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MODERN MANAGEMENT CONCEPTS FOR THE PRODUCTION OF BIOLOGICAL PRODUCTS AND GENETICALLY MODIFIED ORGANISMS AND FOOD

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Abstract: *This report reflects the positions they hold the European Union (including Bulgaria) to conduct organic agriculture and production of genetically modified organisms and genetically modified foods in terms of ensuring the safety of food and feed. The theme of production and markets for the implementation of genetically modified organisms and genetically modified food is particularly relevant to this point in terms of: the ongoing European agricultural policy (including Bulgaria), organic production, food security, hunger worldwide global economic crisis and others. From this position formed two different views regarding the concept of production and use of genetically modified organisms and genetically modified foods and concept of organic production.*

Keywords: *organic production, genetically modified organisms (GMOs), genetically modified foods (GMFs), European Union.*

1. Introduction

In 2009, the area occupied by organic farming in the European Union amounted to 8.6 million ha, representing 4.7% of utilized agricultural area in EU-27. For the period 2006-2009, average annual growth rate in the European Union - 15 is 7.7% and 13% in the European Union - 12. In 2008, organic agriculture employs around 197 000 farms (1.4% of all farms in the EU-27). In 2007, the sector of organic production represents 2 per cent of total expenditure on food in the European Union - 15.

The legal basis for organic food production and delivery of organic farming in European Union is European legislation and in particular:

- Council Regulation (EC) № 834/2007 of 28 June 2007 on organic production and labeling of organic products and repealing Regulation (EEC) № 2092/91 Regulation (EC) № 834/2007 and its implementing regulation;

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- Commission Regulation (EC) № 889/2008 of 5 September 2008 laying down detailed rules for implementing Regulation (EC) № 834/2007 on organic production and labeling of organic products with regard to organic production, labeling;
- Regulation (EC) № 1235/2008 of 8 December 2008 laying down detailed rules for implementing Regulation (EC) № 834/2007 as regards the import of organic products from third countries.

2. Scope of the Concepts of Organic Farming and Genetically Modified Organisms and Food

The dynamic development of the organic production need to focus on three main areas [1]:

- scope of the regulation on organic food, prepared in catering and the possible inclusion of textile and cosmetic products in it.
- ban the use of genetically modified organisms, including the availability of products not produced by genetically modified organisms, a statement of the seller, the feasibility of specific limits on eligibility and their impact on the sector of organic production.
- operation of the internal market and control systems, evaluation and more specifically, whether established practices didn't lead to unfair competition or create barriers to production and marketing of organic products.

Scope of the Regulation on organic food, prepared in catering and the possible inclusion of textile and cosmetic products in it - Catering sector (public and private) includes very different companies - from small restaurants to large chains catering in the preparation of biological products – including restaurants, hospitals, canteens and other eating establishments. It is now subject to European Union rules on hygiene and food labeling, which is prohibited under the labels associated with the production methods to be used in a manner which misleads the buyer [2].

Do you need catering activities are subject to the regulation of the European Union? Limited impact on trade, because the local nature of organic production, creating preconditions for increased complexity of activities catering to the European's Regulation. With regard to organic certification, the question arises whether products such as beeswax, essential oils, or materials may be licensed in accordance with the Regulation, if such products are manufactured according to requirements provided therein.

Recent years have seen significant growth markets for textile and cosmetic products on which there is reference to organic production. Whether the production of organic products of agriculture outside the scope of the current Regulation would put at risk the credibility of the term "organic" as it applies to food and you have basic regulation be changed?

The position of the European Union in respect of textile products is reflected in legislation fiber names and labeling and not to production methods [3]. In this respect, to simplify and improve the regulatory framework in the sector is revised Regulation (EC) № 1007/2011 of the European Parliament and the Council of 27 September 2011 on textile names and related labeling and marking of textile products with respect to their fiber content. Under the voluntary scheme of the European Union Eco-label [4] established criteria for textile products [5]. In the case of cotton - if 95 per cent of the product are made

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from organically grown cotton, the term "organically grown cotton," under this scheme is acceptable.

