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Prepared By: Luigi Castaldi

**Approved By:** Elisa Fertig

## **Report Highlights:**

Public support for agricultural biotechnology in Belgium is roughly divided between the Wallonia and Flemish regions with the latter more receptive. The Flemish region is home to the country's ag biotech cluster where much of the research on biotechnology and experimental field trials take place. There is no commercial genetically engineered (GE) crop production in Belgium; however, the poultry and livestock sectors remain reliant on imported GE commodities for animal feed.

## **EXECUTIVE SUMMARY**

Belgium has a rich history of dedication to the life sciences and biotechnology. Belgian scientists Marc Van Montagu and Jozef Schell created the first genetically modified plant in the world at Ghent University in the 1970s. Since this time, scientific developments have evolved, but most commercial biotechnology practices are used in the health sector and not agriculture. In Belgium, about 80 percent of activity is focused on health-related biotechnology (red biotechnology) followed by about 15 percent for industrial purposes (white biotechnology). Production of food ingredients using fermentation is part of this pillar. Finally, five percent of Belgium biotech activity is focused on agricultural – or green – biotechnology.

Ghent is home to Belgium's ag biotech cluster known as "Tech Lane Ghent," where most biotech companies in Belgium are located. The Flanders Institute for Biotechnology (VIB) is one of the main scientific institutions in this space.<sup>2</sup> The institute has a close partnership with five Flemish universities (Ghent University, KU Leuven, University of Antwerp, Vrije Universiteit Brussel, and Hasselt University), and it is supported by funds from the Flemish government.

However, most of the Belgian population is hesitant to accept the use of biotechnology in crop and food production<sup>3</sup>. Despite this hesitance, Belgium imports GE crops and derived products to supply its livestock farming. The use of agricultural biotechnology is restricted to fundamental research and limited field trials with corn and poplars. Additionally, the support to research is roughly divided between the regions. While the regional government in Wallonia decided to ban the cultivation of GE crops on its territory, the Flemish region is open and more receptive. Flemish farming is typically more intensive, and its livestock sector needs large amounts of protein. Farming in Wallonia on the other hand is usually more extensive and self-sufficient, and organic agriculture is promoted throughout the region.

<sup>&</sup>lt;sup>1</sup> "Belgian Biotechnology," (2011), https://www.abh-ace.be/en/countries-and-statistics/belgian-sectors/all?page=1

<sup>&</sup>lt;sup>2</sup> https://www.youtube.com/watch?v=QPlGh4eeyTk

<sup>&</sup>lt;sup>3</sup> https://europa.eu/eurobarometer/api/deliverable/download/file?deliverableId=38979

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Belgium is a member of the European Union. For more detailed information on EU Regulations and Directives, please see the EU-wide overview provided by the current Agricultural Biotechnology Annual European Union Report as published on <a href="mailto:the GAIN website">the GAIN website</a>.

## **CHAPTER 1: PLANT BIOTECHNOLOGY**

## PART A: PRODUCTION AND TRADE

- a) RESEARCH AND PRODUCT DEVELOPMENT: Belgium has a small but innovative plant breeding sector. See "POLICY: Field Testing" for a list of field trials to date. However, due to the regulations for developing and approving GE crops in the EU, not a single product has been brought to market. Most ag biotech companies in Belgium are located in the biotech cluster in Ghent. Although, many companies in Europe have relocated at least part of their agricultural biotechnology research and development outside of the EU.
- b) COMMERCIAL PRODUCTION: In Belgium, there is no commercial production of GE crops. On March 11, 2015, Directive (EU) 2015/412 was officially released allowing Member States to "opt out" of cultivating EU-approved GE crops on their territory<sup>4</sup>, and the Wallonia region decided to opt out. The region of Flanders did not, however, commercial production of GE crops is not expected due to the EU regulations for biotech approvals, the coexistence rules, and limited producer interest (following perceived consumer lack of acceptance).
- c) EXPORTS: Belgium does not produce or export domestically produced GE crops or products. However, Belgium transships imported GE crops and products to other EU member states and reexports GE materials to non-EU countries. For more information see the Agricultural Biotechnology Annual European Union report on GAIN.
- d) IMPORTS: As there is no cultivation of GE crops on Belgian soil, the country does not import any GE seeds. However, Belgium relies on imports of GE crops and derived products to feed its livestock sector. Most of the animal feed for poultry and pigs is labeled as "GMO" and sold throughout the country. Imported crops and derived products are mainly soybeans from Canada, the Netherlands, <sup>5</sup> and Brazil and soybean meal from the Netherlands, India, and Brazil. The share of shipments that contain GE material is not registered, but those products coming from the Netherlands are estimated to contain mostly GE material as the Netherlands' top suppliers for soybeans are the United States and Canada as well as Brazil and Argentina for soybean meal.

