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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 a leading research institution on biotechnology that supports much of the country's experimental field trials as there is no commercial genetically engineered (GE) crop production in Belgium. 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 (so-called 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.[1]

In fact, the Flemish Institute of Biotechnology (VIB) is a leading scientific institution dedicated to biomolecular research. 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, the Belgian population is hesitant to accept the use of agricultural biotechnology in crop and food production. The use of agricultural biotechnology in Belgium is restricted to fundamental research and limited field trials with corn and poplars.

Despite this hesitance, Belgium imports large quantities of GE crops and derived products to supply its intensive livestock farming. Additionally, the support for agricultural biotechnology in Belgium is roughly divided between the regions. The regional government in Wallonia is opposed while Flanders is more receptive. This is mostly because Flemish agriculture is typically very intensive, and its livestock sector needs large amounts of protein. Farming in Wallonia on the other hand is typically more extensive and self-sufficient. The region vehemently promotes organic agriculture on its territory, excluding all GE crops.

Alongside this mixed attitude towards agricultural biotechnology in Belgium, it is important to note that the capital, Brussels, is home to about 120 international government organizations, 181 embassies, over 5,000 diplomats, and over 1,000 lobbying groups.[2]

[1] https://www.abh-ace.be/sites/default/files/downloads/BIOTECH_WEB.pdf

[2] https://www.abh-ace.be/sites/default/files/Economic_studies/toral_publication/aa048_sectorale_studie_food_full.pdf

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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 the GAIN website.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Belgium has a small but innovative plant breeding sector. However, due to the cumbersome regulations for developing and approving GE crops in the EU, not a single product has been brought to market. Many companies have relocated at least part of their agricultural biotechnology research and development outside of the EU. In 2018, the European Court of Justice (ECJ) ruled that organisms obtained by mutagenesis are Genetically Engineered (GE) and organisms obtained by new mutagenesis techniques do not fall under the article 3, annex IB exemption, of Directive 2001/18 thus they all still currently fall under the "GMO Directive." However, the European Commission is currently undergoing a policy initiative for genome editing, and more information can be found in Part B, Section e on innovative biotechnologies.

b) COMMERCIAL PRODUCTION: In Belgium, there is no commercial production of GE crops, nor is it expected that GE crops will be commercially planted in the next five years due to the cumbersome EU regulations for biotech approvals, the coexistence rules, as well as limited producer interest (following perceived consumer lack of acceptance). On March 11, 2015, Directive (EU) 2015/412 was officially released allowing Member States to "opt out" of cultivating EU-approved GE crop varieties on their territory without a scientific justification[3]. The Wallonia region of Belgium opted out of GE crop cultivation. The region of Flanders did not.

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 re-exports GE materials to non-EU countries. For EU legislation on required documentation and labeling for these transshipments, search the 2020 Agricultural Biotechnology Annual European Union report on GAIN.

d) IMPORTS: Belgium imports large quantities of GE crops and derived products. There is no cultivation of GE crops on Belgian soil, so the country does not import any GE seeds. The vast majority of animal feed for poultry is labeled as "GMO" and sold all over Belgium, even to non-professional livestock holders. The animal feed for pigs will also be labeled as "GMO", but for bulk transports the "GMO" indication will be on the accompanying paperwork. Imported GE crops and derived products are mainly soybeans from Brazil and Canada and soybean meal from the Netherlands,[4] Argentina, and Brazil. The share of shipments that contains GE material is not registered, but those products coming from the Netherlands are estimated to contain more than 85 percent of GE material. The EU is the second largest soybean importer and largest soybean meal importer in the world (most stock going to the Netherlands). Much of the stock from the Netherlands is transshipped throughout the rest of Europe, including Belgium. The Netherlands' top suppliers for soybeans are the United States and Canada as well as Brazil and Argentina for soybean meal. Here is data on Belgium's imports:

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[3] For more information, please see the 2015 Agricultural Biotechnology Annual European Union report: https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Agricultural%20Biotechnology%20Annual_Paris_EU-28_7-23-2015.pdf

[4] However, this may also include transshipments coming from elsewhere, such as Argentina, Brazil, and the United States.

Belgium Soybean Imports					
Partner	**Calendar Year**				
	2016	**2017**	**2018**	**2019**	**2020**
World	***360***	***356***	***680***	***547***	*649*
Canada	148	166	176	206	232
United States	4	88	73	190	2
Brazil	57	0	225	57	235
France	36	44	56	55	76
India	10	16	17	16	13
Netherlands	88	12	122	10	68
Other	15	30	11	13	23
U.S. Market Share	*1%*	*25%*	*11%*	*35%*	*0.3%*
***Thousand Metric Tons (TMT)**					

Source: Trade Data Monitor (EuroStat)

Belgium Soybean Meal Imports						
Partner	**Calendar Year**					
	2015	**2016**	**2017**	**2018**	**2019**	**2020**
World	***1374***	***1372***	***1385***	***1267***	***1425***	***1369***
Netherlands	944	851	841	940	1018	1177
United States	39	46	55	47	55	59
Argentina	216	255	253	152	156	46
Germany	17	15	8	8	35	37
Brazil	99	179	151	71	91	20
Other	21	18	12	5	21	19
France	12	8	12	9	12	13
India	26	0	54	36	39	0
U.S. Market Share	*3%*	*3%*	*4%*	*4%*	*4%*	*4%*
***Thousand Metric Tons (TMT)**						