Raw materials of agriculture such as vegetable oils and plant extracts found in many cosmetic products. In this regard, through its Community legislation regulating the use of claims on cosmetic products [6], which allows legislation to extend protection to the use of the word "organic" to include the textile and cosmetics. Developed common criteria for all types of statements used in respect of cosmetic products, including "Natural and organic" [7].

Prohibition of use of genetically modified organisms, including the availability of products not produced by genetically modified organisms, a statement of the seller, the feasibility of specific limits on eligibility and their impact on the production of organic sector - The dynamic development of the organic production need to focus on one of its fundamental principles, namely the prohibition on the use of:

- Genetically modified organism is an organism (except man), whose genetic material has been altered;
- Products produced from genetically modified organisms (for example oil, starch or protein from genetically modified corn or soybeans, which do not contain genetically modified DNA - Deoxyribonucleic acid) [8] or
- Products produced by genetically modified organisms - food and feed additives (for example vitamins, amino acids) and means supporting the processing (for example enzymes) produced by genetically modified organisms (for example like bacteria and fungi) [9].

The concept for the production of genetically modified organisms and genetically modified food is incompatible with the concept of organic production and consumer perception of organic products. That means that genetically modified organisms and products produced from or by genetically modified organisms should not be used in organic production for food, feed, substances assisting processing plant protection products, fertilizers, soil conditioners, seeds, planting material, microorganisms and animals, except for veterinary medicinal products (for example vaccines, etc.). Whether in practice this is possible?

Since biological systems aren't isolated from the total production chain, low and random presence of genetically modified crops in non- genetically modified farming systems such as organic farming can not be ruled out completely during cultivation, harvest, transport, storage and processing. Sources of possible mixing of genetically modified organisms in seed impurities, cross pollination samoraslyatsi and practices of collection and storage of crops. Another possible source is food and feed additives that are commonly produced from or by genetically modified organisms.

Unintentional traces of genetically modified organisms referred to in Regulation (EC) № 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed [10], where certain common threshold for labeling of 0,9 per cent for the adventitious or technically unavoidable presence of genetically modified organisms or products of genetically modified organisms (such threshold is not set seed).

I justified the high requirements are placed in front of the producers of organic produce and foods in terms of production inadvertent presence of genetically modified organisms? Intentionally or not traces of genetically modified organisms in general threshold 0.9% of the production chain of agricultural production, food and feed supply it possible to produce organic products and foods? Moreover, when the seed is not specified threshold for the presence of GMOs.

The regulation clarifies that the general rules for the unavoidable presence of genetically modified organisms. It introduces specific provisions on liability of organic operators to avoid the presence of genetically modified organisms in organic products. Guiding principles for the lowest possible accidental presence of genetically modified organisms in organic products and to avoid undue restrictions and additional burden on biological operators.

Overall experience with the prohibition on the use of genetically modified organisms - Feed defined as a risk for random presence of genetically modified organisms (available under very low 0.1% down for soya and maize). Opinion of 2009 to the Council and Parliament on the coexistence of genetically modified crops with conventional and organic farming [11] is that genetically modified crops didn't cause visible damage to existing agriculture, which is not genetically modified.

In addition, on July 13, 2010 the Commission published Commission Recommendation [12] on guidelines for the development of national coexistence measures to avoid the unintended presence of genetically modified organisms in conventional and organic crops, which recognizes the potential loss of income to producers of certain products of agriculture such as organic products may result from the presence of traces of genetically modified organisms at levels even lower than the threshold for labeling genetically modified set by European Union legislation - 0,9%.

The mixing of genetically modified organisms has specific implications for producers of organic products, has an impact on the end user, such as the production is often more expensive because it requires effort for strict separation to avoid the presence of genetically modified organisms with a view to ensuring the price increase.

Availability of products not produced by genetically modified organisms - Vitamins, enzymes and amino acids used in processing food nowadays are often made from genetically modified organisms and therefore can't be used in organic production. The regulation provides that the Commission may grant an exception (as it has not provided a) the prohibition on use of products produced by genetically modified organisms when it is necessary to use food and feed additives and other substances that would not be available on the market if not produced by genetically modified organisms. However, some substances such as vitamins B2 (for example riboflavin) and B12 (for example cobalamin) himozin enzymes (for example for cheese) and phytase (for example feed) are only available as produced by genetically modified organisms.