<sup>&</sup>lt;sup>4</sup>For more information, please see the 2015 Agricultural Biotechnology Annual European Union report: <a href="https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Agricultural%20Biotechnology%20Annual\_Paris\_EU-28\_7-23-2015.pdf">https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Agricultural%20Biotechnology%20Annual\_Paris\_EU-28\_7-23-2015.pdf</a>

<sup>&</sup>lt;sup>5</sup> However, this may also include transshipments coming from elsewhere, such as Argentina, Brazil, and the United States.

Here is data on Belgium's imports:

<b>2016 360</b> 148 88	<b>356</b> 166 12	2018 680 176	2019 547 206	2020 649 232	<b>2021 458</b> 156
148	166	176	206	232	156
88					
	12	122	10	69	107
			I		107
57	0	225	57	235	67
36	44	56	54	76	53
4	88	73	190	2	37
10	16	17	16	13	7
15	30	11	13	22	31
1%	25%	11%	35%	0.3%	8%
_	4 10 15 1%	4 88 10 16 15 30	4     88     73       10     16     17       15     30     11       1%     25%     11%	4     88     73     190       10     16     17     16       15     30     11     13       1%     25%     11%     35%	4     88     73     190     2       10     16     17     16     13       15     30     11     13     22       1%     25%     11%     35%     0.3%

Source: Trade Data Monitor

Partner		Calendar Year						
	2016	2017	2018	2019	2020	2021		
World	1372	1385	1267	1425	1369	1290		
Netherlands	851	841	940	1018	1177	998		
India	0	54	36	39	0	81		
Brazil	179	151	71	91	20	51		
Germany	15	8	8	35	37	45		
Argentina	255	253	152	156	46	28		
France	8	12	9	12	13	10		
Other	18	12	5	21	19	21		
U.S. Market	3%	4%	4%	4%	4%	4%		
Share								

Source: Trade Data Monitor

e) FOOD AID: Belgium is not a food aid recipient, but the country provides food aid. This aid likely does not involve GE plant products for human consumption.

f) TRADE BARRIERS: The approval process of new GE events by the European Union has affected U.S. exports to Belgium, in particular corn (see table below), corn gluten feed (CGF), and distiller's dried grains with solubles (DDGS). The EU regulations for the low-level presence (LLP) of GE materials have also affected imports of U.S. long grain rice, following the unintended presence of a commercial supply in 2016. Furthermore, mandatory labeling of the presence of GE ingredients in food has caused processors to avoid ingredients that derive from GE varieties.

Partner	Calendar Year							
	2017	2018	2019	2020	2021			
World	1782	1999	1975	1907	1919			
France	690	978	713	862	817			
Ukraine	488	556	717	419	644			
Netherlands	385	410	411	463	343			
Germany	43	39	76	25	43			
Other	174	15	58	138	72			
U.S. Market Share	0%	0%	0%	0%	0%			

Source: Trade Data Monitor

## PART B: POLICY

a) REGULATORY FRAMEWORK: Belgium follows EU legislation regarding agricultural biotechnology. The following authorities are responsible for implementation and enforcement of the regulatory framework for agricultural biotechnology:

## • The Federal Ministers and their Cabinets

An important part of the decision-making power for biotechnology lies with the Federal Ministers of health, environment, and agriculture and their personal staff, known as the Cabinets. The Ministers choose their Cabinet staff members from a wide range of professions in order to support them in their field. The main responsibility of the Cabinet is the preparation of policy.

