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Prepared By: Andreja Misir

Approved By: Neil Mikulski

#### **Report Highlights:**

Croatia is a net food importer with policies focused on increasing agricultural productivity. However, Croatia competitive advantage remains in marketing premium "natural" agricultural products and is opposed to full and open adoption of biotechnology foods. Croatia follows the European Union's (EU) biotech legislation but has "opted-out" of planting genetically engineered (GE) seeds.

## **EXECUTIVE SUMMARY**

Croatia has adopted EU biotech legislation, but prohibits the planting of genetically engineered (GE) seeds in its agriculture production. Croatia views its competitive advantage in domestic "natural" agricultural production and is cautious of adopting openly pro-biotech policies. There is strong opposition against GE products that are perceived as "unnatural." Additionally, some Croatian politicians and a portion of the public are misinformed about biotech product safety and consider them as potentially dangerous.

Despite general opposition towards GE products, the Croatian livestock sector uses imported soybean meal. The bulk of approximately 150,000 to 180,000 metric tons of soybean meal used in Croatia is GE and is the only major agricultural biotech commodity found on the Croatian market

In 2004 and 2005, the government randomly tested food and seeds specifically for biotech content and several products were withdrawn from the market due to a lack of proper biotech labeling. Since then, Croatia regularly tests products for biotech events both at the border and in the market as part of its annual inspection plans. According to EU law, all biotech products must be labeled.

Several pieces of Croatian legislation regulate the importation and cultivation of GE crops, animals, and foods. Croatia's 2019 Law on "Genetically Modified Organisms" ("GMOs") incorporated EU legislation allowing member states to refrain from planting EU-approved GE seeds. It also elaborated on procedures for the application and use of GE in scientific research, restricted use in closed systems, and introduction into the environment.

Currently, there is no public discussion on biotech use in animals.

There is no public awareness of microbial biotechnology.

For more information on the EU biotech situation please refer to the current EU Agricultural Biotechnology Annual Report, which can be found in <u>the FAS GAIN Report Data Base</u>.

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## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

#### a) RESEARCH AND PRODUCT DEVELOPMENT

Croatia is not developing any biotech crops for research or commercial production. Croatia sees value in developing high-quality "natural" products rather than competing on volume. Additionally, some Croatian politicians and a significant portion of the public are currently misinformed over biotech products considering them as potentially dangerous.

#### **b) COMMERCIAL PRODUCTION**

<u>Croatia's 2019 Law on "GMOs"</u> (link in Croatian) legally incorporated EU legislation allowing member states to opt-out of planting EU-approved GE seeds without the need to provide scientific justification. Prior to the creation of this law, no permits were granted in Croatia for the deliberate release of GE plants—either for field trial or commercial cultivation.

Croatia is a signatory of the Danube Soya Initiative, an initiative to increase non-GE soy production in Europe and reduce GE imports. <u>The Danube Soya Initiative</u> aims to create "GMO"-free soy-producing regions in countries along the Danube River. Another goal of the program is to connect farmers in Eastern European countries, such as Slovakia, Hungary, Croatia, and Serbia, to more affluent consumers in Western Europe who demand non-GE soy for feed or food.

On June 18, 2021, the Parliamentary Committee on Agriculture adopted a Declaration on the GMO-free Alps-Adriatic-Danube Area and sent this Declaration to the Croatian Parliament.

#### c) EXPORTS

Croatia does not export GE crops/products.

## d) IMPORTS

EU-approved events must be appropriately labeled. Some imported GE soybean meal is used in feed, mostly sourced from other EU member states or neighboring countries. There are no direct imports from the United States.

## e) FOOD AID

Croatia is not a food aid recipient or a food aid donor.

#### f) TRADE BARRIERS

Beyond the current legislation on clear food labeling and lengthy EU process of variety registration, there are no additional plant-biotechnology requirements that could affect U.S. exports. For details, please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS</u> <u>GAIN Report Data Base</u>.

## PART B: POLICY

## a) REGULATORY FRAMEWORK

In Croatia, the following laws together regulate the importation, transshipment, production, usage, and sale of agricultural biotechnology products (all food, feed, and seed):

- the Law on "GMOs" (link in Croatian) (Governmental Gazette 126/19);
- the Law on the Application of EU Regulation 1829/2003 (Governmental Gazette 18/2013, 47/2014, 114/2018, 83/22) that includes the EU "GMO" Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from "GMOs" Amending EU Directive 2001/18/EC (link in Croatian);
- the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of "GMOs" (link in Croatian) (Governmental Gazette 81/2013);
- <u>the Law on the Application of EU Regulation 2015/2283 on Novel Food</u> (link in Croatian) (Governmental Gazette 15/2018, 114/2018);
- the Food Act (link in Croatian) (Governmental Gazette 18/23).

