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Genetically Modified Crops in Romania before and after the Accession of the European Union

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Abstract: Modern biotechnology entered the world science arena after 1972, and in less than 22 years the first genetically modified crop was placed on the market. The analysis of relevant biosafety portals and official and scientific documents was applied in this study to reveal positive and negative issues of the Romanian biosafety framework before and after the European Union (EU) accession. The success in cultivating highly productive GM soybean was rapidly embraced by Romania between 1999 and 2005. Before 2007, Romania was cited among the Mega Biotech Countries, with a cultivation of 87.500 ha. After the accession to the European Union, Romania stopped any GM crop cultivation. There was an immense effort to harmonize with the EU regulatory framework between 2005 and 2007. The monitoring system for GM crops has been in place since 2007. Public research on aspects of GMOs started before 1996 and continues to develop. The analysis of our results supports the idea that Romania is a perfect example of a country committed to embracing GM crop cultivation for 7 years, followed by almost complete phasing out of GM crop cultivation to comply with all requirements for EU accession in less than 1 year.

Keywords: biosafety; genetically modified crops; monitoring; register; Romania

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1. Introduction

Biosafety was coined for the first time at the *Asilomar Conference on Recombinant DNA* that took place in 1975 [1]. The main subject that triggered the scope of the conference was the discussion on risks associated with the use of a completely new laboratory technique, namely the recombinant DNA technology, which allows scientists to combine genetic information from different organisms. The major potential of this new technique that was globally recognized lays in its immense contribution to understanding cell functioning. However, to protect the researchers working inside the laboratory and accidental environmental contamination, major concerns were expressed about the full acceptance of using this technique in science. Biosafety was the term required to be defined based on the need to regulate biohazards that may arise from the use of recombinant DNA technology, in terms of genetic modification at the invitation of Paul Berg [2]. For the first time, balanced stakeholders at the global level, professionally involved in developing volunteer guidelines for biosafety risk management related to the recombinant DNA technology, were making use of a precautionary principle and envisaged for both facets of the same subject: benefits for science and risks towards human health and environment [3].

It was also for the first time that an impressive scientific community realized the need of acknowledging the use of recombinant DNA technology and the need to regulate containments' facilities to protect human health and the environment of potential risks associated to contaminating with the molecule of life. Stanley Cohen and Herbert Boyer as well as their co-workers were able, before 1973, to develop the first protocol for genetic modification of bacteria by using modified plasmids as vectors of transformation working

with naked nucleic acids [4]. Moreover, at the Asilomar Conference, scientists recognized that working with nucleic acids, to better understand its functions, enormously contributed to developing ideas for paving the way of success in this challenging scientific domain [5]. Therefore, the precautionary principle was voluntarily embraced by scientists attending this conference [6]. Isolating DNA and applying the recombinant DNA technique also created room for skeptical scientists who started raising questions about the real need of using this technology, and one impressive voice that emerged the following year was that of Erwin Chargaff [7].

It started a completely new era in biological sciences' development. The precautionary principle residing behind the Asilomar Conference, was set based on a scientific approach about how to integrate this new technology and not how to avoid it [8]. Later, in 1989, the term biotechnology was agreed during negotiations at an UN conferences for the first time and became part of the text of the Convention on biological diversity (CBD) adopted in 1992 at Rio de Janeiro [9]. The international-level regulation of modern biotechnology via the transboundary movement of living modified organisms was to be addressed later through the adoption of the Cartagena Protocol on Biosafety (CPB) to the CBD in 2000 [10]. After another 10 years, the subject of liability and redress following the introduction into the environment of living modified organisms was already an agreement text, negotiated and adopted as the Nagoya–Kuala Lumpur Supplementary Protocol to the CPB [11]. As far as can be seen, at the global political level, the precautionary principle defined in Asilomar in 1975 has changed in 1992 and will act more outside the containment conditions of a research laboratory, where science has limited or no access. In this regard, policy, administration and general public-use products and services provided by this technology applied the precautionary principle defined in Rio de Janeiro for a different scope.

Today, at the beginning of the third millennia, new scientific achievements into understanding how to use new technologies for copying and fully exploring the functions and structure of nucleic acids are also paving the way for developing Omics sciences [12]. Moreover, from modified vectors of transformation, we witnessed the complete synthesis of a bacterial genome creating the new domain of synthetic biology [13]. Furthermore, new achievements for the next 10 years are being described for synthetic biology, among which the creation of Clustered Regularly Interspaced Short Palindromic Repeats or CRISPR technology is being underlined [14]. Today, synthetic biology is a subject of negotiation on the highest political agenda to be included into the sustainable development goals for a new era of products and services that can be further provided [15].