# • The Federal Public Service for Health, Food Chain Safety, and Environment (FPS HEALTH)

FPS HEALTH is the coordinating Belgian Federal Government Department in the policy-making process in the field of medical and agricultural biotechnology. As a Belgian federal government body, it employs civil servants. FPS HEALTH is responsible for the enforcement of legislation regarding experimental releases or field trials in co-decision with the Department of Environment and Infrastructure of the Flemish Government, the General Directorate of Natural Resources and Environment of the Walloon Government, and the Environmental Department of the Brussels Capital Region, depending on where the experimental release takes place. The regions have a veto-right, but it is the affected region that co-decides with the federal authorities about the specific release.

The Biosafety Advisory Council (BAC) and the Service Biosafety and Biotechnology (SBB) unit advise FPS HEALTH about the safety of activities involving GE animals and plants. The BAC consists of members, who act as independent experts, and are appointed by the federal and regional Agriculture and Public Health Ministers, as well as the Ministers of Work and of Science Policy. The BAC gives advice on field trials and marketing dossiers. The SBB acts as the secretariat of the BAC and handles all contained use dossiers, which are delegated from the BAC to the SBB. The SBB is comprised of scientists connected to the public health research institution, Sciensano. A list of staff members can be found on the SBB website.

The <u>Belgian Federal Agency for the Safety of the Food Chain (FASFC)</u> is responsible for the documenting and physical controls of food and feed. FASFC implements and enforces the EU legislation concerning the traceability and labelling of GE food and feed products (<u>Regulation (EC) No 1830/2003</u>).

Belgium normally "abstains" its vote in the Committee of the Permanent Representatives of the Governments of the Member States to the European Union (COREPER) and the Standing Committee on Plants, Animals, Food and Feed (PAFF). It sometimes votes "in favor." The two Belgian regions, Flanders and Wallonia, often fail to reach a compromised position that gives the Federal Belgian Government the mandate to vote "in favor" or "against." Furthermore, Wallonia is one of the regions that "opted-out" of GE cultivation (Directive (EU) 2015/412 of March 11, 2015).

When deciding on a Belgian position on a GE plant variety, the Belgian federal government reviews the following: the European Food Safety Authority (EFSA)'s opinion on the specific GE event, the advice of BAC, and other risk management criteria such as the availability of reference materials and detection methods and the quality of monitoring. In cases when the technical review of BAC is not in line with EFSA's opinion, the Belgian federal government starts bilateral discussions with EFSA in order to resolve the diverging issues. However, if they cannot be resolved, the Belgian

government may decide to vote against it or to abstain on the particular GE event. For a particular GE event where the EFSA opinion is positive and the advice of the BAC is in line, the Belgian government may decide to abstain from voting. Please search the Agricultural Biotechnology Annual European Union report in GAIN for more information on the European agricultural biotechnology approval process.

- b) APPROVALS/AUTHORIZATIONS: Belgium accepts the EU approvals listed in the EU's community register of "GM" food and feed.
- c) STACKED or PYRAMIDED EVENT APPROVALS: Belgium implemented <u>Regulation (EC) No 1829/2003</u> on genetically modified food and feed, allowing authorization of stacked events only if the single events have already been authorized.
- d) FIELD TESTING: Field trials have been approved without delays following the procedures in the February 21, 2005 Royal Decree, implementing <u>Directive 2001/18/EC</u> on the deliberate release of GE crops or products into the environment. It has been modified by the Royal Decree of February 19, 2020 (Moniteur Belge/Belgisch Staatsblad of 02.03.2020, p. 12666), which transposes the <u>Commission Directive (EU) 2018/350</u> into Belgian regulations for the environmental risk assessment of GE events.

