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Report Highlights:
Since 2006, Hungary has been one of the strongest opponents of agricultural biotechnology in the European Union. Maintaining the country's GE-free status is still among the Government's highest priorities and is seen as a commercial advantage. However, Hungary's Ministry of Agriculture, financial and professional organizations, and plant breeding and research institutions have recently spoken in support of non-transgenic precision breeding.

Executive Summary

Hungary does not produce any genetically engineered (GE) crops, animals, or cloned livestock. The Government of Hungary (GOH) opposes the use of GE products in agriculture. Political parties in Hungary have historically held a firm anti-GE position.

Hungary's GE-free status is seen as a commercial and/or marketing advantage since EU member states are the primary destinations for Hungarian planting seed and grain exports. Still, the country has a structural shortage of animal protein feed and must import large quantities of soybean meal (more than 80 percent of domestic needs), of which 90 percent is GE. Therefore, research programs and regional cooperation initiatives and agreements are targeted to increase domestic, non-GE soy production and thereby reduce the country's large-scale dependence on protein feed imports.

However, Hungary's Ministry of Agriculture, financial and professional organizations, and plant breeding and research institutions have recently spoken in support of non-transgenic precision breeding and the potential benefit of such technology for Hungary's (agricultural) economy. According to various factions, the EU's Directive on genetically modified organisms (GMOs) should be revised, potentially facilitating a path for these new technologies. Both biotech non-governmental organizations (NGOs) and conservationist groups have called for a new or amended/updated national act on biotechnology activities, including innovative technologies.

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PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

In Hungary, there are no GE plants under development nor are there plans to commercialize such in the near future. The GOH maintains a ban on GE crop cultivation, specifically outlined in the Hungarian Constitution (called the Basic Law). Thus, institutes and universities conduct most of the agricultural biotechnology research. For example, research at the Agricultural Biotechnology Institute focuses on plants' defense mechanisms and host-pathogen interactions. Optimizing the CRISPR-Cas9 system for potatoes is also among public institutions' objectives.

The Center for Agricultural Research of the Hungarian Academy of Sciences (HAS) is also very active in plant science research and is one of the more influential agricultural research institutions in Hungary. Their basic aim is to use local germplasm combined with newest scientific and technical innovations to improve stress-adaption and quality in wheat. The Research Center also sees great potential in genome editing and the applications of the CRISPR-Cas9 system. The Center has made many public comments in support of such innovations.

Since achievable results with traditional breeding techniques are limited and costly, companies and institutes have to decide whether developing products using either genetic engineering, innovative biotechnologies, or traditional breeding methods are the most effective and most profitable way to improve crops. Even though the European Court of Justice's (ECJ) decision put innovative biotechnologies under the EU's restrictive biotech legislation, Hungary's Ministry of Agriculture as well as plant breeding and scientific institutions publicly expressed their support for these technologies seeing them as necessary, and anticipating their positive impact on addressing future challenges of agriculture.

b) COMMERCIAL PRODUCTION

No GE crops or GE seeds on the market are produced in Hungary. In response to the EU Parliament's decision to allow individual member states to ban GE cultivation, the Ministry of Agriculture stated, "It was an especially important strategic interest for Hungary, laid down in its Constitution, to ensure a "GMO"-free agriculture. Under Directive (EU) 2015/412, Hungary demanded that all of its territory be shielded from pending applications to grow gene-altered crops in the bloc. Measures of the directive have been transposed into national law by the amendment of the Act No. XXVII of 1998 on Biotechnology Activities (in Hungarian).

c) EXPORTS

There is no commercial production of GE crops in Hungary and the country does not export GE products. For years, various factions in Hungary (including government, agricultural and business interests) saw the constitutional prohibition on biotechnology in agriculture and the country's stated GE-free status as a marketing advantage since EU member states are the primary destinations for Hungarian exports.

d) IMPORTS

Hungary's imports of biotech crops are controversial in terms of its asserted GE-free status. The country has a structural shortage of animal protein feed and must import more than 80 percent of soybean meal needed, of which 90 percent is GE product. The Hungarian livestock sector uses about 500,000 MT of soybean meal and 72,000 MT of full-fat soybean meal annually, of which only 15-20 percent derives from domestic sources. The other 80-85 percent is imported mainly from Brazil and in lower volume from Argentina as trans-shipped product from other EU countries, especially from Slovenia, Germany, the Netherlands, and Italy. This import dependence makes farmers and feed producers vulnerable to external market movements. Replacing imported (GE) animal feed with non-GE products would result in an estimated, extra cost of about $29 million annually.