It is relevant to underline that, at the global level, modern biotechnology as a concept is defined at a political level by the provisions of Art. 3 of the CPB as "the applications of in vitro nucleic acid techniques"; furthermore, a living modified organism (LMO) is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology". Knowing these two definitions agreed at the global level will imply that all products resulting from synthetic biology need to be regulated under the biosafety regulatory framework. It is worth underlining that the transformation methods known at the time of the adoption of the CPB (e.g., 2000) changed completely in 10 ten years since the discovery of gene editing technology. This is today the reason why, at the European level, as well as at the global level, all events obtained based on gene editing technologies are falling under the biosafety regulatory frameworks [16,17].

At the global level it is a continuously developed gap that is causing delays between top creations and discoveries in science and the transfer of technology into the industry, as well the development of new regulatory frameworks. In the latest case, these delays are due to the lack of tools and means of control and to the need to monitor for ensuring traceability and labeling down to the lowest level of public information and acceptance [1]. We may add that another relevant innovative scientific subject is related to the new era of m-RNA vaccines production for humans [18] and the transfer of this technology in crops for molecular farming [19,20].

On the matter of science progress in genetically modified crops, there are scientific publications dedicated to defining and describing biosafety measures to be applied in containment facilities [1]. However, for each of the countries embracing modern biotechnology products and services, there are a lot of adaptive measures to be accessed in the friendliest and cost-effective manner for developing capacities (i.e., human and financial resources, adaptive management).

The scope of this article is to discuss certain biosafety issues related to the current situation of Romania as a European Union (EU) country as well as a former Mega Biotech Country cultivating large surfaces of GM crops as products of recombinant DNA technologies. In this regard, certain capacity building subjects will be addressed, analyzed, discussed and underlined for biosafety domain starting from research down to the authorization and banning of GM crop cultivation in Romania in less than 2 years, between 2005 and 2007.

2. Materials and Methods

This article is based on the analysis of different official public web portals such as the following: the public database regarding genetically modified organisms (GMO) for EU countries [21], the Biosafety Clearing House [22], Romanian official documentation related to biosafety [23,24] and official portals for Agriculture authority including crop testing and registration into the National Official Catalogue for varieties and hybrids (NOC) [25]. In terms of complying with rules and procedures laid down by the EU biosafety regulatory framework for research into contained facilities (Directives 2009/41/EC), crops field testing (Part B of the Directive 2001/18/EC) and authorization for cultivation (part C of the Directive 2001/18/EC), this article will analyze constraints, need and gaps as well as gains for Romania starting with 1999.

3. Results

3.1. Modern Biotechnology Research

3.1.1. Containment Facilities for Research

The research at laboratory level in the domain of recombinant DNA technology was recorded in Romania after more than 20 years, as compared to developed countries from Western Europe. In 1975, as a coincidence following the Asilomar Conference in the US, the first laboratory for genetic engineering was established at the Institute of Biology at the Romanian Academy [23].

This was rapidly followed by the development of human resources for training and involvement in research projects with researchers from the Faculty of Biology of the University of Bucharest. However, the scientific publications for the next 20 years are not accessible to the public, as Romanian scientific journals are not recorded into the international scientific databases. The first study on the stability of gene constructs inserted in the genetically modified potato appears to be published only in 1996 in an open access journal [26]. The scope of the study was to analyze the effect of plant tissue type for a successful genetic modification mediated by plasmids related to *Agrobaterium tumefaciens*. The research team organized in Bucharest continue to study and publish scientific articles on other species, including *Atropa beladona* [27].

Before entering the EU, research in Romanian laboratories on the recombinant DNA technology expanded into the public arena only for microorganisms and plants and also for the consideration of minimal biosafety measures adopted by the Asilomar Conference. They were not imposed by the existing regulatory framework but rather were implemented on volunteer bases for the scope of science.

As an international political commitment to the UN CBD, between 2004 and 2006 in Romania, a UNEP-GEF project was implemented entitled "Development of the National Biosafety Framework for Romania" contract no. GFL GF/2716-01-4319 [28], as finalized with couples of official publications [23,24]. It was the first time that debates for information, education and awareness went out of the academic laboratories to authorities and

the general public on subjects related to rules and procedures laid down by the CPB [29]. During this project, the research infrastructure was also evaluated in the field of recombinant DNA technology and biosafety measures for containment facilities as well. At the end of the project, a report was published regarding the research capacity in the field of biosafety [23]. Based on this analysis, resulted that 49 research projects were funded by the Romanian Ministry of Research for the period 1998–2006, as stated by the public research institutions and universities. Moreover, Romania was granted funds for research on the topic of recombinant DNA technology under certain international programs such as: (1) the fifth European framework program for research and technological development (FP5), Poland and Hungary Assistance for the Restructuring of the Economy (PHARE); (2) the European Leonardo da Vinci and (3) the World Bank. A further 10 public research and education institutions have also developed research laboratory containment facilities for using recombinant DNA technology up to 2007. The research in the field of recombinant DNA technology increased after the EU accession, and the relevant results will be described under the chapter for field testing.

