations where GMPs are stored, as well as the authorisations for handling in closed environment are made public in a registry maintained by the MEW. For deliberate release, maintaining a specific registry concerning the surfaces for which authorisations have been issued is mandatory. The authorisations for putting GM food products on the market are made public in a registry maintained by the MAF. This Ministry is also responsible for maintaining a public registry of the locations and surface areas of GM crops that have already received market authorisation. However, for all these registers (town, regional, etc.), the Act gives no detail on the precise localisation.

To read the Act:
www.infogm.org/article.php3?id_article=2134

British American Tobacco and Reemtsma threatened Bulgaria with termination of their purchases in the region if trials on GM tobacco continued[7]. Following these initial alerts, in June 2000 Parliament suspended its funding for GMP Research & Develoment on tobacco and grapevines, because of fears for the export market[8]. Yet, more recently, the Ambassador of the United States in Bulgaria did not hesitate, through his Department of Agriculture, to defend the Bulgarian GMP research laboratories. When the AgroBiotech Park, founded by the AgroBio Institute (the former IGE), opened in 2003, US Ambassador J. Pardew made a donation of 7736 euros and insisted on the support of the United States government for the development of genetic engineering in Bulgaria[9].

An Act based on the principle of precaution

Bulgaria thus had a Biosecurity Act from 1996. The aim was to give legal framework to the work of the national laboratories and to attract the seed companies, in order to freely develop commercial research. On 16 February 2004, a new Act on GMPs passed its first reading by Parliament. Drafted within the framework of a project funded by the UNEP-GEF and led by the AgroBio Institute laboratory to satisfy a joint order from State bodies and businesses including Monsanto and other biotechnology companies, this Act initially sought to give a clearer legislative framework to the activities of seed firms. Following the reaction of the NGO coalition *"GM-free Bulgaria"*, Parliament nevertheless introduced numerous amendments and gave new direction to the Act.

The new Act was published in the State Gazette on 29 March 2005[10]. In the end, its objective was to make it possible to put an end to uncontrolled GMP release in the environment and on the market. The Bulgarian Act has therefore established stricter authorisation procedures, with differentiation among contained use, experimental field trials, putting products entirely or partially containing GMPs on the market, and GMP transportation and cross-border movements. The first three categories are under the authority of the Ministry of the Environment and Water (MEW), whereas the latter is under the authority of the Ministry of Agriculture and Forests (MAF). The broad outline of the current Bulgarian Act dealing with the scientific evaluation of authorisation request applications, cultivation conditions as well as labelling and traceability rules are based on Directive 2001/18 (cf. boxed article, page 4).

The Bulgarian government has nevertheless introduced some specific features which are worth pointing out. With regards to the Commission, the members are qualified scientists from the Academy of Sciences in the fields of biology, ecology and agronomy, among others. Several representatives of Ministries are also invited to participate in the Commission sessions, but without voting rights. As representatives of civil society, only three representatives of ecologist organisations have been named members of the Commission: Agrolink, Za Zemiata and EcoSouthWest. No consumer organisation or ethical committee representative has been named.

Another characteristic specific to the country is the ban on several plant species when they are transgenic: tobacco, roses (intended for essential oil production), fruits and vegetables, cotton and wheat. In the eyes of European legislation, these prohibitions could be considered as a moratorium in principle, in opposition to the principle of free competition of Directive 2001/18 (Art. 22 and 23), stipulating that the States cannot stand in the way of the cultivation of a GMP without scientifically justifying an environmental or health risk. Roses, tobacco and wine are higher-added-value Bulgarian productions intended for export and whose brand image the government wants to protect.

