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Review of the regulatory framework on genetically modified food and feed in Albania: a policy perspective

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Abstract:

Recent developments in food production and processing technologies have considerably enhanced man's ability to provide larger quantities and a wider variety of products. However, the recent development biotechnologies has also significantly increased controversy and dispute over the use of food and other goods derived from genetically modified crops instead of from conventional crops, and other uses of genetic engineering in food production. The dispute involves consumers, biotechnology companies, governmental regulators, non-governmental organizations, and scientists. The article reviews the regulatory measures and approaches taken by the government of Albania to assess and manage the risks associated with the development, release and use of genetically modified foods in the country. The review and analyzes is made in light of the processes for harmonization of Albanian's food policies and its legal and regulatory framework with the EU legislation and Acquis Communautaires. It identifies several important legal and regulatory issues and proposes necessary measures and mechanisms to be put in place related to identification and protection of the public interest and increased ability of consumers to be informed about the foods they eat.

Keywords: food biotechnology; food safety; regulation; policy; genetically modified organisms.

1. Background on GMO development and debates

The genetic modification (GM), also known as "genetic engineering" or "recombinant-DNA technology" was first applied in the 1970's and has grown rapidly in the 1990s. The technique allows selected individual genes to be transferred from one organism into another, also between non-related species. It is therefore one of the methods to introduce novel traits or characteristics into micro-organisms, plants and animals. The products obtained from this technology are commonly called "Genetically Modified Organisms (GMOs) [11]. GMOs are officially defined in the EU legislation as "*organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination*" [8].

As an application of modern biotechnology, this technique has opened up new applications in health care, agriculture, food production and environmental. The most common types of GMOs that have been developed and commercialised so far are genetically modified crop plant species, such as genetically modified maize, soybean, oilseed rape and cotton varieties. Such varieties have mainly been genetically modified to provide resistance to certain insect pests and/or tolerance to herbicides [3].

The genetic modification techniques are recognized as providing significant benefits and they,

in principle, hold the promise of meeting fundamental food and health needs around the world. At the same time, this technology also raises important policy and societal issues (i.e. toxicity, allergenicity, horizontal gene transfer, antibiotic resistance, invasiveness and development resistance, biodiversity risk, sustainable use of natural resources, human rights, etc.) and has given rise to broad public debate, due to its potential risks for human health and the environment that differ from their conventional counterparts [6]. From the earliest days of the development of GMOs, policymakers around the world have focused on how to use and develop its potential while adequately addressing the many issues raised by the new technology. Indeed, regulation of GMOs has always been a central part of the general GMO debate. International law constitutes one of the ways in which such concerns are operationalised beyond national level. However, great diversity exists between countries with respect to their capacity to develop, apply, and regulate the new biotech products and services. These differences have become a source of tension in international economic relations [6].

GMOs have now been on the market for 18 years, and some GM crops varieties have reached nearly 100% market domination in a number of countries. According to the ISAAA's 2012 annual global status report, the extraordinary growth trend in the global uptake of GM crops continued during 2012. This year's new record of 170.3 million hectares of

planted GM crops represents a 100-fold increase from the 1.7 million hectares planted in the introduction year 1996. Moreover, during the past 18 years, the accumulated worldwide hectareage has grown to 1.7 billion ha – equivalent to an area 50% larger than the total land-mass of the US or China. Despite these impressive growth numbers, the annual increase rates seem to be slowing slightly. After nearly a decade-and-a-half of double digit growth numbers, in the last two years this have slowed to respectively 8% and 6% annual increase. Perhaps this is indicative that the commercialization peak has nearly been reached and market saturation may be in sight, unless new crops and novel traits (perhaps more consumer-benefit oriented) are developed. [1]

Europe continues to be largely a no-go area for GM crops, with only a rather symbolic total of 129,071 ha of GM maize planted in 2012 throughout the entire continent, of which 90% in Spain, and marginal plots in Portugal, the Czech Republic, Romania and Slovakia. Moreover, some 10 EU Member States have so-called precautionary ‘safeguard bans’ against growing GM crops, Norway has a restrictive regime and Switzerland has a full moratorium in place [1]. Despite the debates and reluctance to GMO production within EU territories, EU remains a one of the largest consumers of products from agricultural biotechnology, mainly in the animal feed sector. The EC continues to wrestle with a regulatory structure that is subject to political decision making rather than being based solely on sound science. As a result, the EU animal feed, livestock, and poultry industries are at constant risk of losing necessary access to world oilseed and protein markets. This challenge is growing as the EU falls further behind other countries in research, development, regulation, and commercialization of agricultural biotechnology events.[5]

2. Nature of regulatory instruments addressing biotechnology

The majority of countries have already adopted some form of regulatory framework related to biotechnology and biotech product, although significant differences exist in the kinds of regulatory approaches countries adopt on biotechnology and biotech products, including GMOs. However there seems to appear two broader groups of approaches. On one hand the group of countries led by the USA that have adopted a regulatory approach closest to a *laissez-faire* model, where biotechnology products are generally considered to be as safe as conventional food and that pre-market approval was only necessary under certain conditions [6]. On the other had the EU and various other countries have adopted a stricter approach, with obligatory prior assessments and

authorisation of the products before being put on the market [7].