The Research Institute of Agricultural Economics (in Hungarian) conducted a study to determine whether the GE-free soybean meal based feeding can become a reality. According to the study, about 60 percent of Hungary's non-GE soybean production is exported to foreign markets and barely contributes to the domestic supply. Analyzing changes in planted area and possible growth in production, it was established that the Hungary's soybean production would be able to satisfy only 50 percent of the annual demand of the domestic livestock sector by 2020.

Considering the significant shortage of protein feed, the National Agricultural Research and Innovation Center (NARIC) signed two strategic cooperation agreements in August 2017 to help decrease the sector's import dependence. Agreements were reached among NARIC, the Magyar Szója Nonprofit Kft (Hungarian Soy Non-profit Ltd; in Hungarian), the Research Institute of Agricultural Economics, and the Hungarian Grain and Feed Association (in Hungarian). The aim of these partnerships is to promote the cultivation of soybean and other protein crops within Hungary.

e) FOOD AID

Hungary is not a food aid recipient country, and its role as a supplier in international food aid programs is not significant. Food aid consignments (e.g. processed and canned foods) are occasionally sent to the Hungarian population of the sub-Carpathian region of Ukraine, but those consignments do not involve any kind of GE food.

PART B: POLICY

a) REGULATORY FRAMEWORK

In Hungary, the Ministry of Agriculture takes the lead on regulating GE crop cultivation, trade, and (food or feed) processing. The National Food Chain Safety Office (NFCSO) (in Hungarian) is the top government organization handling the technical aspects of GE crops such as inspection, testing, and registering plant varieties. In 2006, Hungary developed its GE-free strategy (Parliamentary Resolution No. 53/2006 – in Hungarian). The Act No. LIII of 1996 on nature conservation was the first law in Hungary to include provisions on GE organisms.

Today, the main piece of biotech-related legislation is the Act No. XXVII of 1998 on Biotechnology Activities (English version in effect until June 4, 2015). The goal was to prevent the domestic production from unregulated entry of GE plant varieties and to give expanded powers to environmental, agricultural, and industrial biotechnology authorities. For direct consumption of imported food and feed

containing GE materials, the Act orders the use of legal and administrative procedures corresponding to the EU.

Hungary's legislation on GE crops and their products is fully harmonized with the EU, transposing directives into the national law. EU regulations pertaining to GE products are directly applied. Below is an abbreviated list of those rules and regulations regarding biotechnology. For any specific questions, or information on additional legislation, please contact the FAS Budapest office directly.

- Decree No. 82/2003. (VII. 16.) (in Hungarian) on rules of registration and reporting of gene technological activity, and on the documentation that shall be enclosed in the notification (application for authorization) of such activities.
- Joint Decree No. 111/2003. (XI. 5.) (in Hungarian) on activities that shall be considered as gene technological activity as well as on authorities that are entitled to control such activities.
- Decree No. 128/2003. (XII. 19.) (in Hungarian) on the organization and the activity of the Gene Technological Advisory Committee.
- Decree No. 48/2004. (IV. 21.) (in Hungarian) on production and marketing of arable seeds.
- Government Decree No. 132/2004. (IV. 29.) (in Hungarian) on authorization procedure of gene technological activity as well as on the liaison with the European Commission in the course of that.
- Decree No. 142/2004. (IX. 30.) (in Hungarian) on certain rules of gene technological activity in the field of agriculture and industry.
- Joint Decree No. 31 of 2006 (IV. 29.) (in Hungarian) on imports and distribution of certain genetically modified feeds.
- Decree No. 86/2006. (XII. 23.) (in Hungarian) on coexistence measures on the cultivation of genetically modified, conventional and organic plants.
- Parliamentary Resolution No. 6/2012 (II. 22.) (in Hungarian) on the adoption of the report on the implementation of provisions included in Parliamentary Resolution No. 53/2006 (XI.29) on various issues relating to gene technological activities, their use in agriculture and food production, and the Hungarian strategy concerning them for 2009 and 2010.
- Decree 53/2013. (VI. 17.) (in Hungarian) on safeguard clause procedure on seeds of inbred lines and hybrids of the MON810 corn.

