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**Report Highlights:**

Public rejection of genetically engineered (GE) plants in Germany is widespread. There is no commercial GE crop production and practically no foods labeled as containing “genetically modified organisms” (“GMO”) on the market. Despite this, Germany is home to world-class companies that develop and supply GE seeds globally. The decision of the Court of Justice of the European Union (CJEU) on the regulation of genome editing puts the future of the domestic plant breeding sector in jeopardy. Germany’s livestock industry is a major consumer of imported GE soybeans for use as animal feed.

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**Executive Summary:**

Germany is the most populous and economically powerful country in the European Union (EU). Germany is influential in agricultural policy, both within the EU and globally. Germans are generally open to new technology and willing to innovate, but farming and especially agricultural biotechnology occupies a unique political space. German society is conflicted regarding agricultural biotechnology and this is reflected in mixed government policies and messaging. Public rejection of GE crops is widespread. Polling shows German public opposition to GE foods runs steadily in the 80 percent range with a presumed high degree of familiarity with the issue. For nearly a generation, German environmental and consumer activists have protested against the use of biotechnology in agriculture – both in Germany and globally. Biotech test plots, which are used both as a research tool and are a required part of the EU regulatory approval process, were destroyed by vandals so often that test plots are no longer attempted in Germany today.

In the current environment there is very little prospect of developing a German market for GE crops or foods, other than the existing feed market for soybeans. Political, business, regulatory, and social barriers raise questions about the long-term competitiveness of the German agricultural biotechnology sector. The CJEU's decision to regulate products of innovative biotechnology as GE came as a surprise to many stakeholders and it has sparked a debate about the future of plant breeding in Germany and Europe. There are still around 130 companies engaged in the breeding and marketing of agricultural and horticultural crops in Germany, among them world-class, international seed companies such as Bayer, BASF, and KWS. These international companies are major suppliers of both GE and conventionally bred seeds to markets outside of Europe. However, these major German agricultural companies have since moved research and development operations to sites outside of the EU, for example the United States; Bayer did so in 2004 and completed the acquisition of Monsanto in June 2018. BASF followed Bayer in 2012 and KWS opened its U.S. biotech research center in 2015. This is a reaction to negative attitudes toward biotech crops in Europe as well as non-existent consumer markets. Germany, nonetheless, remains a major consumer of GE products since it imports about six million metric tons of soybeans and soybean meal for animal feed annually.

## **CHAPTER 1: PLANT BIOTECHNOLOGY**

### **PART A: PRODUCTION AND TRADE:**

- a) **PRODUCT DEVELOPMENT:** German seed companies such as Bayer Crop Science, BASF, and KWS develop GE plants or crops. However, as multinational companies they have moved production sites outside of Europe to the United States and other countries such as Brazil, Argentina, South Africa, India, China, and Japan.

- b) **COMMERCIAL PRODUCTION:** There is no commercial production of GE crops in Germany. Additionally, GE seeds are not produced in Germany for sale abroad. However, German seed companies including Bayer CropScience, BASF, and KWS supply biotech seeds to farmers worldwide from production sites in the United States and elsewhere. In the United States, Bayer and BASF moved research to North Carolina, while KWS opened a research center in Missouri. Bayer acquired Monsanto and its U.S. facilities in June 2018.
- c) **EXPORTS:** There is no commercial production of GE crops in Germany. Germany does not export GE crops to the United States or other countries.
- d) **IMPORTS:** Germany is a major livestock producer and is dependent upon imported soy as a feed protein source. Germany imported nearly six million metric tons (MMT) of soybeans and soybean meal in 2020, nearly all of it produced from GE varieties. Soybean imports totaled over 3.8 MMT in 2020. It is estimated that more than 60 percent came from the United States either directly or channeled through the Netherlands. Together, this would add up to over \$700 million in U.S. soybean sales to Germany in 2020. This made soybeans the top U.S. agricultural export to Germany. In addition to soybeans, Germany also imported nearly 2.1 MMT of soybean meal in 2020. For soybean meal, traditionally the United States has a small market share with most of it coming from Argentina and Brazil, and more recently from Russia.
- e) **FOOD AID:** Germany is not a food aid recipient. The Federal Ministry for Economic Cooperation and Development coordinates a special initiative, 'ONE WORLD – No Hunger', and is spending about 6.8 billion Euros a year on food security and rural development. Germany also supports the assistance provided by the European Union and the United Nations World Food Programme (WFP).
- f) **TRADE BARRIERS:** EU policies and legislation lead to biotechnology-related trade barriers that negatively impact U.S. exports.
- **Asynchronous Approvals:** New GE crops are entering the global marketplace at an increasingly rapid rate. The EU regulatory procedures for approving biotech plants takes significantly longer than those in supplier countries. This has led to a widening gap between GE products deregulated and grown in the United States and other countries approving of biotechnology and those approved in the EU, resulting in the partial or complete disruption of trade in affected commodities and processed products.
  - **Low Level Presence:** The effect of asynchronous approvals is reinforced by the EU's policy for low level or adventitious presence of events. Commodity trading companies see the risk to their operations increase when trading with countries that grow GE products, when these products are not-yet approved in the EU.

- Zero tolerance in seeds: Zero tolerance of adventitious presence affects seed trade. The fact that the European Union only allows cultivation of MON810, serves as a trade barrier for U.S. seed exports containing or with adventitious presence of other GE events.