The central issue in the GMO debate concerns food safety and environment safeguard. But from a legal viewpoint, the issue involves two parts: food safety and food labelling, which is known as the food safety and consumer right-to-know dichotomy. To make a clear distinction between two perspectives, the European approach to this dichotomy differs from the unitary approach taken in the USA. In other words, in Europe you do not have to believe GMOs present a serious food safety concern or have evidence of the health risk to argue that consumers have a right to know about the processes and products used in producing their food. This is the source of the EU's "novel food" regulations and the basis for their efforts to prevent the sale of GMO products without adequate labelling. USA does not treat the two issues as distinct - their food labelling system is only designed to address food safety concerns, no matter how the food was developed. Thus USA does not have a food labelling system based on a consumer's right-to-know, and their system involves a consumer's right-to-know only the minimum the law requires (or from the perspective of a food processors or marketers, a right not to tell consumers every little detail about the food they eat). [4]

The core elements for regulation on biotechnology include laboratory control, environmental release, risk analysis, and socio-economic considerations for pre-marketing authorization; also subject to regulation are labelling, traceability and other monitoring measures for post-approval surveillance. Risk analysis covers risk assessment, risk management and risk communication. Precautionary action is also provided for in the risk analysis and regulatory systems of most countries. These measures are expected to allow for a high level of protection of human health, environment and eco-system. These measures at the national level are illustrative of a global trend, which has led to the adoption of several international instruments to address the adverse effects of GMOs. Despite the differences, the measures being taken by most countries reflect a common view that “living modified organisms” (LMO) are not the same as their non-GM counterparts, and that they have characteristics which inherently require the assessment of human and environmental risks. [6]

At the international level, there is no single comprehensive legal instrument that covers all aspects of biotechnology or biotech products. However, a number of existing international agreements are directly relevant to biotechnology. Many international organizations have also undertaken the task of setting standards, in particular dealing with the impacts of biotechnology on health, the environment, agriculture, trade, ethical and socio-economic aspects.[11] These

organizations include the Codex Alimentarius, the World Health Organization (WHO), United Nations Food and Agriculture Organization (FAO), the United Nations Environmental Programme (UNEP), the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the United Nations Industrial Development Organization (UNIDO), etc. [6]

Cartagena Protocol on Biosafety (BSP) to the Convention on Biological Diversity (CBD) is the main international instrument for regulation of biosafety and GMOs. The Protocol was opened for signature in May 2000 and entered into force on the September 2003. Until 2012, 164 countries and the EU have ratified or acceded to the Protocol. Albania ratified this Protocol in 2004 [7]. In October 2012, the Conference of the Parties to CBD serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety convened for its sixth meeting (COP/MOP 6), in Hyderabad, India. A supplementary protocol on liability and redress was approved by Parties at COP/MOP-5, in October 2010, as the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety. A total of 51 States have signed the Protocol, but only 12 had ratified it by March 2013, including the European Union and Albania [1]. In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, the Protocol aims to contribute to ensuring an adequate level of protection in the field for the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, while also taking into account risks to human health. In addition, parties to the Protocol shall ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account the risks to human health. The Protocol also allows parties to take action that is more protective of biodiversity than that called for in the Protocol, provided that such action is consistent with the objective of the Protocol and is in accordance with Parties' obligations under international law. The EC legislative framework on GMOs is one example of such strict regulatory measures. The Protocol can be seen as the most comprehensive and important international agreement on biotechnology, but by no means the only one. Other international agreements also operate in parallel with the Biosafety Protocol in the development and formation of international law on biotechnology.[6]

These biosafety instruments address primarily the risks posed to the human health and environment when GMOs are released into the environment either in small scale during the research or when released for commercial purposes. Food safety instruments focus

in addressing the risks posed to humans by genetically modified foods. The general goal of these instruments is to minimize risks to humans presented by GMOs or their products used as foods themselves or as ingredients in food. Especially in EU, such instruments tend to cover the entire human food chain from "farm to the table" [3]. Accordingly, most of the EU instruments do make no distinctions between regulating food or feed derived from GMOs when feed could find its way into the human food chain. However, despite the attempt to approximate the Albanian legislation with the EU legislation and *acquis communautaires*, the Albanian GMO instruments are still mostly focused human food safety, while animal feed safety is vaguely mentioned in various pieces of legislation.

