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Regulation and use of GMOs in Ukraine: neither forbidden, nor allowed

Authors

Yuliya Ogarenko
ogarenko@apd-ukraine.de

German-Ukrainian Agricultural Policy Dialogue (APD)
Reytarska 8/5 A, 01030 Kyiv
Tel. +38044/ 2356327
info@apd-ukraine.de
www.apd-ukraine.de

Legislation basis for development and use of genetically modified organisms (GMOs) in Ukraine is demanding and complex. Though GMOs are not restricted and genetically modified (GM) crops and products could be used, if state registration is passed successfully, it is very complicated to go through all procedures and meet all legal requirements. As a result, not a single transgenic crop variety is officially registered, whereas GMOs are de facto grown and presented at the Ukrainian food and feed market. As Ukraine has signed the Association Agreement with the EU, legislation concerning GMOs should be approximated with relevant EU acquis in the next two years.

Regulation of GMOs in Ukraine

Ukraine is a party of the Cartagena Protocol¹ since 2000, which is focused on a transboundary movement of any living organisms modified using modern biotechnology, which could have adverse effects on the conservation and sustainable use of biodiversity. In 2007, Parliament of Ukraine approved law #1103-16² on the State Biosafety System at the stage of development, testing, transportation and use of GMOs. The law regulates relations between executive bodies, producers (suppliers), developers, scientists and consumers of GMOs and consumers of GMOs and products with GMO content. Key tasks of the law include protection of human health and environment during genetic engineering operations and use of GMOs, guarantee the right of citizens for safe use of GMOs, establishment of appropriate conditions for safe practical application of GMOs for commercial purposes, etc. Commercial production of GMOs and products with GMO content is forbidden prior to the state registration, which envisions molecular genetic analysis of plant varieties, impact assessment on wild-grown species, etc. One can be refused from registering of a GMO in the case scientifically proven information is available on its harmful effects on human health or environment. In fact, procedure for state registration of GMOs is rather

complicated and all impacts assessment procedures could take up to 2-3 years.

In 2009, the Resolution #468³ of the Cabinet of Ministers established procedures for labelling of products containing GMOs. Products containing the share of GMO higher than 0.9% should be marked as "with GMO". It is also specified that labelling of products containing less than 0.1% of GMOs is voluntary. However, Laws #1778-17⁴ and #1023-12⁵ required mandatory labelling of products either "with GMO" or "without GMO". Thus, all goods on the shelves of supermarket are labelled as "without GMO" often even those products, which in principle could not contain GMO like salt or water. More detailed description of regulation procedures is available in the APD (2010) book "GMO: Current Challenges and Experience of Legal Regulation"⁶.

Several draft laws regarding GMOs are currently considered by the Parliamentary Committees. Particularly, the draft law #3253⁷ suggests improving legislation on biosafety (in the process of production, testing and transportation of GMOs). The draft law #4278a⁸ on biosafety, which proposes to introduce fines for violation of biosafety law as of #1103-16 (see above), was registered in the Parliament in July.

Situation at the market

Legislative deficiencies, dispersion of control functions between different government bodies and insufficient capacities of testing laboratories resulted in situation when reality does not correspond to legislative requirements. According to the Ministry of Health⁹, there are no GMOs or products containing GMOs in Ukraine as not a single GMO is registered. However, according to unofficial information from market players, about 70% of soybean and a third of corn in Ukraine are grown from GM seeds¹⁰. Experts argue that GMO

¹ http://zakon4.rada.gov.ua/laws/show/995_935

² <http://zakon4.rada.gov.ua/laws/show/1103-16>

³ <http://zakon4.rada.gov.ua/laws/show/468-2009-%D0%BF>

⁴ <http://zakon2.rada.gov.ua/laws/show/1778-17>

⁵ <http://zakon4.rada.gov.ua/laws/show/1023-12/page>

⁶ www.apd-ukraine.de/images/Knigi/final_for_web2.pdf

⁷ http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?pf3511=48285

⁸ http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?pf3511=51696

⁹ http://zaxid.net/news/showNews.do?moz_perekonuye_shho_produkativ_z_gmo_v_ukrayini_nemaye&objectId=1268782