The Law on "GMOs" (link in Croatian) incorporates several EU regulations and directives: Directive 2001/18/EC; Directive 2009/41/EC; Directive 2015/412EC; Directive 2018/350 EC; Regulation 1829/2003; EC Regulation 641/2004, EC Regulation 1981/2006; EC Regulation 1830/2003; EC Regulation 65/2004; EC Regulation 536/2014; EC Regulation 503/2013; EC Regulation 120/2014; and EC Regulation 2017/625. This law has incorporated EU legislation that allows member states to opt-out of planting EU-approved GE seeds without the need to provide scientific justification. Furthermore, it included additions such as elaborating on procedures for the application and use of "GMOs" for the purpose of scientific research, detailing the procedures for the restricted use of "GMOs" in closed systems, and detailing the procedures for the introduction of "GMOs" into the environment. This law replaced the 2005 Law on GMOs (Governmental Gazette 70/05), which was amended five times to remain in line with the evolution of the EU biotechnology legislation.

The Law on Application of the EC Regulation 1829/2003, EC Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from "GMOs" that Amends EU Directive 2001/18/EC (link in Croatian), and the Law on Application of the EC Regulation 1946/2003 on Trans-boundary Movement of "GMOs" came into effect with Croatian's accession to the EU in 2013 (link in Croatian) establish the responsible bodies and their tasks relating to the handling of biotechnology products and the penalties for breaching these laws.

The Law on the Application of EU Regulation 2015/2283 on Novel Food (link in Croatian) deals with all aspects of novel food.

<u>The Food Act</u> (link in Croatian) governs responsible governmental bodies and their tasks in regular and biotech food and feed handling, and official controls and legal measures.

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Genetski modificirani organizmi (GMO)	"Genetically Modified Organisms" ("GMO")	Zakon o genetski modificiranim organizmima (the Law on "GMOs") and	An organism, other than a human being, whose genetic material has been altered in a manner not occurring under natural conditions by cross breeding or natural recombination.
Modificirani živi organizam	Living Modified Organism (LMO)	Zakon o provedbi uredbi Europske unije o sljedivosti i označavanju genetski modificirane hrane i hrane za životinje (The Law on Application of the EC Regulation 1829/2003, EC Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from "GMOs" that Amends EU Directive 2001/18/EC, and the Law on Application of the EC Regulation 1946/2003 on Trans- boundary Movement of "GMOs")	Any "GMO" capable of reproduction or transfer of genetic material, including sterile organisms capable of growth.

## i. Table of Legal Terms:

## ii. The responsible government ministry or ministries and their role in the regulation of GE plants (food, feed, seed, and environmental safety issues):

<u>The Ministry of Science, Education and Youth (MSEY)</u>: According <u>the Law on "GMOs"</u> (link in Croatian), the MSEY is responsible for the limited and contained use of GE products. If an institute wishes to research GE products, it must apply to the MSEY.

<u>The Ministry of Environment Protection and Green Transition (MEPGT):</u> The MEPGT is the government body responsible for the intentional introduction of GE products into the environment. According to <u>the Law on "GMOs" and the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of "GMOs"</u> (links in Croatian), the government body responsible for intentional release into the environment is also responsible for implementing regulatory practices and coordinating its activities with the MOH, the MOA, the MSEY and Croatian Customs. It should be noted that the environmental protection has undergone several shifts within government ministries across different administrations. It has moved from the Ministry of Culture to the Ministry of Environment Protection and Energy, to the Ministry of Economy and Sustainable Development, and most recently to the Ministry of Environment, leading to a shift in the body responsible for releasing GE products into the environment.

<u>The Ministry of Health (MOH)</u>: According to <u>the Law on "GMOs"</u> (link in Croatian), the MOH is responsible for GE in food and feed. According to the Food Act, the MOH is responsible for all food safety policies related to food, foodstuffs, and feed containing biotechnology. Additionally, <u>the Law on "GMOs"</u> (link in Croatian) prescribes that MOH oversees the usage of GE products in cosmetics, pharmaceutical products, and products for the protection of human health. Furthermore, <u>the Law on Application of the EC Regulation 1829/2003</u> and EC Regulation 1830/2003 (link in Croatian) names the MOH as the leading Ministry for the implementation of the aforementioned EU Regulations, although, occasionally, the Ministry of Agriculture (MOA) must be consulted.