Related to consumer protection, labelling of food and feed end products resulting from genetic engineering, remains the primary area addressed by Albanian instruments. In general these instruments are designed to: (i) protect the consumers' right to know and the right to make informed choices and (ii) ensure fair trade practices to ensure that consumers are not victimized by false or misleading claims about a product.

The main existing instruments applicable in Albania can be divided into two groups: (i) the strongly binding legal acts, such as national laws food safety and biodiversity protection as well as some key international conventions and agreement approved by Albania; and (ii) the non-binding "soft" law type documents, such as various non-binding national and international codes of practice and technical guidance documents.

At national level the legal systems applying to modern biotechnology in the biosafety, food safety and consumer protection areas vary from country to country. Perhaps the most obvious distinction is that a country can have specific laws on GMOs or it can rely on existing non-specific laws that apply through an expanded interpretation [3]. Among these two broad approaches, Albania in these recent years has opted for the second approach, by not developing a well distinct legislation on GMOs but addressing them on various laws that apply partially and generally through an expanded interpretation. However, gaps remain both in terms of uncovered topics and agencies responsible (overlaps and mismatches) to address them. In addition the Albanian legal instrument is "product-oriented", in the sense that it is the risks posed by the end-product that triggers the review, while less attention is given in the laws to the techniques used to produce the end product.

With its second generation of instruments (e.g. the latest Food Law (2008) and establishment of the National Food Authority), Albania has adopted a step-wise approach, by focusing its effort, resources and capacities in the most critical elements such as risk

assessment and risk management. Although this approach seems logical at the current situation of limited resources, it also presents some of its risks if not well managed. While resources could continue to be limited in Albania (at least in short to medium term), the knowledge, experience and capacity developed and dealing now with most needed steps, they could be adapted and shifted to other areas needing attention as the circumstances present themselves in the coming periods. However, in order to be effective, such a step-wise approach needs to be built in and carefully tied to a suitable regulatory framework that can also be adapted as the circumstances may change during the time.

3. Albanian GMOs legislation and its approximation with EU legislation

While European Union has established an extensive legal framework on GMOs since the early 1990s, Albania has only recently started to develop its regulatory framework related to biotechnology (since 2000) and even more recently (since 2005) related to GMO products for foods and feed destination. These developments in Albania correspond both with the intensification of countries EU integration effort as well as with the new development in EU related to GMO legislation. Starting from 2000, the entire corpus of European GMO legislation has been amended, leading to the creation of a whole updated EU legal framework on GMOs [11]. The EU legislation on GMOs has three main objectives: (i) to protect health and the environment (a food product derived from a GMO can only be put on the EU market after it has been scientifically assessed according to the EU procedures if it presents risks to health and the environment and duly authorised); (ii) to ensure the free movement of safe and healthy genetically modified products in EU; and (iii) to ensure the freedom the freedom of choice for consumers and farmers.

The EU legislation on GMOs is very extensive and ten most important EU legal acts related to GMO include: Directive 2001/18/EC (Deliberate release into the environment of GMOs); Regulation (EC) No.1829/2003 (Genetically Modified Food and Feed); Regulation (EC) No 1830/2003 (Traceability and Labelling of GMOs); Regulation (EC) No.1946/2003 (Transboundary Movement of GMOs); Regulation (EC) No.65/2004 (Unique Identifiers for GMOs); Decision 2004/204/EC (Registers recording information on GMOs); Regulation (EC) No 641/2004 (Implementation of Regulation (EC) No.1829/2003); Regulation (EC) No.882/2004 (Official controls for feed and food law); Recommendation 2004/787/EC (Guidance for sampling and detection of GMOs); Regulation (EC) No.1981/2006 (Implementation of Article 32 of Regulation (EC) No.1829/2003) [11].