As there are no uniform rules and regulation on labeling of GE-free food and feed within the EU, Hungary developed its own system. The Decree No. 61/2016 (IX. 15) (in Hungarian) of the Ministry of Agriculture on labeling GE-free products came into force on September 20, 2016.

b) APPROVALS

In Hungary, the cultivation of GE crops is constitutionally prohibited. There are no GE plants approved for production. Data on authorized experimental releases can be found on the Hungarian Biosafety Website.

Regarding the imports of food and feed with GE content, Hungary applies EU-harmonized legislation. Although the Ministry of Agriculture formally makes approvals, the Gene Technology Advisory Committee (in Hungarian) evaluates biotech activities and products in Hungary. It provides professional opinions on applications submitted to gene technology authorities and makes

recommendations on their acceptance or refusal. The HAS, Ministries, and non-governmental organizations (NGOs) nominates the members of the Advisory Committee. Ministries typically nominate scientists or experts from think tanks.

c) STACKED EVENT or PYRAMIDED EVENT APPROVALS

Hungary follows the European Food Safety Authority's guidelines and the EU's legislation concerning stacked events.

d) FIELD TESTING

Since 2012, GE crop field tests have not been approved in Hungary according to the official database. Tests were mainly conducted in corn and in some cases in tobacco, potato, sugar beet, wheat, and barley only with scientific purposes, without commercialization.

e) INNOVATIVE BIOTECHNOLOGIES

Since 2004, Hungary has been one of the strongest opponents of agricultural biotechnology in the EU. However, Hungary's Ministry of Agriculture, financial and professional organizations, and plant breeding and research institutions have recently spoken in support of non-transgenic precision breeding. Specifically,

- On December 18, 2017, the HAS published a report (in Hungarian) concluding that non-transgenic genome-edited products should not be considered "GMOs" as defined – and prohibited – by the Hungarian Constitution. The HAS also stated that Hungary would stand to benefit from innovative biotechnologies as they become more widely used.
- In May 2018, Hungary's new Agriculture Minister, István Nagy, outlined his supportive opinion for genome editing at his confirmation hearing in front of the Agricultural Committee of Hungary's National Assembly. He argued that precision breeding without the introduction of foreign DNAs must be supported and cannot be regarded as genetic modification. After his swearing-in, the approach of the Ministry of Agriculture and its ally organizations to innovative biotechnologies as well as to dialogues on agricultural innovation have positively changed in support of these technologies.
- Hungary's National Chamber of Agriculture – which is one of the most influential public bodies – recognized the potential of precision breeding and started a comprehensive consultation on precision breeding with NARIC in June 2018, including a panel of experts with biotechnologists, breeders, and representatives of green and organic farming organizations.

After the decision from the European Court of Justice, which included products from innovative biotechnologies under the EU's "GMO" legislation, the Chamber and the Association of Hungarian Farmer Cooperatives and Societies issued a press release, including the following statement: "With delays or neglect of these methods, we run the risk of isolating the European and domestic agriculture from the benefits of innovative developments, as opposed to the rest of the world. In parallel, there is also a risk of losing research capacities that would allow us to join agricultural developments after the risk assessment of these technologies."

Comments made by the Minister of Agriculture at a conference on September 11, 2018, seemed to echo this belief. At this conference, the Minister stated that non-transgenic precision breeding can be the key

for maintaining the sector's competitiveness and the security of agricultural production and supply. According to Minister Nagy, although Hungary has to accept the ECJ's judgement, it should to be revised.

f) COEXISTENCE

The Government approved its Coexistence Regulation in November 2006 (see report HU6015) by the amendment of the Act No. XXVII of 1998 on Gene Technology Activities (Chapter III). This Act, as well as the Decree No. 82/2003 (in Hungarian) and the Decree No. 86/2006 (in Hungarian) outlines the rules for coexistence of organic, conventional, and GE crops. These rules determine all the conditions that are designed to prevent the uncontrolled spread of GE crops and their mixing with non-GE products, including buffer distances, cleaning of machineries, separate storage, etc.

g) LABELING

Hungary follows the EU's labeling standards. If GE content above 0.9 percent, it must be indicated on labels. If products derive from animals fed on GE feed, it is not required to be indicated. Since there are no uniform rules and regulation on labeling of GE-free food and feed in the EU, Hungary developed its own labeling system (for the specific legislation, see Part B - Regulatory Framework). This legislation provides special labeling of GE-free food and feed, and processed products as well as labeling of GE-free honey, and meat, fish, eggs, and milk from livestock fed on certified GE-free feed. The application of the "GMO-free" labeling is voluntary.