<u>The MOA</u>: According to <u>the Law on "GMOs"</u> (link in Croatian), the MOA is responsible for GE seed and other GE plant reproduction material, GE veterinary medicine, and GE plant protection products. While, according to <u>the Food Act</u> (link in Croatian), the MOA is the EU's (EU Commission and other EU member states) contact point for food and feed issues.

<u>The State Inspectorate:</u> Since December 2018, the State Inspectorate has been the separate body responsible for the inspection of food, feed, and seed products that may contain GE.

# iii. Role and Membership of Biosafety Council, Board for Limited Usage of "GMOs" and Board for the Introduction of Biotech Products:

<u>The Council for "GMOs": The Law on "GMOs" (link in Croatian) requires the establishment of</u> a Council for "GMOs" with the specific task of assisting governmental bodies to apply the law. The Council has 17 members appointed by the Government of Croatia based on nominations from the Croatian Government Office for Associations and the Ministries responsible for agriculture, forestry, environment, health and economy. Council membership lasts for 4 years. The Council's work is independent and public. Its tasks include tracking gene technology development and usage; tracking scientific breakthroughs and giving opinions and incentives for the usage of GE and gene technology and giving opinions on social, ethical, technical, scientific, and other conditions of GE use; advising responsible institutions on GE and gene technology issues; informing the public on GE and gene technology development; and presenting viewpoints and opinions.

The Board for the Limited Usage of "GMOs" and the Board for the Introduction of Biotech Products into the Environment: The Law on "GMOs" (link in Croatian) also calls for establishing a Board for the Limited Usage of "GMOs" with 11 members composed of scientists from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental protection, and occupational protection. In addition, <u>the Law on "GMOs"</u> (link in Croatian) requires the establishment of a Board for the Introduction of Biotech Products into the Environment that consists of nine scientists from the fields of genetics, ecology, nature protection, environmental protection, agriculture, forestry, veterinary medicine, biochemistry, molecular biology, microbiology, and medicine.

These two boards provide opinions on biotech usage in terms of legal procedures as outlined by <u>the Law on "GMOs"</u> (link in Croatian), put forward proposals for preparing legislation on GE products. According to the law, these two boards should report to the "GMO" Council once a year.

## iv. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology:

Biotech opponents in Croatia have been emboldened by the perceived success of Austria and Slovenia declarations as "GMO-free." Currently, Croatia sees itself as a niche market for "healthy foods" which includes conventional (non-biotech) and organic products. There has been limited demand for biotech seed imports to combat drought, pests, or soil problems. Government officials acknowledge the legal obligation, regarding approved GE events in the EU, to open their agricultural market to imports, but actively declare Croatia to be "GMO-free" as part of a strategy to promote the country as a "healthy" tourist destination. The Croatian public is generally opposed to biotech production which is viewed as unhealthy.

## v. Regulatory distinctions made between GE plant products containing DNA in the final form of the product and those products of GE plants that do not (oil, sugar, etc.):

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

## vi. Regulatory distinctions made between GE plant products considering living (able to increase in size and number) versus non-living (such as meal, cake, etc.):

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

# vii. Regulatory distinction made between the regulatory approval/authorization treatment for food, feed, fiber, pulp, processing, and environmental release:

The procedures to approve biotech food and feed products are lengthy and complicated. At the end of the regulatory procedure for food and feed, companies must gain special permission to put the biotech product on the market. However, biotech seeds, additionally require specific permits for market release, including authorization for their intentional introduction into the environment. Furthermore, all agricultural seed varieties, both biotech and conventional, must undergo a variety registration process with the Croatian Seed and Seedlings Institute. This process involves the registration of the variety and its subsequent inclusion on the list of approved seed varieties that can be marketed within Croatia. Nevertheless, Croatia has opted out of planting genetically engineered (GE) seeds, so this procedure has never been put to the test.

Please, also see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS GAIN Report Data Base</u>.

#### viii. Legislation or regulation that have the potential to affect U.S. exports:

Please, see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

#### ix. The timeline usually followed for approvals/authorizations:

Please, see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

#### x. If no legislation and/or regulations are in place:

N/A

## xi. Is an additional product and or seed registration required, beyond GE plant approval/authorization, prior to its use:

Please, see chapter 1, part B, subpart vii. of this report.

Please, also see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS GAIN Report Data Base</u>.

#### xii. Is re-registration required:

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

#### xii. Are approvals/authorizations limited:

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

#### b) APPROVALS/AUTHORIZATIONS

There have been no direct applications to Croatian authorities to approve domestic planting of biotech crops for food or feed use; Croatia has never approved any biotech seed varieties for planting nor is any biotech seed variety in the process of being approved in Croatia.