However, the following are two main legal instruments that set the GMOs specific regulatory framework:

- **The Directive for the deliberate release of genetically modified organisms into the environment** (the Directive 2001/18/EC) aims to protect human health and the environment. It outlines the principles for, and regulates the deliberate release of GMOs into the environment in the EU. It has replaced the first EU Directive on GMOs (the Directive 90/220/EEC, adopted in 1990) and covers two major types of GMO activities: (i) the experimental release of GMOs into the environment; (ii) the placing on the of GMOs in the market.
- **The EU regulation for genetically modified food and feed** (the Regulation (EC) No 1829/2003) outlines the principles for, and regulates the placing on the market of food and feed consisting of, containing or produced from GMOs. It aims to: (i) to protect human and animal health by introducing at EU level a safety assessment of the highest possible standards, before any GM food and feed is placed on the market; (ii) to have in place harmonised procedures for risk assessment and authorisation of GM food and feed that are efficient, time-limited and transparent; and (iii) to ensure clear labelling of GM food and feed in order to respond to consumers' concerns and enable them to make an informed choice.

The Albanian legislation about GMO products remains yet very limited, consisting mainly of ratified international conventions and protocols and limited number national laws referring briefly and generally to GMOs products in various articles. The main laws that are currently regulating GMO products are the "Food Law" (Nr.9863, dated 28.1.2008) and the Law (Nr. 9199 dated 26.02.2004) "On the production, processing, certification, and marketing of "Bio" products". However, this last law, although mentions the GMOs, it does not focus much on them, as the object of the law – as can be noted from the title – is the "Bio" or organic products [7]. In addition, in the context of EU legislation approximation, a large package of environmental laws were approved by the Albanian parliament since 2002, some of which include here and there some clauses on various biosafety elements and might be closely linked with the biosafety legal framework (e.g. the law "for protection of environmental", the law "for protected areas", the law "for environmental impact assessment", etc.). However none of them seem to have taken the subject very seriously and could only be considered a good attempt.

In Albania, the key legal act that tends to regulate the use of GMOs in food and feed products is the Food Law. This law consists of a general framework

act and defines the main regulatory elements related to food and feed products. This law provides a framework for Food Safety and Consumer protection. Major issues regulated within this law include: the handling of risks; import and export issues, particularly the control of imported food; approval and registration of establishments; obligations of the food business operators; issues of novel food and also feed; labelling and advertising of food; food control and authorization of control laboratories; crisis and emergency management; and organizes the State bodies on consumer protection.

The attempts to initiate regulation of GMOs mostly within articles related to placing of new products in the market and labelling. However, it treat GMO food and feed in very general terms and almost equivalently to non-GMO products, while transferring the responsibility to the Ministry of Agriculture for further development of the necessary by-laws for specific elements related to the risk assessment and risk management. Such by-laws are still to be developed and they are now also an urgent requirement by the EU integration and legal approximation processes. The key issues identified with the current GMO regulatory framework which need to be addressed as soon as possible are presented below.

There are differences in the determination of what GMOs are, and indirectly what they are not. The Albanian Food Law defines GMOs as “*Genetically modified organisms*” are live organisms that possess a new combination of genetic material, produced through the use of modern biotechnology”, while the EU definition of GMOs as laid down in article 2 of Directive 2001/18/EC is: “*an organism in which the genetically material has been altered in a way that does not occur naturally by mating and/or natural recombination*” [8].

The Albanian legislation does not make it clear enough if placement of GMO products in the market does need a prior assessment and authorisation and how that process should happen. This is an important issue to be tackled, not only for the internal market but especially in the context Albania’s EU integration process and attempt to foster its exports to the EU market. In this respect, Albanian legislation need to be harmonised with the Regulation (EC) No 1829/2003 which includes as a general requirement that a GMO food/feed cannot be placed on the EU market unless it is covered by an authorisation granted according to rules and procedures set forth in this Regulation. Accordingly, in EU, all products from GMOs must be considered just as safe as their conventionally derived counterparts according to tests using the most advanced knowledge and technology available. If this isn’t the case, the GMO will not receive authorisation.

The Albanian regulatory system has long to go to reach such levels of compliance.

The Albanian legal framework related to application for placing GMO on the market and related risk assessment is not yet fully developed.

In line with the EU regulations and procedures in force, Albania still needs to develop its by-laws and regulations for establishment a more harmonised, efficient, time-limited and transparent procedure for all applications for placing on the market of GM food/feed products (whether they concern the GMO itself or the food and feed products derived there from). The regulatory system developed during the last year in EU (based on the Regulation (EC) No 1829/2003) allows operators to file a single application for the GMO and all its uses (including possibly cultivation), that a single risk assessment is performed and that a single authorisation is granted for a GMO and all its uses (cultivation and/or importation and/or processing into food/feed and/or industrial products), in line with the so-called “one door - one key” principle [11].

The technical and professional capacities and independence of institutions responsible for GMO risk assessment and management need to be further strengthened.