#### Current and Past Field Trials:

- A field trial with GE Bintje potatoes (cisgenic late blight resistant) was conducted in 2011 and 2012. The 2011 trial was vandalized, but it did not occur again.
- A field experiment with GE corn (increased energy content) in 2012 and 2013.
- A second GE corn trial was performed in 2015 and 2016 with plants that had larger leaves and more biomass.
- A field trial with GE poplar trees ended at the beginning of 2016. A new trial with poplars was planted in 2014 and was completed in 2020. The GE poplar tree variety is developed for the purpose of bioethanol production.
- In 2018 and 2019, another GE corn with modified growth characteristics was tested in the field.
- In 2017, 2018, and 2019, corn edited using the CRISPR/Cas9 system was grown. The edit impaired the crop's DNA-repair mechanism. Only in 2019, a corn field trial permit was obtained (after the ECJ ruling) with three comparable CRISPR/Cas9 edits to impair the DNA-repair mechanism was performed. It was meant to investigate the possibility to use this corn as a biosensor to measure environmental stress. For the two first years there was no GMO field trial permit because the federal authorities were at that time of the opinion that this was not necessary.
- From April 2020 to October 2022, GE corn with elongated duration of growth and thus larger leaves and more biomass will be tested in the field.
- In June 2021, a new four-year field trial started with GE poplar that has an altered wood composition.

• In April 2022, after favorable opinions from the Biosafety Advisory Council, the Belgian federal authorities authorized three new field trials with genome-edited corn with modified growth characteristics, improved digestibility, and increased resistance against environmental stress. The field trials will be performed over a three-year time period to better estimate the effect of the genetic alterations on the complete life cycle of the plant in real agricultural growth conditions.

The list of notifications for the deliberate release of GE plants into the environment (through experimental field trials – not for market) is available on the European Commission's Joint Research Center (JRC)'s website. Belgium has contributed 15 plant notifications (three in 2022) since the implementation of Directive 90/220/EEC (21 October 1991). Since 1991, 22 EU Member States have notified 915 cases of the deliberate release of GE plants.

e) INNOVATIVE BIOTECHNOLOGIES: Belgium is complying with the European Court of Justice's (ECJ) ruling in treating novel genomic techniques as outlined in the EU "GMO" legislation. Due to its innovative plant breeding sector and scientific experience in biotech, the research community of Flanders was hoping for innovative biotechnologies to be exempt from the "GMO" legislation. However, the ECJ ruling linking innovative biotech and genetic engineering has influenced the debate. This debate, combined with Wallonia's standpoint towards agricultural biotechnology, has left the government conflicted.

Regardless, genome editing is being widely used in Belgian laboratories in plants and microorganisms, as well as in red biotechnology in vertebrate cells and laboratory animals. This is mostly in the context of research, not with the goal to develop a product. The larger breeding companies are using innovative biotechnology in their breeding programs. Some small and medium sized breeding companies are using innovative biotechnology in their laboratories, but unless they work on programs to develop varieties for the non-European market, this will not result in a product for market. Research institutes have been working on innovative biotechnology crops, such as late blight resistant Bintje potatoes, non-allergenic celery, and non-bitter chicory and endive. However, these have not been fully developed and brought to market and it seems unlikely that they will while the EU's "GMO" Directive still applies.

On April 29, 2021, the European Commission published a report titled, "Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16." The study concluded that the "GMO Directive is not "fit for purpose" for these newer biotechnology products and a targeted policy action is needed (see GAIN <a href="here">here</a>). The study also says that genome editing can contribute to the objectives of the European Green Deal's F2F and Biodiversity Strategies. The Commission indicated that it is engaging in a wide-ranging communication effort with co-legislators and stakeholders in the EU.