The cultivation conditions also include major specific characteristics. For example, a buffer zone of 30 km free of GMP crops is mandatory around protected zones, within the framework of the National Ecological Network. Organic farming zones are not strictly protected by a protection area broader than that provided by the isolation distances; however, one article specifies that *"the MEW can refuse an authorisation for deliberate release of GMPs (for non-commercial and commercial purposes) in the environment, if organic farming zones exist in the adjacent fields"*. All GMP crops containing antibiotic resistance genes are banned (whereas European legislation bans GMPs containing genes of resistance to antibiotics still used in medicine). Prior to cultivation, it could be the responsibility of the person who wants to grow GMPs to make sure in the first place that his neighbours (including in the isolation areas) are not growing the same species of non-GM plant the same year. Less specific, but also worth highlighting is the definition in the Act itself of the isolation distances to respect in the case of cultivation. Contained in Annex 2 of Articles 51 and 71, these distances apply to GMP crops regardless of whether their purpose is for R&D or for development. These distances have been established by plant (cf. table below).

A final Bulgarian characteristic is that the results of public consultation regarding authorisation requests must be published in at least one national daily newspaper and by Internet. This last detail does not generally exist in the other national laws.

The Bulgarian government has thus followed the broad outline of European regulations and even added some typically national measures. On the other hand, the Act does not deal with the control mechanism to be set up. No administration seems to have been designated as monitoring body for the implementation of the Act. A Bulgarian laboratory will be a member of the network of European laboratories on GMPs: the AgroBio Institute. Following the report by the group of experts named by the European Commission to assess the national laws in comparison with the European laws, discussions are currently underway within the Ministry of Agriculture in order to propose a new Act modified at the Bulgarian Parliament. These modifications will concern all the articles that are not in accordance with European legislation, namely the prohibitions concerning certain plants, the protection measures for organic agriculture and the labelling threshold of non-food products, currently set at 0.5% (which will thus have to be set at 0.9%).

The actual situation in 2006

The real expectations come from the implementation of this Act, and first of all from the establishment of the authorisation request system. More than one year after the passing of the Act, the Advisory Commission, the key

The isolation distances provided for by the Act

Cereals		*Fibre crops*		*Linseed*	*20 m*
Rice	*60 m*	*Peanuts*	*20 m*		
Maize	*800 m*	*Mustard*	*800 m*	*Forage crops*	
		Soya bean	*20 m*	*Brassica*	*800 m*
Vegetables		*Hemp*	*from 800 to 6000 m*	*Alfalfa*	*800 m*
Chick-peas	*60 m*				
Beans	*300 m*	*Rape*	*400 m*	*Potatoes*	*200 m*
		Sunflower	*6000 m*		

Source : Annex 2 to Article 51 (4) and 71 (3) of the Bulgarian Act

body for granting authorisation for growing GMPs and putting them on the market, has still not been set up. Therefore, there is no authorisation granting system to date. The persons named as representatives of environmental organisations have not yet been invited to a meeting. No authorisation request has been submitted to date.

Yet, articles appearing in national newspapers have reported that GMP crops have allegedly been grown, especially rape: *"Growing GM rape in Bulgaria is of great interest. There are already GMP rape crops in the Véliko-Turnovo region"*, asserts Voémir Pétrof, a representative of Biotechnica, a company that makes and sells machinery and equipment for producing biodiesel. According to him, farmers are open to growing GMPs. In this same article, Tchavdar Dotchev, an official at Pioneer Seed Bulgaria, asserts the opposite, that *"it's for the moment impossible to conduct experiments on transgenic rape because the Act is very restrictive and does not allow GMP field trials"*[11]. According to the ISAAA, an body partially funded by the seed companies and that supplies a report each year on GMP crops around the world, no growing of transgenic plants occurred in Bulgaria in 2006[12]. Galia Tonkovska, from the bulgarian Ministry of Environment, told Inf'OGM that no voluntary dissemination in the environment nor importation of transgenic products occured in 2006. At the same time in some companies seed's list for 2006 and 2007 like Monsanto are listed GM hybrids like Roundup Ready maize. At the meetings with farmers AgroLink was said that is very easy to buy GM seeds and nobody control the selling of GMO seeds. Finally, in December 2006, a collective of associations declared that it discovered GM soya for sale in supermarkets. Out of five non-labelled products, three turned out to contain GM soya. The associations have questionned the authorities about this[13].