#### c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS</u> <u>GAIN Report Data Base</u>.

#### d) FIELD TESTING

According to <u>the Law on "GMOs"</u> (link in Croatian) and subsequent regulations, field tests of biotech crops are permitted after all conditions prescribed by the laws and regulations have been satisfied. However, no such tests are currently being conducted in Croatia.

#### e) INNOVATIVE BIOTECHNOLOGIES

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS</u> <u>GAIN Report Data Base</u>.

## f) COEXISTENCE

<u>The Law on "GMOs"</u> (link in Croatian) prescribes that the coexistence between organic agriculture, integrated agriculture (integrated agriculture involves farming systems with environmental, economic, social, and intergenerational sustainability), and GE crops will be regulated by a separate legal act.

## g) LABELING AND TRACEABILITY

According to the Law on the Application of EU Regulation 1829/2003 that includes the EU "GMO" Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from "GMOs" Amending EU Directive 2001/18/EC (link in Croatian), food and feed containing agricultural biotechnology ingredients must have special, additional information on the label that informs consumers of its characteristics. Based on the EU law, for any food or feed product that are EU-approved, if the biotech content is above 0.9% (per ingredient), the product must be labeled. The biotech threshold is 0.0% for seed and biotech products that are not EU-approved.

## h) MONITORING AND TESTING

Croatia regularly tests products for biotech events at the border and in the market. Products containing unapproved or unlabeled GE events will be withdrawn from the market, and the responsible company will be charged a fee. Following market withdrawal, products containing unapproved GE events will be destroyed.

## i) LOW LEVEL PRESENCE (LLP) POLICY

Croatia does not have a policy on low-level presence. It does follow the "technical solution" guidance that defines zero as an allowance of 0.1 percent, as outlined in EU Regulation 619/2011. This regulation lays down the methods of sampling and analysis of official control of feed regarding the presence of any agricultural genetically modified product for which an authorization procedure is pending or has expired.

## j) ADDITIONAL REGULATORY REQUIREMENTS

Please see the current EU Agricultural Biotechnology Annual Report which can be found in <u>the FAS</u> <u>GAIN Report Data Base</u>.

## k) INTELLECTUAL PROPERTY RIGHTS (IPR)

A range of laws safeguard the protection of intellectual property in Croatia, e.g. <u>Patent Law, Trademark Law, Copyright Law</u>, etc. However, plant varieties are protected under the <u>Plant Variety Law</u> (link is in the Croatian language). In addition, Croatia is a member of the International Union for the Protection of New Varieties of Plants (UPOV).

## I) CARTAGENA PROTOCOL RATIFICATION

Croatia signed the Cartagena Protocol on Biosafety in September 2000 and ratified the Protocol in September 2003. Officially, there is no trade in Living Modified Organisms (viable seeds).

## m) INTERNATIONAL TREATIES AND FORUMS

Croatia is a member of the International Plant Protection Convention (IPPC) and Codex Alimentarius (Codex). However, Croatia does not take an active position regarding plant or animal biotechnology in these organizations.

## n) RELATED ISSUES

Please, see current EU Agricultural Biotechnology Annual Report which can be found in <u>the FAS GAIN</u> <u>Report Data Base</u>.

## PART C: MARKETING

## a) PUBLIC/PRIVATE OPINIONS

Croatia has Non-Governmental Organizations (NGOs) such as Green Peace and Green Action that are actively campaigning against biotechnology and the Croatian press has generally taken a negative stance on biotech. The average Croatian consumer has a very negative attitude towards biotech crops and food derived from biotech crops.

#### b) MARKETING ACCEPTANCE/STUDIES

The average Croatian consumer views food derived from biotech crops negatively. Consequently, many farmers are hesitant to grow biotech crops. There is a pervading opinion that biotechnology is "unnatural", and food should be "natural." These opinions are based largely on emotions rather than an informed study of the issue.

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: PRODUCTION AND TRADE

### a) RESEARCH AND PRODUCT DEVELOPMENT

In Croatia, genetic engineering and/or cloning are not being used to develop the production of agricultural animals. Nor are such techniques used to develop animals to produce pharmaceuticals or organs for transplants. There is no ban on these techniques, however, public perception is preventing companies from engaging in these activities.

#### **b) COMMERCIAL PRODUCTION**

The Croatian livestock sector is not actively employing the use of GE animals or products derived from GE animals or clones. There is no ban, however public perception is preventing companies from engaging in these activities. Post has no information on potential developments in the biomedical space.

#### c) EXPORTS

Croatia does not export GE animals, livestock clones, or products from these animals.