Declaration of the seller - How is it possible the control and quality assurance products and food chain from producers to consumers in terms of production of genetically modified organisms and foods? When broadcasters buy organic raw materials needed for their production processes, they must verify that these materials have not been genetically modified organisms or products produced from or by genetically modified organisms. In Article 9, paragraph 2, the Regulation stipulates that operators can rely on the labels accompanying the

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products or any other accompanying document attached or provided in accordance with Directive 2001/18/EC [13] Regulation (EC) № 1829/2003 [14] or Regulation (EC) № 1830/2003 [15], except if they have information indicating that the labeling of the product isn't in accordance with these regulations, for example, when a threshold of 0.9% labeling of accidental presence of genetically modified organisms has been exceeded.

Products produced by genetically modified organisms and products produced from genetically modified organisms that aren't food or feed are not covered by legislation on genetically modified organisms and therefore they do not impose obligations on labeling and traceability. Therefore, the Regulation provides in Article 9, paragraph 3 in such cases, biological operator to ask for confirmation or statement of the seller [16], which are signed by the supplier of the products. In this document, the seller must declare that his product isn't produced from or by genetically modified organisms. Vendor declaration represents a commitment by the supplier of legal action, but insufficiently reliable and efficient.

Feasibility of specific limits on eligibility (for adventitious or technically unavoidable presence of genetically modified organisms) and their impact on the sector of organic production. The European Union position is that the current legislative framework provides sufficient guarantees in respect of the ban on genetically modified organisms in organic production system. It ensures that products marketed without reference to genetically modified organisms on the label contain only incidental and unavoidable levels that are lower than 0.9%. The determination of a specific threshold will increase the complexity and costs to be borne by producers and consumers.

Functioning of the internal systems of control, evaluation and more specifically, whether established practices don't lead to unfair competition or create barriers to production and marketing of organic products - Successfully introduced the compulsory use of the sign of the European Union on all biological products²⁸ produced in the Community, effective July 1, 2010, a transitional period until June 30, 2012. It is to harmonize and simplify rules for organic production in the Community.

To improve transparency, the Commission adopted Regulation (EC) № 426/2011 [17], which requires Member States to develop publicly available an updated list of operators from 1 January 2013 on cases of violations and irregularities, the Commission considers that it is possible to improve the exchange of information and in particular in terms of timeliness and completeness of notifications. The Commission recognizes that the system of control can be further improved and to start procedures for violations when control systems are not in accordance with the laws of the European Union.

3. Application of the Import

With the United States, the European Union is a leading producer of organic produce, attract exports from third countries (about 95% of global organic sales). The regulation includes provisions and harmonized procedures for imports of organic products on the Community market with two options:

- in accordance with the laws of the European Community in the field of biological products;
- based on the equivalence between the standards and control systems.

Out of these imports, another of equivalent import organic products into the European Union is based on import licenses to be granted by the authorities of the Member States for each item for a limited period of time. This opportunity is transient and will gradually be phased out [18].

Imports under the regime of equivalence - Equivalent in describing different systems or measures means that they are able to achieve the same objectives and principles by applying rules which ensure the same level of assurance of compliance [19]. Equivalence agreements may encourage the development of standards and controls adapted to local conditions. They're encouraged by the World Trade Organization. Specific guidelines of the Codex Alimentarius for organic foods represent an international benchmark, designed to facilitate the harmonization of requirements for organic products worldwide.

Recognition of third countries, providing equivalent guarantees - The recognition process starts with the national authorities a formal application to the Commission. It includes a detailed assessment of third country standards for organic products and the control system to determine whether they are equivalent to those of the European Union. This evaluation requires substantial resources. Small differences can be adopted, but rather various rules may lead to restrictions on imports. Must demonstrate that control measures are as effective as in the Community. This is a complex procedure and requires expertise. The Commission is unable to provide the necessary resources to cover the whole process and subsequent monitoring of the list.