3.1.2. Registering Genetically Modified Microorganisms for Modern Biotechnology Research

For research at the laboratory level, in containment conditions, Romania had no biosafety framework before its accession to the EU and therefore no notifications regarding the use of genetically modified organisms were recorded [23,24]. Furthermore, all research realized in the country on recombinant DNA technology after 1975 strictly complied with the research legislative framework and followed the principle for *competing top priorities in science* as well as the principle *to continuously scientific up-date* [3].

3.1.3. Registering Genetically Modified Microorganisms for Modern Biotechnology Research after 2007

In 2006, the process of regulatory framework harmonization was started according to the former European Union biosafety regulation, namely the Directive 90/219/EEC on the contained use of genetically modified micro-organisms [30]. Thus, the Governmental Emergency Ordinance 44/2007 modified by the Law 8/2008 provides the first legal framework required to record any use of genetically modified microorganism as well as collections [31]. Based on the provisions of this regulatory framework, each research laboratory working with genetically modified organisms is requested to send a simple notification on the topic of their research for contained use to the Romanian competent authority (i.e., National Environmental Protection Agency) to be recorded in the National register. It is relevant to underline that the National register entered into force late, after 2017. In the meantime, the old EU Directive was replaced with the new EU Directive 2009/41/EC and changes were accordingly made in the Romanian biosafety regulatory framework. However, one research event is recorded, starting with 2017, for a public university in the field of GM bacteria and another one for private research in the field of GM fungi [32]. At the EU level, a register regarding genetically modified microorganisms open to the general public is not functioning yet.

3.2. Genetically Modified Crops for Field Testing

The timeframe for developing the biosafety capacity in Romania related to genetically modified crops followed the cultivation at a large scale of the Roundup Ready soybean (RR soybean), which started in the spring of 1999. The first biosafety regulatory framework entered into force later in January 2000 based on the approval of the Emergency Governmental Ordinance (EGO 49/2000), which mostly followed the same procedures as those provided by the European Directive 2001/18/EC adopted two years later. It can be considered that the lobby pressure from industry at the governmental level was very high to catalyze the starting of GM crop field testing and cultivation one year before entering into force the official regulatory framework [23].

We also need to underline that these provisional procedures laid down in the future EGO 49/2000 were implemented in the summer of 1999 as transient measures for fully implementing the biosafety regulatory framework. We further mention that, at the global level, starting with 1990, the world was really still skeptical about the success of crop cultivation for commercial purpose [33]. One of the main messages for supporting GM crops' acceptance for cultivation was the growing of the world population and the need to feed it [34].

To better understand the political framework, we mention that Romania as a signatory Party to the CBD since 1994 and a further Party to the subsequent adopted protocols was committed to also developing a biosafety capacity in the public administration due to a strong lobby of biotech industry. In this regard we underline that our country was involved at official governmental level in the process of negotiating and approval of the CPB to the CPB for monitoring the transboundary movement of any living modified organism (LMO) adopted in 2000, which entered into force later in 2003. Under these political engagements, for the period between 1999 and 2006, Romania was aware of the relevance of implementing further international obligations related to the transboundary movements of the GMOs, including GM crops that were taken under the international trade agreement [24].

Between 1999 and 2007, it was clear that a time overlap between, on the one hand the period of authorizing GM crops for field testing and cultivation and, on the other hand, the change of political orientation towards joining the EU biosafety regulation was one of the strictest regulatory frameworks in the world [35]. Politically, all administrative internal tasks were shared between two authorities—agriculture and environmental—and these pioneered the EU biosafety regulatory framework implementation before joining it in January 2007.

The entire biosafety system from field to fork was already described and analyzed before 2006 [23,24], and after 2007 for fulfilling the EU requirements [36].

In the case of Romania, there are two different periods: before and after the EU accession in direct connection to GM crops field testing and commercialization. Thus, before 2007 the monitoring system for GM crop testing or cultivation into the field for authorization was not implemented for biosafety inspection under the environment authority either under the part B for testing or part C for commercial cultivation of the EU Directive 2001/18/EC. After 2007, the entire regulatory framework changed and biosafety capacity was in place according to the EU requirements for field testing, as well as for biotech crop cultivation for commercialization [29,36]. Crop cultivation, monitoring field crops system, traceability and inspection are among the major procedures to be discussed below.

3.2.1. Notification System Regarding GM Crops for Field Testing before the EU Accession

Before 2007, for 7 years (i.e., between 2000 and 2006), Romania strictly followed the regulatory framework under agriculture authority for registering crop varieties and hybrids, including biotech crops. One relevant administrative step before the placing on the market of any crop variety or hybrid is related to the fulfilment of all requirements imposed by the International Union for the Protection of New Varieties of Plants (UPOV), a convention that Romania has been party to since 1961 as a communist country, and it renewed this cooperation in 2001 [37,38]. Thus, the placing on the market of any crop variety or hybrids in Romania fall under the agriculture authority with the support of the State Institute for Testing and Registering Plants Varieties (SITRPV). This institute is working at the county level as a network of County Centers for testing and registering crop varieties and hybrids where they are applying for these to be recognized at the global level of standard procedures [39]. The notification system under this procedure is generally closed to the public. Moreover, a biosafety inspection system for ensuring traceability, labeling or monitoring into the field was not in place before entering into the EU.