On September 24, 2021, the European Commission launched a policy initiative and roadmap on

"Legislation for plants produced by certain new genomic techniques." The initial feedback period lasted from September 24 to October 22, 2021 and received more than 70,000 comments. On April 29, 2022, the Commission launched a public consultation to seek additional views from stakeholders on this policy initiative (see GAIN). The proposed legislation is expected to be published in quarter two of 2023. Bio.be/essenscia, the Belgian federation for life sciences and biotechnology, supports the breakthrough in the debate about these innovative biotechnologies and is hopeful that the legislation will provide a clear framework for Belgian biotech stakeholders to develop, produce, and apply these technologies.

- f) COEXISTENCE: The two Belgian regions Flanders and Wallonia, are responsible for formulating and implementing coexistence policies. In March 2007, the Flemish Government developed a framework for the coexistence regulations, which was enforced in May 2009, including specific requirements for corn and potato. The regulations reportedly guarantee free choice for the farmer to plant GE crops and include a liability fund. In February 2006, the Walloon government approved coexistence regulations, which came into force in August 2008. According to the Walloon government, the regulations on cultivating GE crops are as restrictive as possible within the scope of the harmonized EU regulations. The regulations contain possibilities to impose "biotech free" zones, and a liability fund paid by the farmer planting GE crops. In addition, Wallonia is one of the regions that has "opted-out" of GE cultivation Directive (EU) 2015/412.
- g) LABELING AND TRACEABILITY: Belgium implements Regulation (EC) No 1830/2003 concerning the traceability and labelling of "GMOs" and the traceability of food and feed products produced from GE events.
- h) MONITORING AND TESTING: In Belgium, the FASFC performs enforcement activities related to possible GE traits in imports. Actual testing is performed by three official GMO testing laboratories (one in each region). Positive tests are submitted to the European Rapid Alert System for Food and Feed (RASFF) if a non-authorized event is found. Actions following a positive test can be destruction or transport out of the EU.
- i) LOW LEVEL PRESENCE (LLP) POLICY: Belgium follows the latest EU legislation, which allows a 0.1 percent limit for pending unapproved biotech events in feed shipments (technical solution that defines zero), as long as the application was submitted to EFSA. For unapproved biotech events found in shipments of food to the EU, a zero tolerance is still in place.
- j) ADDITIONAL REGULATORY REQUIREMENTS: None.
- k) INTELLECTUAL PROPERTY RIGHTS (IPR): Belgium follows the EU's <u>Directive 98/44/EC</u> for the regulation and legal protection of biotechnological inventions. However, IPR is not applicable since commercial production of GE crops is absent in Belgium.

- CARTAGENA PROTOCOL RATIFICATION: Belgium has signed, ratified and implemented the Cartagena Protocol on Biosafety (CPB) to the United Nations' Convention on Biological Diversity. FPS HEALTH is responsible for the implementation of the CPB.
- m) INTERNATIONAL TREATIES and FORUMS: Belgium is an active participant in the International Standard Setting Bodies (ISSBs). It is a member of Codex Alimentarius and a contracting party of the International Plant Protection Convention (IPPC). Brussels hosted the first World Food Safety Day in June 2019 in coordination with FAO and the European Union. Belgium does not usually weigh in or speak out on issues regarding biotechnology in these forums.
- n) RELATED ISSUES: None.

## PART C: MARKETING

- a) PUBLIC/PRIVATE OPINIONS: A Special Eurobarometer report on biotechnology released in 2010 indicated that 54 percent of Belgians surveyed believed that biotechnology and genetic engineering "will have a positive effect on (the) way of life in the next 20 years." However, 65 percent of Belgians did not agree that "the development of GE food should be encouraged" (26 percent agreed). Based on the survey, Belgians surveyed mostly disagreed about encouraging artificially introducing a resistance gene from another species into a new plant, but the majority agreed with encouraging artificially introducing a gene found naturally in that species. Eurobarometer reports are carried out for the European Commission, and they are released annually or on a special basis. The last report on biotechnology report was released in 2010; however, a special report on "Europeans, Agriculture, and CAP" and another on "Making our food fit for the future" were published in October 2020. "Making our food fit for the future" indicated that 95 percent of EU respondents "think that agriculture and rural areas are important for (the) future of the European Union."
- b) MARKET ACCEPTANCE/STUDIES: The Flemish Farmers Organization (Boerenbond) is pragmatic and in favor of planting biotech crops but has also the position that biological material protected by patent rights should be freely available for the development of new varieties. Conversely, there is reported resistance from retailers and consumers to accept food products containing biotech ingredients, in particular to export markets such as Germany. As noted above, the Belgian livestock sector depends largely on feed imports from third countries, mainly soybean meal, which for a major part is GE. There is no resistance from consumers for meat from animals fed with biotech feed, however, such meat does not have to be labeled as fed with GE feed (for more information, see Regulation (EC) No 1830/2003 concerning the traceability and labelling of GE food and feed products).

