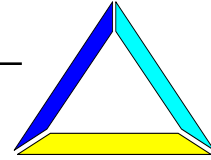




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**AgPP 16**

## **Policy Paper No.16**

### **Comment on the Law of Ukraine No 1103 “On the State Biosafety System for Developing, Testing, Transportation and Usage of Genetically Modified Organisms”**

#### **Disclaimer:**

This paper was prepared by the author using publicly available information and data from various sources. All conclusions and recommendations included in this paper in no circumstances should be taken as the reflection of policy and views of the German Federal Ministry of Food, Agriculture and Consumer Protection.

## Executive Summary

Commercial use of genetic modification is a highly controversial issue all around the world. The hopes are that genetically modified organisms (GMOs) could have a role in ensuring food security. On the other hand, the scientific community is not yet in a position to give a definitive answer as to the dangers of GMOs for human health and the environment. Thus, law and policy makers find themselves in a difficult position of legislating in a very sensitive area, Ukraine being no exception.

On Mai 31, 2007 the Verkhovna Rada adopted the Law of Ukraine "On the State Biosafety System for Developing, Testing, Transportation and Usage of Genetically Modified Organisms" (referred to further as the Law on GMOs). It is expected to bring a new quality into the relevant Ukrainian legislation as it is the first legal act in Ukraine that provides for a systematic approach in GMO handling. This comment starts with an overview of the GMO-related situation in Ukraine before the adoption of the Law on GMOs, continues with the presentation and assessment of the mechanisms introduced by the Law and ends with the recommendations on its improvement.

## Background

According to the report of the USDA Foreign Agricultural Service<sup>1</sup>, Ukraine imported products valued at USD 39 million in 2005 that could contain GMOs, including soybean meal, soy sauce and soybeans. In 2006, these products accounted for almost USD 62 million. In this situation, it is of vital importance for Ukraine to develop a comprehensive set of legislative and organisational norms regarding GMOs to ensure their safe use. From human health perspective, it is necessary to have regulations in place that would allow on the market only these GMOs and products derived therefrom that successfully underwent safety testing and registration. For environmental safety it is necessary that measures to ensure coexistence are taken to avoid crossing of GMO plants with conventional ones. Finally, clear regulations on importation, sale and labelling of GMOs and products derived therefrom would create predictable sales conditions for interested importers and traders.

Until now, Ukraine was lacking a legal act that would provide for a systematic approach in GMO handling. Provisions related to biotechnology were scattered in several different laws (e.g. the Law on Quality and Safety of Food Products<sup>2</sup>, the President's Decree on the Interdepartmental Commission on Biological and Genetic Safety under the Council of National Safety and Defense<sup>3</sup>). Mandatory labelling of GMO food is required by article 15 of the Law on Consumer Rights Protection<sup>4</sup>. But this labelling provision is unclear on threshold and for this reason difficult to enforce. The Ukrainian biosafety system was launched in 1999 solely for genetically modified plants<sup>5</sup>. Even the ratification by Ukraine of the UN Cartagena Protocol on Biosafety in 2002 did not result in the development of a biotechnology regulatory system.

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<sup>1</sup> Olena Pereyatenets "Ukraine Agricultural Biotechnology Report" 2007

<sup>2</sup> Law No 771/97 of 12 December 1997

<sup>3</sup> Decree No 672/2004 of 23 June 2004

<sup>4</sup> Law No 1023-12 of 12 Mai 1991

<sup>5</sup> Resolution of the Cabinet of Ministers "On Provisional Order for Importation, State Testing, Registration and Usage of Transgenic Plants" No 1304 of 17 August 1998; under this resolution no biotech crop has ever been registered for cultivation in Ukraine (in total, five applications were received in 1997 – 1999).

In 2002, this legislative vacuum was addressed by the draft law “On the State Biosafety System for Developing, Testing and Usage of Genetically Modified Organisms”. It was passed in the first reading by the Verkhovna Rada already in November 2002. Since then, the draft was pending final approval by the Parliament. Quite unexpectedly, on May 30, 2007, it was replaced by the draft law “On the State Biosafety System for Developing, Testing, Transportation and Usage of Genetically Modified Organisms”<sup>6</sup>, passed by the Verkhovna Rada under a priority procedure on the following day. The draft law was submitted by the Cabinet of Ministers, together with nine other laws required for Ukraine’s WTO accession passed on that day.

The Law “On the State Biosafety System for Developing, Testing, Transportation and Usage of Genetically Modified Organisms” entered into force on the day of its publication on June 21, 2007. Its adoption fills the dangerous legislative vacuum, and is an important step towards the development and implementation of a comprehensive regulatory framework on commercial use of genetic modification in Ukraine.