Based on the records published in the National Official Catalogue of varieties and hybrids (NOC), the first RR soybean event S2254RR) was tested in the field in 1999. At the same time, the EGO 49/2000 entered into force 1 year before adopting the Directive 2001/18/EC.

The Romanian biosafety legislation established the National Biosafety Commission (NBC) as a scientific forum comprising scientists, researchers and other personalities from public institutions with a major role in decision making. Based on the agreement tabled by the NBC, authorizations for GM testing in the field and for commercialization were approved by authorities responsible for the environment [40]. These allow for further testing before new RR soybean events are placed on the market of the other four international companies [22]. A maximum of 14 events was reached in 2004 a very important year from a political point of view, since that was the year that Romania concluded the negotiations for entering the EU (Figure 1). In 2005, the political pressure to enter into the EU created the political environment for starting to transpose biosafety regulation with high fidelity. Thus, in 2006 a complete list of all genetically modified soybean events that were permanently removed was published in NOC. This was the moment when Romania was proved to have the appropriate capacity to quickly change not only politically but also technically considering the adoption in 2007 of a completely new biosafety regulation covering also the monitoring of traceability and labelling as well as biosafety inspection and laboratories.

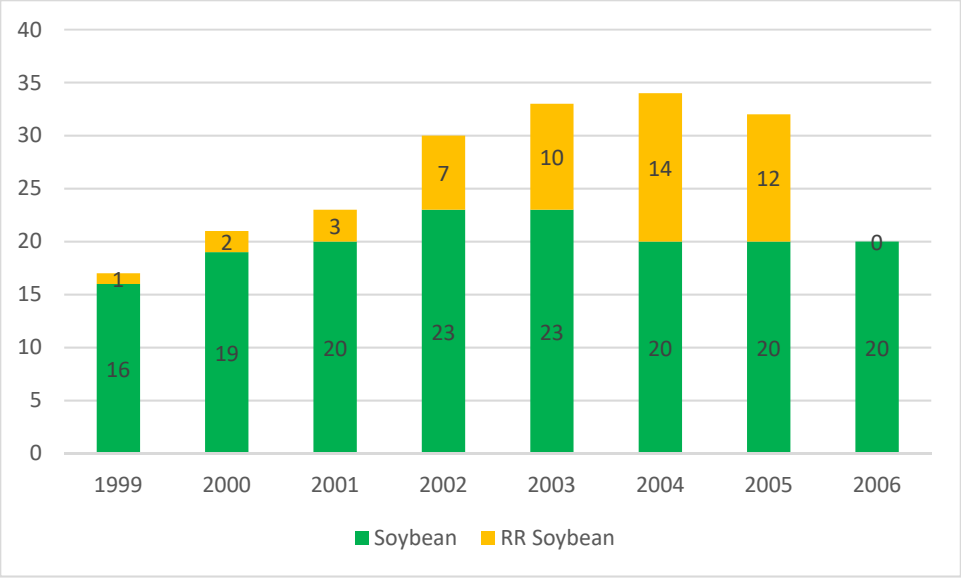

Figure 1. The dynamics of registering traditional soybean cultivars and Roundup Ready soybean (RR soybean) events into the National Official Catalogue (NOC) between 1999 and 2006. Graphic realized based on data collected from the published NOCs.

3.2.2. Notification System Regarding GM Crops for Field Testing after the EU Accession

After the accession to the EU, the entire biosafety system completely changed, as well as the notification types. By analyzing the scientific part of the total 59 notifications applied for in Romania between 2007 and 2022 and published into the European portal [21], certain results can be presented. All GM crops tested in the field in Romania were the result of two transformation methods applied in the research laboratory of industry outside the country, either based on *Agrobacterium* transformation [41] or based on particle acceleration, also known as gene gun or microprojectile bombardment, which was invented 5 years later [42]. No partnership was recorded to be concluded between the public research and the industry to develop and implement such methods and, furthermore, to be field-tested, or anything else, for commercial cultivation. Connecting these results to the laboratory public research, it can be seen that all projects developed inside these laboratories are based on the common scientific exchange with other research laboratories from abroad.

Starting in 2010, the Romanian Fruit Research and Development Station from Bistrita (i.e., located inside Transylvania) is the first public institution that continuously applied to test the GM plum tree for Plum-Pox-Virus [43,44]. The plot requested for testing GM

trees is no larger than 50 m^2. This GM event 'HoneySweet' (C5) was first produced based on mutually agreed terms convened between researchers from the US and France, followed by testing in certain European countries including Poland [45,46]. The first notification for field testing applied for by a public University came very late, in 2017, by the University of Agronomic Sciences and Veterinary Medicine of Bucharest. They are working on a genetically modified rice for a public-funded project that aims in the end to achieve a decrease in greenhouse gas emissions. The transformation event is produced in the University of Stockholm and tested in Romania [47].