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

## PART D: PRODUCTION AND TRADE

- a) RESEARCH AND PRODUCT DEVELOPMENT: There are no GE or cloned animals under development that will be on the market in the coming five years. However, some basic research with GE animals is occurring mostly for medical and pharmaceutical research purposes. In Belgium, various research centers are active on innovative biotechnologies and extensive biomedical research programs use both plant and animal-based models in the development of new diagnostic tools and disease treatment solutions in both human and veterinary medicine. FAS/Brussels does not know of any research currently performed including cloning of animals and considers the development of animal clones highly unlikely.
- b) COMMERCIAL PRODUCTION: There are no GE or cloned animals used commercially. GE animals are authorized for use as laboratory animals for medical research at universities and academic hospitals.
- c) EXPORTS: As domestic production of GE and cloned animals does not exist. Belgium does not export domestically produced GE or cloned animals or their reproductive materials.
- d) IMPORTS: Belgium has likely imported semen and embryos from cloned animals or their offspring. The specific quantity of these imports is not available.
- e) TRADE BARRIERS: No applications have been filed for the approval of animal biotech products or cloned animal products.

## PART E: POLICY

- a) REGULATORY FRAMEWORK: Belgium has implemented EU legislation on animal biotechnology and animal cloning. The federal government has a joint responsibility with the three Belgian Regions, Flanders, Wallonia, and the Brussels Capital region for authorization of the use of GE animals. The SBB has a coordinating role and advises the government about the safety of using GE animals. GE animals are authorized for use as laboratory animals for medical research at universities and academic hospitals. Cloned animals may be used for scientific research as well.
- b) APPROVALS/AUTHORIZATIONS: No applications have been filed for the approval of animal biotech products. No GE animals or animal clones have been authorized for entrance into the food chain.

- c) INNOVATIVE BIOTECHNOLOGIES: Belgium follows the ECJ's ruling in treating novel genomic techniques as outlined in the EU "GMO" Legislation.
- d) LABELING AND TRACEABILITY: The Belgian Government will likely support an EU ban on food products derived from clones but is not opposed to product produced from the progeny of clones. However, the Belgian Government has the opinion that labeling should be required for any product derived from a clone's progeny as it is the consumers right to know. Belgian officials acknowledge labeling will be hard to impose as the origin of the product is difficult to trace.
- e) ADDITIONAL REGULATORY REQUIREMENTS: None.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): <u>Directive 98/44/EC</u> is the EU legislation followed by Belgium for the regulation and the legal protection of biotechnological inventions.
- g) INTERNATIONAL TREATIES AND FORUMS: Belgium is a member of the World Health Organization for Animal Health (OIE). It does not voice any opinion on GE animals or cloning.
- h) RELATED ISSUES: None

#### PART F: MARKETING

- a) PUBLIC/PRIVATE OPINIONS: Government and livestock sector representatives are educated on animal biotechnology, but they do not support the use of cloning. Overall, Belgian citizens and consumers do not support the use of cloning and genetic engineering technologies by the agricultural sector. These practices are not accepted by the majority of Belgian livestock producers, dairy farmers, and breeders due to marketing concerns.
- b) MARKET ACCEPTANCE/STUDIES: There are no Belgium specific surveys that FAS/Brussels is aware of on either cloning or genetic engineering of animals. The 2010 Eurobarometer report on biotechnology indicated that 76 percent of Belgians surveyed disagreed that "animal cloning in food production should be encouraged" (17 percent agreed).