It is important to note that there was no public debate over this draft law. Despite the fact that the issue of GMOs in seeds, crops and food is a very controversial one, the environmental NGOs, consumers’ associations and other potentially interested stakeholders had no opportunity to provide comments and suggestions on the draft law to the responsible parliamentary committees.

### **What this note is about**

The aim of this note is to give a comment on the above Law on GMOs. Its positive aspects – as regards food and environmental safety – will be discussed and the aspects that require further improvement pointed out. The analysis is made in a wider context of the gradual approximation of Ukrainian legislation to European Union law.

It should be noted that the European Union has the strictest code of laws governing GMOs in the world, reflecting the serious reservations that many countries still have, from both health and environmental perspectives. The EU allows the use of genetic engineering in agriculture and food production but, at the same time, sets tight safety standards to protect consumer health and environment.

### **Content of the Law on GMOs in brief**

According to article 5 of the Law on GMOs, following activities fall within its scope:

- genetic engineering activities in the closed environment;
- genetic engineering activities in the open environment;
- state registration of GMOs and products produced using GMOs (further – GMO products);
- putting into circulation of GMOs and GMO products;
- export, import and transit of GMOs.

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According to this resolution, import of biotech crops requires a mandatory permission of the Ministry of Agricultural Policy.

<sup>6</sup> Draft law No 3595 of 30 May 2007

The Law introduces following instruments:

- mandatory state registration of GMOs and GMO products, including plant protection agents produced using GMOs and GMO-based crop varieties and animal breeds; a time limit of 120 days for granting or refusing registration; first registration to be limited to a maximum of 5 years and may be renewed (article 14);
- release of GMOs into the environment as well as production, putting into circulation and import of GMOs and GMO products is prohibited until they are state registered under the Law on GMOs. There are two exemptions in place: 1) import of non-registered GMOs and GMO products for the purposes of study, research and testing and 2) releasing of GMOs into the environment for the purpose of testing (article 16 and 13 respectively);
- mandatory permission for 1) import of non-registered GMOs for the purposes of study, research and testing, 2) import of GMO products for the purposes of study and research, 3) transit through Ukraine of non-registered GMOs as well as for 4) release of GMOs into the open environment; a time limit of 45 days for granting or refusing permission (article 19);
- mandatory licensing of genetic engineering activities carried out in the closed environment (article 12) and in the open environment (article 7);
- environmental risk inspections of GMOs to be carried out by the Central Executive Authority of Environment and Natural Resources (article 9);
- sanitary and epidemiological inspections of GMOs and GMO products to be carried out by the Central Executive Authority of Health Care (article 10);
- monitoring of GMO food products as well as feed products to ensure that only registered GMO sources are used - to be carried out by the Central Executive Authority of Health Care and Central Executive Authority of Agricultural Policy respectively (article 10 and 11);
- the possibility of establishing GMO free zones as well as mandatory space between fields with conventional and GMO plants in case of cultivation (article 14);
- mandatory information on GMO usage to the public (article 20);
- the possibility of the competent authority to reject the registration of GMOs or GMO products if sound scientific information proves that their designated use brings hazard to human health or the environment (article 14).

### **Assessment of the Law**

As can be seen above, the Law on GMOs introduces several important mechanisms as regards GMO handling in Ukraine. Some of them, like monitoring of GMO products, have been introduced in Ukraine for the first time, the others, like registration, were available until now only for biotech plants. Monitoring of GMO

products is of special importance as it allows to control the GMO products after their putting into circulation.

Also important, the Law provides a framework for further measures. It foresees, amongst others, the approval of the safety criteria for GMO handling, the procedure for licensing genetic engineering activities in closed and open environments and the procedure for granting permission for the transit of GMO through Ukraine.

The Law on GMOs is not a large document, particularly when bearing in mind that EU legislation in this area is made up of several different regulations and directives<sup>7</sup>. At the same time, it covers a wide range of GMO related issues from the registration of GMO-based crop varieties to activities related to GMO products. As a consequence, it is in some aspects rather general and would need secondary legislation. The most striking example is storage of GMOs, which is addressed by one general sentence only (see article 17). Likewise underregulated is the issue of transportation and recycling of GMOs. Additionally, some mechanisms introduced by this Law to ensure biosafety need specification, above all the procedure for state registration, which is at the heart of the system. These issues will have to be covered by secondary legislation.

The analysis of the objectives of the Law on GMOs gives information on the intended Ukrainian policy regarding commercial use of GMOs in the nearest future. Article 3 of the Law provides that its objective is to ensure conditions for a safe usage of GMOs. According to this article, protection of human health and the environment has priority over possible economic advantages of GMOs. On the other hand, the Law foresees state support both to genetic engineering and to research in the area of biological and genetic safety in the developing, study and practical usage of GMOs. It means that Ukraine intends firmly to benefit from GMO technology. As a result, we can expect increased scientific research in this field.