By analyzing the notification from research centers, it can be considered that, at the European level, interest increased for new innovative methods for improving genetic materials in plants that trigger hopes for avoiding biosafety system or at least for simplifying it. In this regard there are at least two notifications recorded in 2020 for Spain that are dealing with the CRISPR technology [48] on 'K326' a GM tobacco cultivar. In both notifications, it is well specified in the title that the cultivar is self-pollinated in order to underline the almost zero risk of cross-pollination with other species.

As a general observation, regarding the plot surfaces request for field testing into the EU notification system, these range from 50 (e.g., for research use) to 5000 m^2 (e.g., for official catalogue registering).

The interest in applying the notification's dossiers into the EU biosafety regulatory framework is presented in Figure 2, where a proportion in between research and companies is presented. Some of the EU countries have no records (e.g., AT, BG, CY, EE, GR, HR, LU and MT), or very few (e.g., FI, IE, IS, IT and LT), but there is a group of countries where an impressive number of notifications were recorded for field trials, such as Spain followed by Germany, France, Slovenia and Romania.

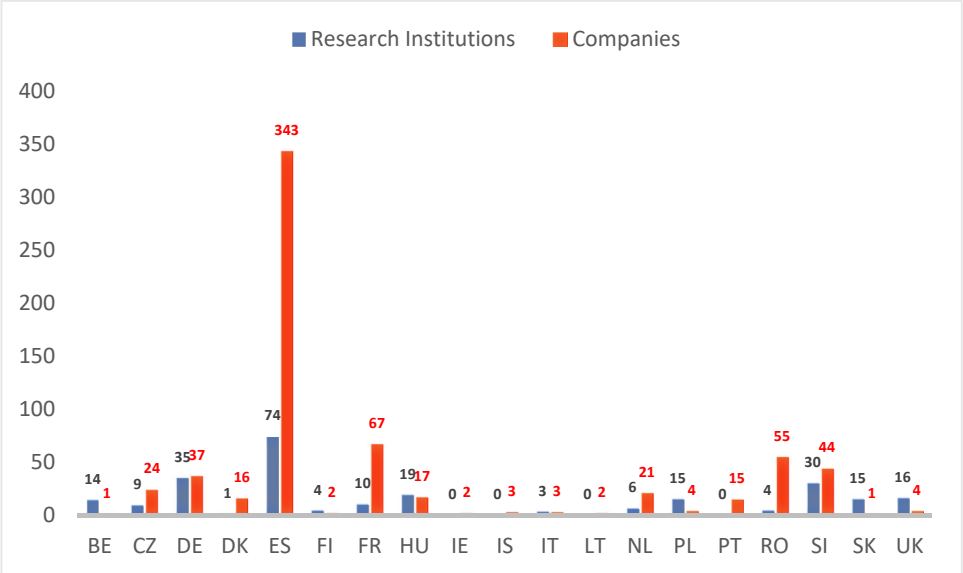

Figure 2. The number of notification dossiers applied for field testing GM crops in the EU members states. It is obviously that the largest number was applied in Spain with high interest in agriculture, followed by France, Germany, Slovenia and Romania. The EU countries without any record are not introduced into the graph.

By analyzing the timeline of the notifications' submission data it can be concluded that, after 2012, there was a major slowdown regarding interest in applying these types of notifications into the European countries. If, after 2002, crop field trials started to be relevant in certain countries, after 2014 the notifications number decreased (e.g., Germany, France). There are at least several causes, among which the main ones are related to the complex public acceptance policy of biotech crops inside the EU, as related to the strict implementation of the biosafety regulatory framework where a very important stake is

occupied by the highly expensive GM monitoring and very expensive taxes required for applying the dossiers for notifications.

- Genetically modified potato for field testing.

No notification for GM potato was recorded for Romania, even though it is well recognized that it is among the major crops cultivated in the country [49,50]. However, we mention that, starting with 1996, Romania lost the potato seed trade market due to phytosanitary quarantine (e.g., *Globodera pallida* and *G. rostochiensis*) [38]. This may be seen as a reason why no institutions either for research or company were interested in this regard.

However, for other European countries there are at least 110 notifications, the most recent being recorded for Sweden in 2021 for changing the resistance to pathogens. All three notifications are tabled by a research institution, and these were the subject of gene editing (the CRISPR technology). In this regard, researchers are looking to improve the resistance of crop species to specific pathogens by identifying and mutating genes that are working to increase their sensitivity to attack. Such mutations can be deletion, insertion or others and are seen to be similar to classical breeding, as no foreign DNA is introduced into the native one [51]. The progress in science is immense and has already reached a social landmark, where principles for sustainable development once taken for developing and implementing international regulations for the GM trade over the borders are seriously questioned [52].