Albania has good progress on streamlining the food safety control responsibilities with the establishment of the National Food Authority and Institute of Food Safety and Veterinary as the two key institutions directly responsible for the majority of the food safety matters in Albania. However, it significant effort are still needed to strengthen its professional and technical capacities as well as further development and modernisation of its laboratories. Based on the EU practices, where the GMO authorisation process is based on an independent Community risk assessment carried out by the EFSA, Albania should further increase its effort towards fostering the independence and professional capacities in GMP risk assessment processes;

Although the Food Law requires mandatory GM labelling of GM food and feed products (based on the content of GMO and GMO elements contained), such labelling requirement should be further improved and harmonised with EU requirements. Labelling is the most important tool for ensuring the freedom of choice, a freedom that is required by consumer protection laws both in Albania and EU. For all food and feed products consisting of or containing GMOs, the Albanian Food Law (being in line with the EU requirements) requires that operators indicate on a label that “this product contains GMOs” or “this product contains GM... and specify name of organism(s)”. However, it do not specify if they should be based on the detectability of genetically modified DNA or protein in the final products and do not set any trace threshold for the unavoidable presence of GM material in food or feed.

The EU legislation exempted from GMO labelling and traceability requirements when conventional products contain unintentional traces of GMOs below 0.9%. [11] EU rules require that whenever GMOs are intentionally used in a food product, it must be clearly stated on the label. Every consumer is thereby entitled to make an informed decision. The EU requirements include mandatory GM labelling for GM food and feed, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product (while before 2003, EU regulatory requirements on GM labelling were based on the detection of DNA or protein resulting from the genetic modification) [11].

Albania would need to develop an effective traceability system for products which consist of GMOs or which contain GMOs and food products derived from GMOs and which are or will be authorised to be placed on the market. The EU traceability rules (EU Regulation 1830/2003) make it mandatory on the operators concerned (i.e. all persons who place a product on the market or receive a product placed on the market within the Community) to be able to identify their supplier and the companies to which the products have been supplied. Such a system is still to be developed for GMO related products and is still not yet fully effective also for the conventional products.

Albanian has yet to develop its requirements related to testing and validation methods for detection of GMOs necessary for the approval process. Such requirements need to be developed as soon as possible, as the articles on placing GMO food and feed products on the market have already entered into force in January 2014, and both the operators and the competent public authorities need them to process applications. Submission and validation of GMO detection methods are an integral and important part of the EU regulatory approval.

As regards the regulation of the release of GMOs into the environment and ensuring the coexistence, be it for experimental purposes (field trials) or for commercial purposes (placing on the market), **Albania has still to make significant efforts in development of appropriate legislative acts and institutional capacities.** As mentioned above, various environmental laws mention GMOs but only on general terms while applicable rules and procedures for authorisation procedure for experimental releases, authorisation procedure for commercial releases, transboundary movements of GMOs as well as ensuring coexistence measures are still to be developed. Such co-existence measures in areas where GMOs are to be cultivated in Albania is to avoid unintended presence of GMOs in other products, prevent potential economic losses and impacts of the admixture of GM and non-GM crops, including organic crops.

Albania has ratified the Aarhus Convention which is an important source of principles from which the national level lawmakers could draw. One of such important principle concerns public participation in decision making related biosafety and GMOs on food and feed. Although not happening yet, this participation is even more important in Albania as the first generation of laws has started to be developed and which will set the foundations of how the GMO matter will be addressed not only now but also in the future. While consumer protection instruments examined above do not seem to promote public participation per se, they should at least promote access to information (as a cornerstone of public participation) in order to enable consumers to make informed choices and to prevent fraud as well as help to realize the benefits and avoid the risks of modern biotechnology.

Conclusions

The concept of Biosafety in Albania is still new and the development of the regulatory framework related to both placing of GMOs food/feed products on the market and the release of GMOs in the environment is significantly lagging behind. The approximation of countries legislation with the EU legislation and *Acquis Communautaire* is now a very important and need to be addressed as soon as possible. The key areas to be improved include, but not limited to, five major directions: (i) approximation of the legislation with the EU legislation related to the placing of GM food and feed products in the market (including risk assessment, risk management, authorisation and registration, testing procedures, labelling and ensuring the right of customers and farmers to choose, etc.); (ii) clarification of roles and responsibilities of various institutions involved in addressing and management of GMO related matters, including a segregation of responsibilities to improve efficiency and avoid conflict and interest and fraud; (iii) improvement of professional skills and technical capacities of the responsible institutions, including establishment of reference laboratories and training of staff in application of modern procedures to sampling and testing as well as other important aspects of the risk assessment and risk management; (iv) strengthening law enforcement; and (v) improving public participation and information.

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