For a product to be labeled "GMO-free," it must not contain any GE organisms or derive from livestock fed on GE material. Labeling claims must be verified by the producers. Producers and traders of food labeled as being GE-free are obliged to ensure the traceability of the products including raw materials. According to the national law, minute GE content (traces of GE material up to 0.1 percent, provided that it is adventitious or technically unavoidable) is permitted; product can still be labeled as "GMO-free." In 2017, Hungary amended the related labeling regulations via the Decree No. 27/2017. (V. 30.) (in Hungarian) of the Ministry of Agriculture because the permitted level of GE content was too low causing problems in technical implementation. According to the amendment, animal feed can be used in GE-free production if it is not required to be labeled due to its GE ingredient content under the Regulation (EC) No. 1829/2003. Practically, it means that the permitted GE content of 0.1 percent in "GMO-free" labeled products has been raised to 0.9 percent.
The "GMO-free" label cannot give the impression to customers that the product has special sensory and nutritional features, and its effect on environment and health is better than similar products. In addition, products that have no licensed GE version on the market cannot be labeled as "GMO-free."

Certifying mark for labeled products derived from GE-free production

h) MONITORING AND TESTING

Since Hungary is a major seed exporter, genetic purity of seeds is highly important. Plant propagation materials (including seeds) go through sampling and laboratory analyses for the presence of GE traits. Official control is both on Hungarian crops and on seeds from the EU and non-EU countries. Under the rules, third country seed imports are subject to mandated testing for GE presence, paid for by importers or distributors. Imported seeds from EU member states must be accompanied by a negative GE test from an EU accredited laboratory. Farmers can only use seeds that have been proven as GE-free.

Corn, rapeseed, and soybean are the most common targets of GE testing efforts. The authorities carry out monitoring and testing continuously. Soy drinks were also tested by the NFCSO checking their various nutritional attributes as well as the presence of GE ingredients. Petunias were tested for GE traits too; authorities sampled 121 different petunia varieties at importers, growers, wholesalers, and retailers.

i) LOW LEVEL PRESENCE POLICY

Hungary has a zero tolerance policy for low-level presence of GE products in feed following the measures of the Commission Regulation (EU) No. 619/2011. It lays down the methods of sampling and analysis for the official control of feed as regards presence of GE materials. The EU defined "zero" with a "technical solution" level of 0.1 percent.

j) ADDITIONAL REGULATORY REQUIREMENTS: N/A

k) INTELLECTUAL PROPERTY RIGHTS

In Hungary, there is no specialized intellectual property legislation for GE products. GE crops cannot be planted commercially. In general terms, the country is against the patents on genetic materials. Application for national plant variety protection can be filed with the Hungarian Intellectual Property Office, while the application for EU plant variety protection can be submitted directly to the Community Plant Variety Office.

Hungary is an active participant of negotiations under the International Union for the Protection of New Varieties of Plants and the International Convention for the Protection of New Varieties of Plants.

l) CARTAGENA PROTOCOL RATIFICATION

The Hungarian Parliament ratified the Protocol on January 13, 2004. Government Decree No. 226/2008 (IX.11) (in Hungarian) laid down the rules of the implementation of the Protocol. The publication of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was by the Act No. CLXXI of 2013 (in Hungarian).

With respect to the Convention on Biological Diversity (CBD) (see the fifth national CBD report), Hungary created a new National Strategy for the Conservation of Biodiversity in 2015-2020 (NSCB). To comply with the Aichi Targets, the NSCB contains highlighted objectives to eliminate harmful effects on biological diversity.