- Genetically modified maize for field testing.

It is relevant to underline that in Romania a total of 47 notifications for genetically modified maize have been tested into the field, starting with 2007 up to the latest, in 2017. Among these, at least four notifications were not implemented at all, and another 14 have been shortened to 1 year of 3 or 4. We may mention also that all genetically modified maize hybrids or lines were of foreign origin. It is also obvious that the following four companies had particular interest in this matter: Pioneer Hi-Bred Seeds Agro SRL (18 notifications), Syngenta Agro SRL (15 notifications), Monsanto Europe SA (10 notifications) and Limagrain Central Europe SE (2 notifications) [23]. No notifications were applied for in Romania in the last 5 years (i.e., between 2017 and February 2022).

Maize is one of the most common GM crops for field trials all over Europe, a total of 425 notifications being recorded, starting in 2003 and ending in February 2022. As it was generally mentioned before, if in the beginning the modification was set with classical methods (i.e., modification with *Agrobacterium* sp. or gene gunshot), in the last few years we have been witnessing the use of innovative new gene editing technologies. In Romania no field trials are in place for GM maize subjected to the gene editing technology of today. As an example, the *Flanders Institute for Biotechnology* from Belgium has had such an interest since 2019, including in different crops such as maize and poplar, all making use of the CRISPR technology. What is relevant, for the new wave of GM field crop testing, is that the modification is inside the genome of the species itself. This time period, for almost 10 years between 2012 and 2009, creates the opportunity for science to be engaged with a completely new technology. As an example (also taken from Belgium), new CRISPR-TSKO technology for *Arabidopsis* sp. [53] was developed with infinite opportunities for developing new breeds by specifically associating susceptible genes (S-genes) with plant diseases [54].

3.3. Genetically Modified Crops for Authorizing the Cultivation for Commercial Purpose

As mentioned before, between 1999 and 2005 Romania authorized at the national level the commercial cultivation of GM soybean based on the first national regulatory framework for biosafety (i.e., before accessing the EU). In this regard the report for 2005 of Clive James clearly underlines that for 2005 a land surface of 87.500 ha (over 67.3%) was cultivated with GM soybean from a total of 130.000 ha, including Romania into the group of Mega Biotech Countries [55]. In terms of income, the same report specifies increases of over 31% for yield and over 20% in the farm net income. It is also claimed that during these 7 years

a total net income of 60.7 million dollars was recorded. Moreover, in weed control, the cost saving during the 7 years increased from 162.08 $/ha in 1999 to 239.05 $/ha. These financial advantages were very well underlined in all reports at international level, as edited by Clive James. In this regard, based on the evaluation of Environmental Impact Quotient (EIQ), a net reduction was calculated in the EIQ load from 34,016 in 1999 up to 192,025 in 2007, or a fall of 4%. Moreover, they calculated that 2% more pesticides were applied to non-GM soybeans. In terms of greening agriculture and exploring today's tools for decreasing CO_2 emissions, such concluding remarks may support not only the financial benefits but also the positive impact on the reduction of carbon emissions [56,57]. Today it is well recognized that Clive James founded in 1996 the International Service for the Acquisition of Agri-biotech Applications (ISAAA) to bridge industry to developing countries for facilitating the continuous crop biotechnology transfer [58]. It is one of the main mechanisms that may further work for supporting the continuous development of industrialized countries as well as international companies [59].

4. Discussion

We are approaching almost 100 years since the first genetic modification on *Pneumococcus* sp. was realized [60] by Frederick Griffith, who tabled for science as the subject of heredity for microbial pathogeny, devising a wonderful experiment by using heat, microbes and mouses. Oswald Avery and co-workers rediscovered the transformation process in 1944, based on other experiments, proving there to be no doubt that the hereditary molecules of life are nucleic acids and that they are the agent of genetic transformation [61]. In parallel, in plant science in the beginning of the century, in 1902 Gottlieb Haberlandt proposed the totipotency theory considering that each specialized plant cell may, under certain conditions, undergo metabolic transformations required for the formation of an entire plant [62]. This was just before George Schull obtained the first hybrids in maize, starting with 1905 [63], which proved to be the best solutions for supporting food security during the Green Revolution initiated and lead by Norman Borlaug after the Second World War [64]. In 1953 the DNA molecule was discovered, and Indra Vasil, one of the most prominent professors in plant biotechnology, published in 2008 one of the most comprehensive histories of plant transformation [8]. If it was in 1983 that the first events of transformation of plant cell using Agrobacterium tumefaciens were realized in the United States and Western Europe countries, it was after 1989 that such research took place in Romania, and not for developing transformation vectors. An increased delay in spreading the transformation vectors' construction for plant transformation techniques was recorded between the Western and Eastern European countries due also to constraints related to accessing technology and scientific literature as a result of differences in political regimes [65]. The continued transformation of the country was not in favor of further developing the research infrastructure [66]. According to the results of the national survey published in 2006, only after 2004 did the access of European and international funds for research largely contribute to an increase in the research infrastructure [23]. After the Romanian accession into the EU, the research infrastructure became more developed, but there is still a lack of transformation techniques development for plants. The biosafety measures to be adopted in the research laboratories were also delayed, as they were not well understood at the policy level for taking into consideration all provisions of the complete EU biosafety regulatory framework [23].