¹⁰ <http://agronews.ua/node/44794>

soy is largely used for domestic consumption and not exported. Otherwise, traders would control purchase process more rigorously. Genetically modified potato, barley and cotton are also grown in the territory of Ukraine but in much smaller quantities (APD, 2010). Estimates of GMO content in final food produce vary greatly. According to Ukrainian Centre for Food Research about 5% of food products contain GMO (as of 2011)¹¹. Head of the laboratory for molecular genetic research of the Ukrainian Scientific-Research and Training Centre of Standardization, Certification and Quality Problems¹² mentioned that there are about 30% of food products containing GMOs. These are in the first place products containing soybean as an additive, particularly, sausages, pastry and chocolate products.

Ukrainian agricultural businesses¹³ suggest legalising those GMO-crops, which were already tested in the EU and were proven to be safe for human health and environment because Ukraine does not have the capacity for its own investigations and such research projects require serious financial resources and might last for years. Agricultural producers are supporting cultivation of GMO crops because there is a significant demand for such products at the international market, especially, in the East Asia. Head of the Agricultural Union of Ukraine argues that Ukraine should allow application of the genetically modified crop varieties already tested in the EU and in the USA for three years until biosafety system will be properly functioning in Ukraine. General Director of the Ukrainian Agribusiness Club believes that GMO crops could be used for feed or technical purposes (e.g., bioethanol production) as this is a world-wide practice but GMO materials should not be used for food production. Though these suggestions of business representatives sound quite reasonable it is also necessary to ensure that other important norms such co-existence of genetically modified crops with conventional and organic farming should be developed and rigorously implemented.

¹¹ <http://tsn.ua/groshi/lishe-5-ukrayinskih-produktiv-mistyat-gmo.html>

¹² Mentioned in www.apd-ukraine.de/images/Knigi/final_for_web2.pdf

¹³ <http://www.day.kiev.ua/uk/article/ekonomika/iz-gmo>

Regulation of GMOs in the EU

Application of genetic engineering technology is strictly regulated in the EU. GMO as well as food or feed containing GMO is a subject to a comprehensive authorisation procedure, which involves risks assessment to human health and the environment, before the company is allowed to place GMO on the market. Release of a GMO into the environment and placing of it on the market for cultivation, trade, or processing purposes is mainly regulated by the Directive 2001/18/EC¹⁴. The Directive introduces principles for environmental risk assessment, mandatory post-market monitoring requirements (including long-term effects associated with the interaction with other GMOs and the environment), mandatory consultation and provision of information to the public, obligations for consultation of the Scientific Committee(s)/ European Food Safety Authority (EFSA), the possibility for the Council of Ministers to adopt or reject a Commission proposal for authorization of a GMO by qualified majority, etc. It is specified in the Article 26a of the Directive 2001/18/EC that Member States may take necessary measures to prevent dissemination of GMOs due to flow of pollen of GMO crops into areas designated for conventional or organic farming. Though it is the responsibility of the Member States to develop and implement national co-existence policies, European Commission adopted a Recommendation (2003/556/EC)¹⁵ on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.

Regulation (EC) No 1829/2003 provides a centralized, uniform and transparent procedure for placing on the market a GMO itself or food and feed use containing GMO. Labelling of GMOs and traceability requirements are specified in the Regulation 1830/2003¹⁶.

All GMOs authorised for cultivation, import as well as food and feed production in the EU are recorded in a publicly accessible register of

¹⁴ <http://rod.eionet.europa.eu/instruments/559>

¹⁵ ec.europa.eu/agriculture/publi/reports/coexistence2/guide_en.pdf

¹⁶ <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32003R1830>

genetically modified food and feed¹⁷. As of November, 2014, it includes 8 GM varieties of cotton, 3 – of rapeseed, 7 – of soybean and two GM microorganisms. However, most of these crops can be imported to the EU and processed but not cultivated. Only GM maize (MON810) that contains gene inserted to confer resistance to lepidopteran pests is currently allowed for cultivation. At the same time, two GM hybrids of maize and three hybrids of rapeseed and derived products are subject to the EC decisions on withdrawal from the market. Moreover, registration of 23 varieties of GM crops is currently pending.