Source: Trade Data Monitor (EuroStat)

e) FOOD AID: Belgium is not a food aid recipient, but the country occasionally provides food aid. This aid never involves GE plant products for human consumption.

f) TRADE BARRIERS: The slow approval process of new GE events by the European Union has significantly affected U.S. exports to Belgium, in particular corn, corn gluten feed (CGF), and distiller's dried grains with solubles (DDGS). Despite U.S. rice industry efforts, the impracticable EU regulations

for the low-level presence (LLP) of GE materials have permanently affected imports of U.S. long grain rice, following the unintended presence of the commercial supply of U.S. long grain rice with the Liberty Link 601 GE trait in 2016. Furthermore, mandatory labeling of the presence of GE ingredients in food has caused processors to avoid ingredients that derive from GE varieties.

Belgium Corn Imports

Partner	Calendar Year				
	2016	2017	2018	2019	2020
World	***1697***	***1782***	***1999***	***1975***	***1907***
France	717	690	978	713	862
Ukraine	478	488	556	717	419
Netherlands	220	385	410	411	463
Germany	32	43	39	76	25
Other	248	174	15	58	138
U.S. Market Share	*0%*	*0%*	*0%*	*0%*	*0%*
***Thousand Metric Tons (TMT)**					

Source: Trade Data Monitor (EuroStat)

PART B: POLICY

a) REGULATORY FRAMEWORK: Belgium has implemented 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, the so-called 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 Belgian Federal Agency for the Safety of the Food Chain (FASFC) 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 (Regulation (EC) No 1830/2003).

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. When the EFSA opinion is positive and the advice of the BAC is in line, the Belgian government may decide to vote in favor of the particular GE event if the other risk management criteria are fulfilled.

Please search the Agricultural Biotechnology Annual European Union report in GAIN for more information on the European agricultural biotechnology approval process.

b) APPROVALS: 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 Regulation (EC) No 1829/2003 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 Directive 2001/18/EC 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 Commission Directive (EU) 2018/350 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 will continue until 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, VIB started a new four-year field trial with GE poplar that has an altered wood composition.

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.[5] Belgium has contributed 12 plant notifications (one in 2020) since the implementation of Directive 90/220/EEC (21 October 1991). Since 1991, 22 EU Member States have notified cases of the deliberate release of GE plants, and Belgium has the eighth most notifications.

e) INNOVATIVE BIOTECHNOLOGIES: Belgium is complying with the ECJ's 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 research, the region 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 dismissive standpoint towards agricultural biotechnology, has left the government conflicted.

Regardless, genome editing is being widely used in laboratories in Belgium 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

[5] https://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx

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 already developed innovative biotechnology crops, such as late blight resistant Bintje potatoes, non-allergenic celery, and non-bitter chicory and endive. However, these have not been 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 Court of Justice ruling stated that products of genome editing fall under the "GMO Directive." However, the Commission's study concluded that this Directive is not "fit for purpose" for these newer biotechnology products and a targeted policy action is needed (see GAIN here). The study says that genome editing can contribute to the objectives of the European Green Deal's F2F and Biodiversity Strategies. The Commission indicated that it will engage in a wide-ranging communication effort with co-legislators and stakeholders in the EU.

On September 24, 2021, the European Commission published its roadmap to develop a legislative initiative for plants produced by certain genome editing techniques. This initiative will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. The policy roadmap is based on the findings of the Commission's study. The publication of the roadmap is the first step in the legislative process. It began with a 4-week feedback which ended on October 22, 2021. A more comprehensive public consultation process will take place in 2022 (see GAIN here).

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 tests for GE traits in imports. Positive test results are submitted to the European Rapid Alert System for Food and Feed (RASFF). 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 Directive 98/44/EC for the regulation and legal protection of biotechnological inventions. However, IPR is not applicable since commercial production of GE crops is absent in Belgium.

l) 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) 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, the Flemish Institute for Biotechnology (VIB) is very active on innovative biotechnologies and was involved in improving the efficacy of the CRISPR techniques. VIB's 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: 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 products 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): Directive 98/44/EC 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 and its modified genetic material.

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 https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-brussels-capital-region
- Flemish Region
    - Please see https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-flemish-region
- Wallonia Region
    - Please see https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-wallonia

b) APPROVALS: Please search the Agricultural Biotechnology Annual European Union report in GAIN for more information.

c) LABELING and TRACEABILITY: If the Contained Use Directive (Directive 2009/41/EC) is applicable to the product, there is no labeling obligation. If the microbial biotechnology products are thoroughly purified to make sure all traces of GE microorganisms are gone, no "GMO" labeling is

required. 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.

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 Directive 98/44/EC for the regulation and legal protection of biotechnological inventions.

g) RELATED ISSUES: None.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS: The Belgian public is not aware of microbial biotech in food production. FAS/Brussels is following the application for a GE microorganism by one U.S. food company. The company feels confident that the EU public will not be deterred by the "GMO" label on its products. The application is currently undergoing the EU's "GMO" approval process.

b) MARKET ACCEPTANCE/STUDIES: There are no market acceptance studies available.

Attachments:

No Attachments