It can be considered that Romania supported the development of research capacity in the field of recombinant DNA technology, by applying the two major principles in developing sciences: competing top priorities and continuously scientific update. The country's close cooperation with Biotech Industry after 1999 developed new skills and competencies in research and further supported the maintenance of a good infrastructure for studying different transformation methods and GM crops. Before 2007, in any research facilities in our country, it was not possible to develop new innovative transformation vectors, but only to analyze their effects on different species recipient or under different

experimental conditions. After 2007, the research capacity (i.e., resources and infrastructure) were developed further and today it can be considered that synthetic biology can be also realized in any domain, at least in 13 research centers around the country [67]. One hundred and thirty-seven public research centers/laboratories in Romania are currently working with DNA. In the field of crop research, Romania is still in the beginning of its synthetic biology era. Moreover, a relevant gap is represented by the lack of Research Development Partnerships with Industry for patenting and transfer of technology. The best positioned research needs to be supported by such partnerships in order to access intellectual property rights and subsequent revenues for implementing patenting. Regarding the national Register for genetically modified micro-organisms, Romania complies to the EU rules, but these procedures are not well received by the scientific community as only two notifications have been recorded, considering that at least 13 national research laboratories are dealing with genetic modifications.

As mentioned before, capacity building for public authorities related to biosafety in Romania started early in 1999 (late compared to many other European countries), and it was mainly dedicated to field testing for authorization and commercial cultivation of RR soybean until 2006. The immense pressure of biotech industry at the central agricultural authorities widely opened the doors for GM crop cultivation. In this regard, a primary regulatory biosafety framework was in place due to the environmental authority working closely with the agriculture authority, as inspired by the draft text of the future EU Directive 2001/18/EC [22,23]. However, it took another 2 years for the Member States to finalize this Directive, and it took a further 2 years to entered into force after the Romanian biosafety legislation. It can be considered that it was a clear political commitment and positive signal from the Romanian authorities to hasten the introduction of field testing and cultivation at a large scale for GM crops. Human resources were already trained for developing administrative procedures and to test and further develop them up to the accession into the EU. Romania was the one Eastern European country to be highly committed to cultivating GM crops.

The field testing of GM crops in Romania before 2007 was not completely following the EU provisions from the Part B of the Directive 2001/18/EC, and no monitoring system was in place to be controlled at the level of the environmental authorities by creating a specialized biosafety inspection body and to support the development of a biosafety laboratory for testing GM crops, food or feed. These gaps became visible before the accession to the EU during the TAIEX seminar on biosafety that took place in 2006 [68]. Between 2006 and 2007, the entire biosafety regulatory framework was harmonized according to that of the EU, making a tremendous effort by taking into consideration the banning of the commercial cultivation of GM soybean as well as the continuation of applying notifications for field testing GM crops according to Part B of the Directive 2001/18/EC. We mention that, starting in 2007, a dossier was charged for a lump-sum that ranged between 1200 Euros to 1600 Euros per event of transformation, which became prohibitive even for big biotech companies.

After January 2007, all GM crops notifications for field testing were transmitted to the European Commission to be published and open to the public. In terms of developing biosafety scientific capacity in supporting authorities, there are at least eight laboratories for GMO detection supporting the biosafety inspection that are functioning today, all of them being accredited according to the EU regulatory framework. This proves that the biosafety scientific capacity for monitoring the food and feed market in our country was harmonized according to the EU rules and procedures [69].

If, before 2007, the GM cultivation was saving money in industry and it was considered as an El Dorado in terms of economic gains, after the Romanian accession this economic activity was banned for GM soybeans [70]. In 2007, Clive James underlined that Romania, together with other European Countries such as Czech Republic, Germany, Poland, Portugal and Slovakia, dramatically decreased their arable land cultivation with GM crops [71]. In the case of Romania as EU Member State after 2007, which is no longer

cultivating GM soybean due to EU authorization procedures, the report showed that only 350 ha of GM maize approved into the EU (NK601 and MON810) were recorded. Moreover, imports from Brazil in Germany, France and Netherlands increased for soybean oil. Spain is cited as the single EU country cultivating GM crops on a surface of over 75,000 ha (i.e., genetically modified maize) in 2007. In 2008, Romania reported a surface of 7146 ha for GM maize cultivation that progressively decreased [55]. The most affected from an economic point of view were GM soybean producers, with about 500 million Euro estimated in total losses [40]. It is considered to be one of the most impressive losses, socially and economically. This tribute was not foreseen before entering the EU, as at the political level no action was performed for negotiating transient measures in the biosafety domain for a certain period of time.