Recognition of supervisory bodies and supervisory authorities as providing equivalent guarantees - As regards imports of organic products from third countries which are not recognized, the Commission began to implement the recognition of equivalence of supervisory authorities, the first applications were submitted in 2008 the first list of recognized control bodies approved by the European Commission [21] will be updated regularly. It will apply from 1 July 2012. The Commission considers that the list of control authorities and control bodies could provide a viable approach to imports, subject to oversight to ensure proper functioning of the regime. The competent authorities of Member States responsible for the control of all imported organic products of release for free circulation within the European Union [22].

Import regime in conformity - Under the regime under an operator who is not from the European Union must fulfill all the requirements of Community law, including all the detailed rules for the production and labeling. Unlike the system of equivalence rules must be identical, not equivalent to those applied in the European Union. The operator must be subject to control by the control body or control authority recognized by the Commission for purposes of compliance.

Compliance regime is not yet activated. Commission set a deadline for receipt of the first applications of control authorities and control bodies October 31, 2014, and thus allow time for the deployment of the system of equivalence.

Based on experience so far is doubtful that the compliance regime will ensure better access to European Union market and to bring benefits to palnitelni-European Union trading partners, compared with what is already provided by the system of equivalence. It will bring significant benefits to consumers in respect of the imported organic products that can not be distinguished in the market. Furthermore, the system creates additional

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administrative work comparable to the system of equivalence, without carrying any additional benefits. The Commission therefore prefers to focus its efforts on equivalence, not conformity, whose usefulness and effectiveness should be reviewed together with trading partners in light of current and future biological businesses.

Certificate of Inspection - Release for free circulation in the shipment of biological products under the regime of equivalence is subject to submission of an original certificate of inspection issued by the supervisory authority or control authorities, which are supervised by a recognized third country or the Commission or competent authority of a Member State (under the regime of import authorizations). On entry into the Community, the shipment is verified on the basis of information contained in the certificate of inspection (tags and batch numbers identifying organic products), the certificate shall be certified by Customs.

Certificate of inspection thus constitutes a key element for traceability of each batch of biological products from third country producer to the importer in the European Union, traceability, which can be used to track the subsequent distribution of the product in the Community if it becomes necessary to withdraw it from market. Operators call for the possibility of electronic filing of certificates of inspection. Such a system would facilitate the rapid reaction of the Member States, in cases of breach block non-compliant products.

4. Areas with Genetically Modified Organisms for the Period 2006-2010

In the European Union all area cultivated under genetically modified organisms for commercial purposes refers to maize while in third countries the genetically modified organism can be soya, maize, cotton, rapeseed and sugarbeet. Potatoes, tobacco, squash, papaya and sweet pepper genetically modified varieties are also cultivated yet in small areas.

Authorization for marketing of genetically modified food is a continuous process involving risk assessment of potential adverse effects of genetically modified organisms and genetically modified foods on human health and the environment. Each and every genetically modified genetically modified food be individually authorized.

Decisions of the European Commission, the European Food Safety Food and all members are valid throughout the European Union. From 2004 to apply strict European labeling requirements.

European legislation lays down strict requirements for labeling of genetically modified foods. If the food contains, are composed of or produced from genetically modified organisms, this must be reflected in the labeling accordingly.

Such labels must be present example, the tomato paste from genetically modified tomatoes, pizza, chocolate with lecithin from genetically modified soya beans, instant soups, glucose syrup from starch from genetically modified maize, confectionery, sauces, flour corn, popcorn, etc. For example, if Bulgaria is growing genetically modified crops - whether it is made with experimental or commercial - should be made public record of the exact location of the particular variety and growing genetically modified crops. Similarly, should provide information to the public for all authorized genetically modified organisms and genetically modified foods.

Based on the officially published information on area planted with genetically modified organisms in the European Union (countries) can make the following observations. [23] In global area planted with genetically modified organisms in relation to those countries in the European Union can be summarized as follows.