In the field as well, the coalition *"GM-free Bulgaria"*, created in 2004, has worked hard to highlight the GMP problem in the country. The main NGOs involved are Agrolink, Za Zemiata, Ecoglasnost and the Center for Environmental Education and Information. Representatives of political parties (the Greens) and scientists have joined in with the coalition. Since its creation, the coalition has been working in two directions: carrying out awareness-raising actions among the population (press conferences; roundtables that bring together students, farmers, scientists; debates; petitions) and writing draft amendments to the Act. The coalition has been authorised to participate in discussion on the Act within the Parliament's Environment Commission, as well as that currently underway. The coalition work has brought the issue of GMPs back into the public arena and brought out clashing discussions, with some MPs even leaning towards the idea of proclaiming a moratorium on the growing and commercialisation of GMPs up to 2007.

A campaign is also being carried out in Bulgaria, seeking to convince the citizens and their elected representatives to declare themselves GMO-free zones. The cross-border Rhodopes region, situated between Greece and Bulgaria, was declared a GMO-free zone in late January 2007, thus joining the network of Euopean regions declaring themselves against the introduction of GMP crops[14]. Agrolink had launched this project in autumn 2005, having chosen the Rhodopes region for its heritage and environmental value. Five meetings were organised in the winter and spring of 2006 in the Rhodopes region (towns of Smolian, Satovtcha, Kardzali, Haskovo and Asénovgrad) in order to open up discussions with the governors of the regions and with the mayors of 23 municipalities. The meetings, which were co-organised with the support of the local authorities, were opened to all, with invitations to representatives of farmers, state agencies, scientists, local business, students, tourists organisations, agriculture advisory services, environmentalists, and consumer's organisations. They were held in two parts, a first one devoted to shedding light on the scientific, legal and economic aspects of the subject, and a second to open debate on the proposal for the *"GMO-free Rhodopi"* declaration. Most of the mayors react by indicating their concern and seem favourable to the project. This latter includes a local development portion, by giving local authorities the opportunity to establish a participative decision-making process with civil society regarding local choices. By February 2007 five municipalities (Satovtcha, Banite, Kardzali, Ivaylovgrad in Rhodope mounting region and Zlataritsa, in Central Bulgaria) officially declared themselves hostile to the introduction of GMPs on their territory.

Issues on the horizon in 2007

The Bulgarian legislative framework thus seems favourable to supervision and limitation of GMPs in the environment and in the food chain. Several clauses of the Act represent moratoria in principle with regard to European laws. The European context is complex, and the case of Bulgaria has just been added to the countries that have taken measures to ban GMPs in their country (moratorium of Poland, Hungary, Austria and Greece, etc.). As elsewhere, NGOs such as Agrolink, Za Zemiata, Ecoglasnost and the Bulgarian Biodiversity Foundation have relied on European Community and international law, by interpreting the articles of Directive 2001/18 in a way that restricts the introduction GMPs, and they have gone further by proposing a more limitative law in some respects. The NGOs opposed to GMPs must now make the choice of whether or not to adopt a political strategy for urging the maintenance of moratoria that have been disapproved by the European Commission elsewhere. Such a choice implies that they must now support governmental authority faced with the European Commission in order to uphold the articles that clash with the European directives and recommendations. The hesitations of local authorities to sign the declarations for the Rhodopes region to be GMP-free also show the reluctance of elected representatives to accept initiatives that come from outside *"legal frameworks"*.

NOTES

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3. Nikolova, S. "Bulgaria between two chairs, Process of legislation on GMOs and involvement of Bulgarian NGO's" www.gmo-free-regions.org/countries/bulgaria/bulgary.rtf
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12. www.isaaa.org/default.html
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