Special attention deserves a safeguard clause (Article 23) of the Directive 2001/18/EC, which gives the right to Member State to provisionally restrict or prohibit the use and/or sale of GM products, which was authorised by the EC, on its territory if there are justifiable arguments that GMO could pose a risk to human health or the environment. This provision was used nine times¹⁸ during the late 1990s and in 2000. EU Member states submitted their justifications for consideration of the Scientific Committee(s) of the European Union. Although Committee(s) came to conclusion that there are no new evidence, which would question original authorisation decision, Regulatory Committee did not reach a qualified majority either in favour or against of European Commission decisions requesting the Member States to withdraw their national safeguard measures. Then, Commission proposals¹⁹ were transmitted to the EU Council, which rejected the proposals. Currently, cultivation of GMOs is *de facto* banned in Austria, France, Greece, Hungary, Germany and Luxembourg. More detailed description of GMO regulation procedures are described in the APD (2010)²⁰ and at the European Commission website²¹.

Harmonisation of Ukrainian legislation with the EU regulations of GMOs

Although certain amendments to the law #1103-16 were recently introduced²² to harmonise regulation of GMOs in Ukraine with the one in the EU, particularly, regarding the registration of GMO sources instead of products produced from them. However, a lot of other provisions are yet to be incorporated into the Ukrainian legislation.

On 17th of September, Cabinet of Ministers approved the action plan on the implementation of the Association Agreement between Ukraine and the EU and by that defined timeline and responsible bodies for adaptation of legislation to all sectors of the economy, particularly, agricultural one. According to this plan Ukraine should approximate its biosafety legislation with relevant EU regulations *during* next two years.

Legal acts required for the implementation provisions of the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms should be developed and submitted for consideration by the Cabinet of Ministers by August, 2016. The Directive envisions *inter alia* establishment of an effective inspection and control system to ensure compliance with its provisions, especially, regarding non-authorized GMOs, as well as risk assessment and notification procedures for releases of GMOs, etc. Moreover, confidentiality of information and intellectual property rights should be ensured.

Ukrainian government is also responsible for development of legislative acts to implement provisions of the Regulation (EC) No 1946/2003 of 15 July, 2003, on transboundary movements of genetically modified organisms²³ by August, 2016. The Regulation requires establishment procedures for deliberate release of GMOs into the environment and direct use of GMOs as food, feed, or for processing.

¹⁷ http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

¹⁸ Three times by Austria, twice by France, and once each by Germany, Luxembourg, Greece and the United Kingdom.

¹⁹ In accordance with EU comitology procedures.

²⁰ www.apd-ukraine.de/images/Knigi/final_for_web1.pdf

²¹ http://ec.europa.eu/food/food/biotechnology/qanda/d4_en.htm#d

²² Amendments were introduced with the law #1602-18, available at <http://zakon4.rada.gov.ua/laws/show/1602-18>

²³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003R1946>

By August, 2017, provisions of the Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMMs)²⁴ should be incorporated into national legislation of Ukraine. The directive describes general principles as well as protective measures, classification of GMMs, ensuring users carry out risk assessments, establishment of notification procedures and criteria for emergency plans.

Summarising, the government of Ukraine should investigate true situation with the turnover of genetically modified crops and materials at the domestic market, implement relevant legislative changes and improve state regulation in this area. The right of consumers for true information on GMO content in food must be ensured so that they are able to choose products, which meet their preferences. Approximation of the Ukrainian legislation with relevant EU regulations will facilitate establishment of operational biosafety system in Ukraine.

²⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009L0041>