Hungary's NSCB sets out the following measures needed between 2015 and 2020:

- "Introduction of safeguard clause procedures and/or urgency measures for "GMOs" that are permitted for production in the EU and have harmful effects.
- Preparing a study of social, economic, and environmental reasons for banning the production of GMOs in general, a group of GMOs, or individual GMOs on a case-by-case basis (such as preserving environmental and landscape characteristics, habitats and ecosystems, as well as specific ecosystem functions and services).
- Active monitoring and testing of GMO contamination in plough-land located close to Hungary's borders.
- Contacting neighboring countries and concluding diplomatic treaties with them in order to keep the areas close to Hungary's borders GMO-free.
- Active monitoring of gene technology-related activities.
- Providing technical requirements and funding for environmental and health impact studies in Hungary concerning GMOs' undergoing authorization procedure in the EU."

m) INTERNATIONAL TREATIES/FORUMS

Hungary is an active member of different intergovernmental and standard setting international organizations (e.g. Organization for Economic Co-operation and Development; World Trade Organization; Codex Alimentarius; Food and Agriculture Organization of the United Nations - International Plant Protection Convention; etc.). At these meetings, Hungary often seeks to leverage its influence through its membership in the EU and, particularly, the Visegrad Group (V4). For example, Hungary launched an initiative entitled "Alliance for "GMO"-free Europe" in January 2015. As a follow-up action, Hungary and Germany later submitted a joint proposal on the adoption of the European Soy Declaration at the EU Council meeting on June 12, 2017. Participating ministers welcomed the initiative and underlined its potential role in boosting GE-free soy production in Europe. On July 17, 2017, agriculture ministers of 14 EU member states officially signed the Declaration.

The county is also an active member of the Donau Soja (Danube Soy) Organization. Since Hungary is only 15-20 percent self-sufficient in soybean meal, the country's participation in the Donau Soja program stimulates the region's non-GE soybean production and aims to reduce the large-scale dependence on imports.

n) RELATED ISSUES

In 2017, at the China-Europe Soy Symposium, Hungary promoted the cultivation of non-GE leguminous plants for use by the food industry and for feed purposes. The Director-General of NARIC highlighted the fact that replacing GE soy was a major challenge, and accordingly could not be realized without comprehensive cooperation on European protein policies.

This summer, Donau Soja and the Hungarian Soy Non-profit Ltd (in Hungarian) jointly organized an expert meeting in Hédervár, Hungary on strategies to optimize soy nutrition. Experts and scientists from Central Europe, Brazil, and China attended the event, where the Chinese Academy of Sciences and Donau Soja signed an agreement on educational cooperation in accordance with their regional objectives.