The Biosafety Commission organized before 2007 also has the administrative power to scientifically approve the cultivation of GM crops as having negligible risks on human health and environment, and authorities only agreed the authorization of the RR soybean cultivation. Among the major reasons for scientifically granting these authorizations, we may cite: that soybean has no wild relatives in the country. However, the Biosafety Commission organized after 2007 no longer has the authority to approve GM crop cultivation: they have only an advisory role in the authorizing process that is in place at the EU level and not at the national level.

The technical procedures laid down at the governmental level, and even at the EU, should be harmonized to peculiarities from the field in bottom-up and top-down approaches. If, at the political level, it was decided in 1999 that it should be important for the country to develop a biosafety framework in line with all international agreements in force at the time, it should be noted that the procedure should be pure technique. In this regard, this procedure should smooth the administrative tasks for ensuring the workability of the process.

For 7 years Romania implemented and further developed a routine process to implement a biosafety framework similar with that of the EU up to 2007. This is a considerable gain in terms of capacity building, the administrative personnel from agriculture and environment being more informed and educated regarding the gaps or the imperfections of the system in place. It can be considered that by joining the EU, Romania also successfully harmonized the EU biosafety framework as well as complied to all obligations as a country regarding the banning of GM soybean cultivation. However, over time, certain subjects became relevant for GMO traceability and labelling, such as the potential environmental contamination [72]. Again, in this regard respecting regulatory framework, for each GM crop farmers have to be supported by all farmers or householders that are not cultivating GMO crops; however, there are in the neighboring or in the vicinity of the plots, housewares in the entire chain food from the farm to fork. The level of education or poverty are only some attributes that impede the functioning of administrative procedures in such peculiar socio-economic environments. In this regard, illegal trade cases have already been recorded in Romania as well as in other European countries [73]. There are numerous cases where the entire chain of biosafety measures and procedures have been really difficult to be put in place, and each of the countries has their own peculiarities in terms of society, economy or environment.

The case of GM maize cultivation in Romania and other European countries may be the subject of new discussions. By analyzing the Fiscal Transcription of Transylvania of 1750, maize entered as a garden crop in all villages. In less than 200 years maize became almost as important as wheat, and our mission in the field of Sibiu County villages revealed the presence of at least 18 landraces of maize (i.e., Lăpușneag, Red of Moșna all located in Sibiu County) kept in the field due to the locals' taste for polenta and other traditional culinary dishes, as well due to their connectivity with their ancestors [74]. We further mention that the Carpathian arch creates a specific unique landscape for agriculture, that arable land plots are not larger than 10 ha and are fragmented by rivers, forests and other natural elements. In these areas, it will not be possible during the present time to implement

the full cultivation of GM maize, as the landowners are cultivating small plot areas mostly under 5 ha. In these rural areas exist a tremendous heritage of genetic resources kept by householders for decades and even more, being first recorded in 1928 [74]. Furthermore, by analyzing the database of Suceava Gene Bank, we realized that 5105 accessions are recorded, most of them originating from local populations collected from householders from all over the country [75]. This is the subject that was never taken into consideration in the GM crops' notification system: the potential to threaten indigenous and local genetic resources for food and agriculture, which should be protected under the Plant Treaty according to the provisions of Art. 5. Another gap in Romania, as well as in other Eastern European countries, is the lack of a strategy and action plan for implementing the Plant Treaty with the scope of protecting the natural heritage represented by genetic resources for food and agriculture to ensure food security in the long term. During this analysis, it was noticed also that, aside from production and financial revenues, another important factor is the analysis of GM crop cultivation impact on the traditional knowledge of local communities in hilly-mountain rural areas. This subject was never questioned during the older Romanian GM notification system.

5. Conclusions

Romania has 23 years of experience in developing, testing and implementing the biosafety regulatory framework for GM crops' field testing and commercial cultivation. This experience is of the utmost importance in underlining the robust experience of administrative staff working inside the biosafety system. However, the economic costs associated with the monitoring system during field testing and cultivation is detrimental to the final price of GM products. Moreover, the large number of landowners for small surfaces is making the implementation of all of the provisions that the EU biosafety regulations are imposing almost impossible. The development of new transformation events, such as gene editing technologies, will not further support the cultivation for commercialization of such GM crops inside the EU Member States according to the current regulatory framework. However, the main positive effect of genetic transformation is, and remains at, the research level and comes with all potential applications in confinement conditions. The Cartagena Protocol on Biosafety, as the major multilateral environmental agreement dealing with modern biotechnology, needs its terminology related to gene editing techniques revised in the near future for those instances when no genetic differences are recorded after the release of the new GM crops in the field. New threats such as climate change may increase the need for simplified administrative procedures to be accepted for the new generation of GM plants.

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