A very positive feature of the Law on GMOs is that it introduces mandatory information on GMO usage to the public. Its article 20 ensures availability of this information to the public, which is in line with EU laws. Additionally, according to article 14 of the Law, the registers of GMOs and GMO products shall be published on the Internet website of the responsible central authority and in media. Only confidential data under Ukrainian legislation can be kept secret, but the Law states clearly that information on effects of the GMO on human health and on the environment can in no case be considered confidential.

However, EU legislation goes a step further - the public in the EU should be consulted during the process of granting authorization for the proposed GMO release into environment. At present, due to the lack of the relevant secondary legislation, it is impossible to say whether Ukraine will follow the EU in this regard.

The major weakness of the Ukrainian Law on GMOs is that it does not introduce a single control agency that would take on responsibility for ensuring the safe developing, testing, transportation and usage of GMOs. Instead of that, regulatory

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<sup>7</sup> Directive 2001/18/EC on the deliberate release into the environment of GMOs; Regulation (EC) No 1829/2003 on genetically modified food and feed; Directive 90/269/EEC as amended by Directive 98/81/EC on the contained use of genetically modified microorganisms; Regulation (EC) No 1946/2003 on transboundary movements of GMOs; Regulation (EC) No 1831/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs, and some other instruments that have been adopted in connection with this legislation.

and control responsibilities are divided amongst five central bodies: the Cabinet of Ministers and the Central Executive Authorities of Education and Science, Environment and Natural Resources, Health Care, and Agricultural Policy. The authority of each body is specified in articles 7 – 11, and it is the Cabinet that coordinates the actions.

The Law does not introduce a requirement for labelling either. The relevant provisions are contained in the resolution<sup>8</sup> (postanova) of the Cabinet of Ministers of 1 August 2007, issued for the execution of the Laws on Consumer Rights Protection and on Children Foodstuff. It foresees mandatory labelling of foodstuff containing GMOs. According to the resolution, GMO content that is over the prescribed threshold – set at 0.9% - is subject to mandatory labelling. This particular provision aligns with EU norms, which also set the threshold at 0.9%. As a result, import into Ukraine and sale of food products containing more than 0.9% of GMO material will be only possible under the condition that they are properly labelled<sup>9</sup>. Additionally, the resolution introduces a ban on imports, production and sales of children foodstuff with GMOs.

Apart from the above, it is article 12 of the Law on GMOs that merits attention: according to it, each company seeking a license for carrying out genetic engineering activities in the closed environment should set up a commission, comprising of its employees, whose task would be to carry out the initial risk assessment. If Ukraine decides to follow EU legislation, this risk assessment will then be examined by a competent authority, and on this basis the decision of granting or refusing a license will be taken. In this case, law makers should clarify the methodology to be followed and elements to be considered to perform the risk assessments that would allow for their uniform carrying out by the companies. The Law on GMOs does not provide for such rules. In no case the risk assessment conducted by the interested company should be the sole basis for the final decision.

## **Conclusion**

The adoption of the Law on GMOs was a first and absolutely necessary step in dealing with an important issue of food and environmental safety in both practical and legal terms. Still, the Law needs further improvement and development, and it is the relevant secondary legislation adopted on its basis that will determine the effectiveness of the system.

Based on the above analysis, we recommend to:

- adopt as soon as possible implementing regulations on the basis of the Law and for its execution to make the system workable. First, the registration procedure for GMOs and GMO products should be specified - as this procedure is a main instrument for ensuring biosafety in GMO handling – and system of control over the observance of safety rules in genetic engineering activities developed;
- establish a single control agency that would take on responsibility for ensuring the safe developing, testing, transportation and usage of GMOs to

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<sup>8</sup> Resolution No 985 of 1 August 2007

<sup>9</sup> Resolution will come into force on November 1, 2007

ensure transparency and avoid loopholes in the biosafety system that could result from splitted responsibilities;

- include provisions on labelling of GMO food products in the Law on GMOs as the laws have higher legal force than resolutions. It should be noted that the labelling of GMO products is a unique instrument for ensuring consumers the freedom of choice – choice between conventional and GMO products;
- establish a common methodology to conduct the risk assessment; it should take account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment;
- involve the public in the decision making process regarding the intended GMO release; arrangements for such consultation, including a reasonable time period, should be laid down in order to give the public and interested groups/organisations the opportunity to voice their opinion.

And last but not least, special attention should be paid to ensuring the enforcement of the Law. At present, there are three laboratories in Ukraine where GMOs can be identified in food and other products that contain or may contain GMOs. It is crucial for Ukraine to set up more independent test centers engaged in estimation of GMO concentration. Without operational laboratories and keeping up with the newest technologies, it would be impossible to detect GMOs and thus to make the provisions of the Law enforceable.

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