PART C: MARKETING

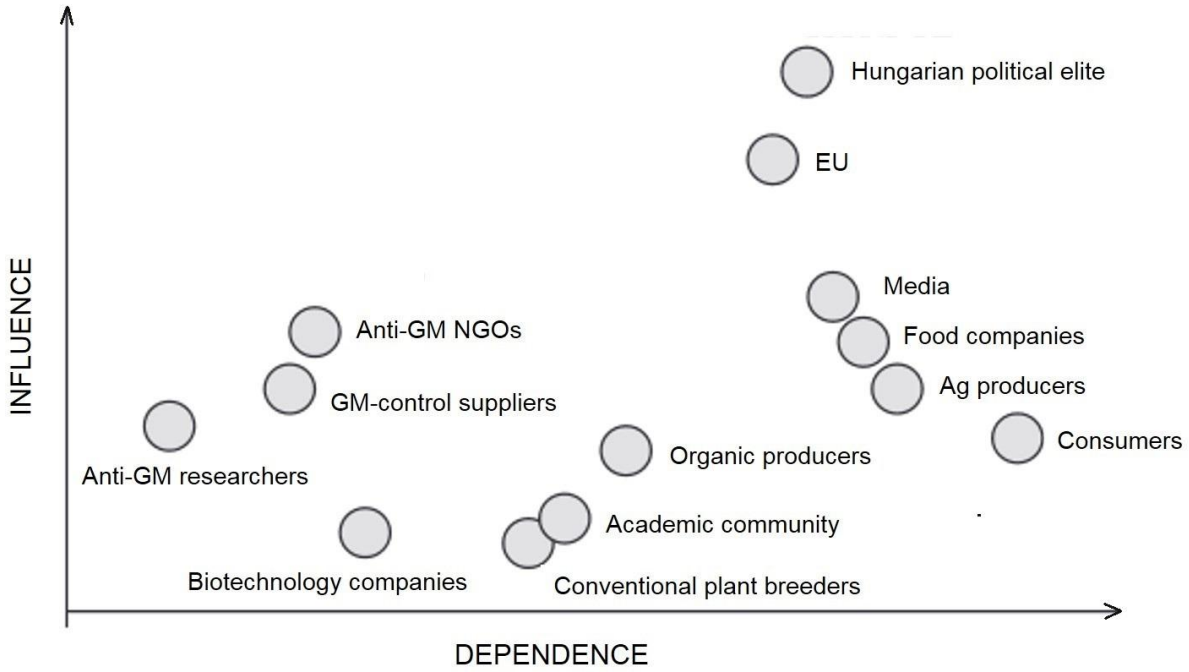
a) PUBLIC/PRIVATE OPINIONS

Hungarian consumers' attitude to GE products has been under pressure from anti-technology (i.e. anti-GE, and anti-"GMO" orgnizations) campaigns for years. The press often publishes negative opinions about GE ingredients in food and feed. At the same time, the number of pro-biotech publications and outreaches are increasing as well. For example, the Association for Innovative Agricultural Biotechnology (AIAB; in Hungarian) represents all branches of green biotechnology. This association is very active in dissemination of new results that can play an important role in global sustainability. Although more and more information is available to the public, consumers' choices and attitudes are influenced by price sensitivity, the awareness of new technologies and products, and the availability of substitute goods.

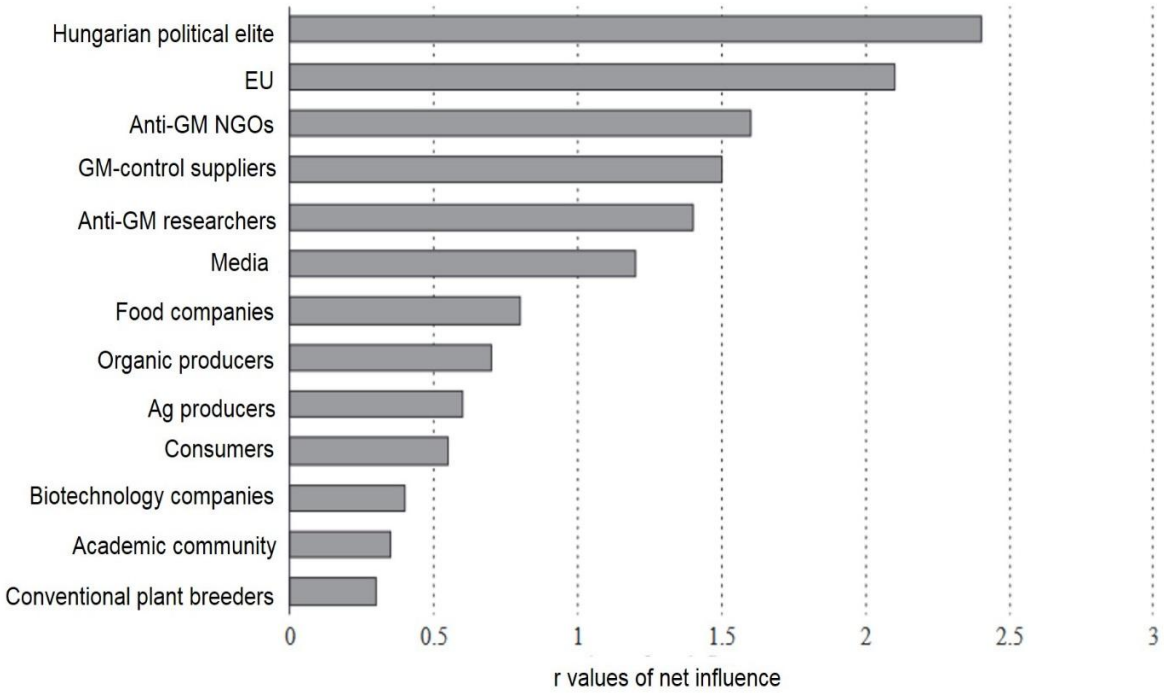
b) MARKET ACCEPTANCE/STUDIES

While several surveys point to the increasing health awareness of domestic buyers, other studies have shown that price continues to be the most decisive criterion for buyers in Hungary. In this regard, it is important to note that the replacement of GE soybean meal in livestock production with non-GE (conventional) one would make food prices 10-20 percent higher since there is no real or available protein feed alternative yet.

Regarding market acceptance, "there is an urgent need to change the communication strategy of pro-"GMO" scientists and other stakeholders instead of taking a defensive position; pro-active communication should be adopted," according to a study, a research article about "GM-regulation game" in Hungary (Popp et al. 2017, *International Food and Agribusiness Review*).