#### d) IMPORTS

Croatia does not import GE animals, livestock clones, or products from these animals. There is no legal ban.

#### e) TRADE BARRIERS

Please, see the current EU Agricultural Biotechnology Annual Report which can be found in <u>the FAS</u> <u>GAIN Report Data Base</u>.

#### PART E: POLICY

#### a) REGULATORY FRAMEWORK

Aside from <u>the Law on "GMOs"</u> (link in Croatian) and EU legislation, Croatia does not have any legislation in place specifically related to the development or commercial use and/or import of GE animals or their products. Presently, food from clones falls under the scope of the EU Regulation on Novel Foods (EU Regulation 2015/2283), please see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

### b) APPROVALS/AUTHORIZATIONS

There are no animal clones, GE animals, or products thereof, approved for import or use in Croatia.

### c) INNOVATIVE BIOTECHNOLOGIES

Please see the current EU Agricultural Biotechnology Annual Report which can be found in <u>the FAS</u> <u>GAIN Report Data Base</u>.

### d) LABELING AND TRACEABILITY

There are indications the Croatian Government may consider traceability and mandatory labeling requirements for products derived from GE and cloned animals. Government entities that would likely regulate these technologies include the MOA, the MOH, the MEPGT, the Croatian Agency for Food and Agriculture, and the Council for "GMOs."

### e) ADDITIONAL REGULATORY REQUIREMENTS

Please see the current EU Agricultural Biotechnology Annual Report which can be found in <u>the FAS</u> <u>GAIN Report Data Base</u>

### f) INTELLECTUAL PROPERTY RIGHTS (IPR)

A range of laws safeguard the protection of intellectual property in Croatia, e.g. <u>Patent Law, Trademark</u> <u>Law, Copyright Law</u>, etc. However, Croatia does not have IPR legislation on animal biotechnology.

#### g) INTERNATIONAL TREATIES/FORUMS

Croatia is a member of Codex Alimentarius (Codex) and the World Organization for Animal Health (OIE). However, Croatia does not take an active position regarding animal biotechnology in these organizations.

## h) RELATED ISSUES N/A

## PART F: MARKETING

#### a) PUBLIC/PRIVATE OPINIONS

There are active organizations that lobby against the genetic engineering or cloning of agricultural animals and Croatia's press has not been favorable toward these types of innovations.

## b) MARKET ACCEPTANCE/STUDIES

Currently, there are no known cloning or GE animal production market studies. The initial reaction to these products is unlikely to be favorable.

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

## PART G: PRODUCTION AND TRADE

## a) COMMERCIAL PRODUCTION

There is no information available on the use of microbial biotechnology in commercial applications. For more details, please see the current EU Agricultural Biotechnology Annual Report which can be found in the FAS GAIN Report Data Base.

## **b) EXPORTS**

Croatia exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients. However, there is no specific information available on the use of microbial biotechnology in products that may be exported.

### c) IMPORTS

Croatia imports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

### d) TRADE BARRIERS

Please see the current EU Agricultural Biotechnology Annual Report which can be found in <u>the FAS</u> <u>GAIN Report Data Base</u>.

## PART H: POLICY

## a) REGULATORY FRAMEWORK

Aside from <u>the Law on "GMOs"</u> (link in Croatian) and EU legislation, Croatia does not have any additional regulatory framework in place covering microbials. For more details, please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS GAIN Report Data Base</u>.

#### **b) APPROVALS/AUTHORIZATIONS**

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS</u> <u>GAIN Report Data Base</u>.

#### c) LABELING AND TRACEABILITY

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS</u> <u>GAIN Report Data Base</u>.

#### d) MONITORING AND TESTING

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS</u> <u>GAIN Report Data Base</u>.

#### e) ADDITIONAL REGULATORY REQUIREMENTS

Please see the current EU Agricultural Biotechnology Annual Report which can be found in the <u>FAS</u> <u>GAIN Report Data Base</u>.

#### f) INTELLECTUAL PROPERTY RIGHTS (IPR)

A range of laws safeguard the protection of intellectual property in Croatia, e.g. <u>Patent Law, Trademark</u> Law, Copyright Law, etc. However, microbial GEs are not specified.

## g) RELATED ISSUES N/A

#### PART I: MARKETING

## a) PUBLIC/PRIVATE OPINIONS

There are active organizations lobbying against genetic engineering. Historically, Croatia's press has not been favorable toward these types of innovations.

#### **b) MARKET ACCEPTANCE/STUDIES**

Currently, there are no known market studies on microbial biotechnology.

#### Attachments:

No Attachments