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

## PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION: It is difficult to obtain information about the development and production practices of GE microorganisms. However, both GE and gene editing of microorganisms are widely used in laboratories in Belgium. The use of fermentation to produce food enzymes and food additives holds numerous advantages over the chemical production of these components and

will gain even more importance in the future. The genetic engineering of microorganisms is key to this success.

- b) EXPORTS: Belgium may export products that contain microbial biotech-derived food ingredients to the United States or other countries. In Belgium, as in the rest of the EU, the end product does not need to be labeled as containing "GMO" if it is free from the GE microbe.
- c) IMPORTS: Belgium imports microbial biotech-derived food ingredients or processed products without distinction to similar food produced without GE microorganisms. In consequence, no quantitative data is available. Traces of GE microorganisms have been found during import controls, leading to RASFF notifications and sanctions under the EU's "GMO" legislation.
- d) TRADE BARRIERS: The GE microorganism and its modified genetic material must be absent in the end product for it not to be considered a "GMO" by the EU. If this condition is not met, the product must be labeled as containing "GMO" and the GE microorganism has to be approved under the EU's "GMO" Directive.

## PART H: POLICY

- a) REGULATORY FRAMEWORK: See the policy section in chapter one for more information. If no GE microorganisms (or their recombinant DNA) are present in the final food or feed product, the EU's "Contained Use" Directive (Directive 2009/41/EC) can be applied. Please see the plant section for references to the Belgian regulatory framework. In Belgium, "contained use" is defined as "any activity in which organisms are genetically modified or in which genetically modified and/or pathogenic organisms are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment." These activities occur in a "closed environment," which includes laboratories, animal units, greenhouses, production units, and hospital rooms. The use of GE organisms in clinical trials as part of gene therapy or in veterinary trials may in some cases also be considered "contained use," and they are notified separately. According to the Belgian Biosafety Server, "The scope of the Belgian regional legislation is broader than the scope of the EU Directive since it includes, in addition to genetically modified microorganisms (GMMs), genetically modified organisms (GMOs), and pathogenic organisms." Contained use activities are regulated at a regional level (Wallonia, Flanders, Brussels-Capital) and included within the environmental laws for classified installations referenced in the plant section.
  - Brussels-Capital Region
    - Please see <a href="https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-brussels-capital-region">https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-brussels-capital-region</a>
  - Flemish Region

- Please see <a href="https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-flemish-region">https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-flemish-region</a>
- Wallonia Region
  - o Please see <a href="https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-wallonia">https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-wallonia</a>
- b) APPROVALS/AUTHORIZATIONS: Please search the Agricultural Biotechnology Annual European Union report in GAIN for more information.
- c) LABELING and TRACEABILITY: If the Contained Use Directive (<u>Directive 2009/41/EC</u>) is applicable to the product, there is no labeling obligation. If the final products are thoroughly purified to make sure all traces of GE microorganisms are absent, no "GMO" labeling is required. Belgium implements <u>Regulation (EC) No 1830/2003</u> concerning the traceability and labelling of "GMOs" and the traceability of food and feed products produced from GE events.
- d) MONITORING AND TESTING: Belgium tests for evidence of genetic engineering in imports of processed products. Tests are performed by the FASFC. Positive tests are submitted into the RASFF. Actions following a positive test can be destruction or transport out of the EU.
- e) ADDITIONAL REGULATORY REQUIREMENTS: None.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): Belgium follows the EU's <u>Directive 98/44/EC</u> for the regulation and legal protection of biotechnological inventions.
- g) RELATED ISSUES: None.

## **PART I: MARKETING**

- a) PUBLIC/PRIVATE OPINIONS: The Belgian public is generally not aware of microbial biotech in food production.
- b) MARKET ACCEPTANCE/STUDIES: There are no market acceptance studies available.

#### **Attachments:**

No Attachments.