Different Players' Influence on GE Issues in Hungary, and Their Dependence on Influencing Factors (e.g. policies, public opinion, economy, market conditions, financial background, information, etc.; source: IFAMA)



Decisive Role of Different Groups Based on Their Influence on GE Issues in Hungary (source: IFAMA)

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

In Hungary, there is no commercial use of GE animals and clones for agriculture. Biotechnology for genetic improvement is mainly related to livestock breeding. The Agricultural Biotechnology Institute of the NARIC and the Biology Research Center of HAS are the most active research facilities in animal biotechnology. The Department of Animal Biotechnology at the Institute has three research groups such as the Applied Embryology and Stem Cell Research Group, the Ruminant Genome Biology Group, and the Rabbit Genome Biology and Bio-model Group. They focus on exploring the genetics of bovine diseases and work on the adaptation and development of genome editing tools for precision breeding. They are also involved in the functional characterization of pluripotent stem cells, and the bio-model group is working on models for biotechnological applications.

b) COMMERCIAL PRODUCTION

Hungary does not produce any livestock clones, offspring of clones, GE animals, or products derived from animal biotechnologies.

c) EXPORTS

Hungary does not export GE animals, livestock clones, or products from these animals including genetics.

d) IMPORTS

Currently, no legislation regulates the imports of semen or embryos from clones. Despite this fact, livestock clones or genetics from these animals are not likely imported into Hungary, according to top distributors. There are no imports of GE animals.

e) TRADE BARRIERS

One of the most sensitive issues in Hungary is the maintenance of the country's GE-free agriculture. GOH has an opposing stance to the use of GE crops and GE animals in agriculture. In this respect, all parties in Hungary hold an anti-GE position.

PART E: POLICY

a) REGULATORY FRAMEWORK

Genetic engineering, including animals, are regulated by the Act No. XXVII of 1998 on Biotechnology Activities (English version in effect until June 4, 2015; operative Hungarian version). The Ministry of Agriculture takes the lead and makes decisions regulating biotech issues. The NFCSO is the top government organization that handles technical aspects such as inspection and testing. The administrative body, that receives and evaluates GE applications for biotechnology experiments, is the Gene Technology Advisory Committee (in Hungarian).

Hungary has no country-level legislation related to the commercial use and trade of clones, their offspring, or products derived from these animals. GOH supports the EU's efforts to create common EU legislation and institutions governing animal cloning. Hungary is still a vocal opponent of any kind of GE plant or GE animal products.

b) INNOVATIVE BIOTECHNOLOGIES

In Hungary, many breeding and scientific institutions see the necessity and the potential of genome editing, and publicly support such technologies [See Part B e)].

c) LABELING AND TRACEABILITY

Hungary does not produce or trade in any livestock clones, GE animals and their offspring or products. Although laboratory animals are used in animal biotechnology experiments, they are not released. Therefore, there is no policy for labeling and traceability related to livestock clones and GE animals.

d) INTELLECTUAL PROPERTY RIGHTS

There is no specialized intellectual property legislation for animal GE products. Applications for animal patents can be filed with the Hungarian Intellectual Property Office.

e) INTERNATIONAL TREATIES/FORUMS

Hungary actively participates in the work of several multilateral and intergovernmental organizations such as the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health and Codex Alimentarius related to animal health and food safety issues. In general terms, the country is against GE animals, but there is no specified position on animal biotechnologies.

f) RELATED ISSUES: N/A

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The Hungarian public is quite critical of products coming from advanced production technologies. Animal cloning and food products made from cloned animals are unpopular and trigger concerns. The Hungarian population is skeptical of the necessity and usefulness of food made from cloned or GE animals. At the same time, public opinion is quite positive about animal biotechnology used for medical purposes.

b) MARKET ACCEPTANCE/ STUDIES

Public views on animal products connected with cloning and genetic engineering are expected to be similar to those held for GE crops. These products are likely to be rejected by most of the food retail chains in Hungary.

Although several biotechnology companies, university knowledge centers, and bio-incubators deal with research on animal biotechnology in Hungary, market surveys on sale and use of GE animals and clones are not available. Biotech companies could gain ground mainly on the market of veterinary molecular

diagnostics and marker-assisted selection.