For the period as the largest producer of genetically modified organisms is formed Spain. Znachitlno is in Romania to manufacture its priemanev European Union. Relatively constant quantities produced godiini Czech Republic and Portugal. But in general the production of genetically modified organisms for the time period 2006-2010, marked persistent downward trend in the European Union.

To compare information about world areas sown to genetically modified organisms by country to country in the European Union allows the following conclusions. Compared to the rest of the world largest producers formed the United States with 66,800 ha, followed by Brazil (25,400 ha) and Argentina (22,900 ha). For 2010, in percentage terms this amounts to 45.1% - the United States, Brazil - Argentina and 17.2% - 15.5%.

Information for world regions cultures genetically modified organisms (including the European Union) in countries allows for the comment. For the period (2006-2010) with the largest share in terms of area and world production is soybeans (73.3% by 2010), followed by maize (46.8%) and cotton (21%). It appears that this is not only socially, but also economically important crops.

There are other genetically modified organisms cultivated in the world yet in very small field areas. The European Union values its rich culinary heritage and encourages users to be aware of the issues of food quality. [9]

To this end, Community legislation protecting organic farming and quality products and requires that consumers be informed of the presence of any genetically modified organisms in food. Not only have established certain parameters for the classification of organic and quality food, but the signs of quality logos provide consumers with the guarantee that these parameters are met. [10]

Marketing of genetically modified organisms for human consumption or animal feed is regulated at all stages and their presence is indicated on product labels. Measures are taken to ensure a legal framework to control the distribution and transboundary movements of genetically modified organisms.

5. Conclusion

The topic of genetically modified foods cause extensive discussion in public environments. "The European agricultural model" aims to create sustainable agricultural practices to ensure the overall market orientation of agriculture and to enable farmers to benefit from the skills of the market to provide products demanded by consumers, namely the achievement of sustainable development, quality health products and methods for environmentally sustainable production.

On the one hand, the scarcity of land as a resource, the global economic crisis, food security, global hunger and other factors require the creation of sustainable nature-weather species. On the other hand, insufficient safety information on the species of the production, dissemination and application of genetically modified organisms and food require state intervention.

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The agricultural sector is a strategic sector, requiring the application of economically sound measures of the government to seek solutions to control and eliminate potential negative consequences in terms of providing normal conditions for the existence of humans, plants and animals and the environment. The globalization of the food chain constantly brings new challenges and risks to health and consumer interests in the European Union.

The main objective of European policy food safety is to achieve the highest possible level of protection of human health and consumer interests in relation to food. Community industry ensure that food is safe and appropriately labeled, taking into account diversity, including traditional products, effectively functioning internal market. For this purpose, the European Union has developed legislation for food safety, which is constantly controlled and based on risk analysis.

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4. Regulation (EC) № 66/2010 of the European Parliament and the Council of 25 November 2009 on the EU Ecolabel
5. Commission Decision of 9 July 2009 (2009/567/EO)
6. Article 20 of Regulation (EC) № 1223/2009, OJ L 342 of 22.12.2009
7. ISO / NP 16128
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SAVREMENI KONCEPT UPRAVLJANJA ZA PROIZVODNJU BIOLOŠKIH PROIZVODA I GENETSKI MODIFIKOVANIH ORGANIZAMA I HRANE

Rezime: Ovaj rad analizira pozicije Evropske unije (uključujući i Bugarsku) za sprovođenje organske poljoprivrede i proizvodnju genetički modifikovanih organizama i genetski modifikovane hrane u smislu obezbeđivanja bezbednosti hrane. Tema proizvodnje i tržišta za implementaciju genetički modifikovanih organizama i hrane je posebno važna sa sledećih stanovišta: tekuće Evropske poljoprivredne politike (uključujući i Bugarsku), organske proizvodnje, bezbednosti hrane, gladi u svetu, globalne ekonomske krize i drugo. Sa ovog stanovišta su formirana dva različita pravca u vezi koncepta proizvodnje i upotrebe genetički modifikovanih organizama i hrane.

Ključne reči: organska proizvodnja, genetski modifikovani organizmi (GMO), genetski modifikovana hrana (GMH), Evropska unija.