## PART B: POLICY

a) **REGULATORY FRAMEWORK**: Within the EU, GE crops and their products are authorized on a case-by-case basis for the uses defined by the applicant. Member States carry out initial risk assessments for the cultivation of GE crops and for the food and feed imports. After weighing the available information, at the EU level, Member States take a majority vote to approve or deny the authorization for imports or to cultivate the GE variety throughout the EU.

i. **Responsible government ministries and their role in the regulation of GE plants**

The Federal Office of Consumer Protection and Food Safety (known by its German abbreviation BVL) is the German authority responsible for regulating agricultural GE products. The BVL is an autonomous part of the Federal Ministry of Food and Agriculture (BMEL).

Germany does not independently approve GE products; approvals are made via the EU approval process. In this process, applications for a GE approval can be submitted to the competent authority in any given member state. If a company decides to apply in Germany, it has to file the application with BVL. BVL passes the notification of a GE approval request and the notification dossier to the European Food Safety Authority (EFSA). After checking the completeness and quality of the data supplied in the dossier, EFSA evaluates the risk potential. At this stage, all member states may submit comments. In Germany, BVL prepares national comments in consultation with the Federal Agency for Nature Conservation (BfN) and the Robert Koch Institute (RKI). In addition, the BVL obtains comments from the Federal Institute for Risk Assessment (BfR) and the Julius Kühn Institute (JKI). EFSA takes the national comments submitted by the member states into consideration and issues its safety opinion.

BVL also evaluates the safety of biotech crops that are used in contained systems (i.e., for research or industrial production), and issues environmental release permits and conducts environmental monitoring. BVL does this under the authority of Germany's Genetic Engineering Act, which implements EU guidelines as national legislation. While primary responsibility for GE policy in Germany rests with BMEL, the ministries of Economics and Energy (BMWI), Health (BMG), Education and Research (BMBF), and Environment, Nature Conservation, and Reactor Safety (BMU) are also involved in the opinion and decision-making process and need to approve Germany's voting decision in EU committees and councils.

ii. **Biosafety Committee and its Role**

BVL hosts the Central Committee for Biological Safety (Zentrale Kommission fuer Biologische Sicherheit, ZKBS, [https://www.zkbs-online.de/ZKBS/EN/Home/home\\_node.html](https://www.zkbs-online.de/ZKBS/EN/Home/home_node.html)), which examines and assesses applications for approval of biotechnology facilities on safety-relevant questions of genetic engineering and for the classification of microorganisms as donor and recipient organisms for genetic engineering. It examines applications for approval of a release and placing on the market of GE organisms, and prepares responses and opinions as well as the procedures for decision-making on the applications.

The ZKBS consists of 20 independent members with a designated deputy for each member. The members are divided into two groups a) experts in the field of microbiology, cellular biology, virology, genetics, plant breeding, hygiene, ecology, toxicology, and safety technology; and b) competent persons of a social interest group (labor unions, occupational safety and health, economy, agriculture, environmental protection, nature conservation, consumer protection, research, and funding organizations). The members of the ZKBS and their deputies are appointed for the duration of three years by the BMEL in agreement with the following ministries: BMBF, BMWI, Labor and Social Affairs (BMAS), BMG, and BMU.

iii. **Political factors that may influence regulatory decisions**

As the largest EU Member State, Germany plays a significant role in the regulatory acceptance of GE crops in Europe. This includes voting at the EU level on approvals; transferring and incorporating EU laws into German legislation; establishing liability for GE ‘contamination’ (the inadvertent comingling of unapproved GE products with conventional products); and enforcement. Germany also exerts its influence in the politics of biotechnology when it abstains from voting because a quorum of countries is necessary for legislation to pass in the EU. This abstention has become a regular occurrence in recent years due to disagreements between Germany’s government ministries.

iv. **Regulatory distinction between GE plant products containing DNA in the final form of the product and those that do not**

This is regulated on the EU level, please refer to the respective section in the EU report.

v. **Regulatory distinction between GE plant products considered living versus non-living**

This is regulated on the EU level, please refer to the respective section in the EU report.

vi. **Distinctions between regulatory treatment of the approval for food, feed, processing and environmental release**

EU regulations provide a detailed approval process for GE products. Requirements differ depending on whether the GE products are intended for import, distribution, processing, or

cultivation in the EU. For details, please refer to the EU report.

vii. **Pertinent pending legislations or regulations**

An EU directive that allows Member States to ban the cultivation of GE crops in their territories for non-scientific reasons was adopted in March 2015. There has been disagreement within government as to whether the ban might cover the entire country or be decided individually by each of the German states (*Länder*). The coalition agreement of the new German government, published in spring 2018, states that the ban on the cultivation of genetically engineered plants (opt-out) will be regulated nationwide. The legislation has not yet come into force. It will only affect cultivation and not U.S. exports to Germany.

viii. **Timeline followed for approvals**

This is regulated at the EU level, please refer to the respective section in the EU report.

- b) **APPROVALS:** The German voting pattern on approvals at the EU level in some ways contrasts with its local regulation of GE crops. While there is no GE cultivation or open field trials in the country, Germany abstained from almost every vote since May 2012.
- c) **STACKED OR PYRAMIDED EVENT APPROVALS:** Stacked events are subject to risk assessment at the EU-level. The approval process is the same as for single events. Risk assessment of stacked events follows the principles provided in EFSA's Guidance Document, which stipulates that where all single events have been assessed, the risk assessment of stacked events should focus mainly on issues related to stability, expression of the events, and potential interactions between the events.
- d) **FIELD TESTING:** Basic plant science research is very strong at German universities, where biotech plants are routinely created to test gene function and answer other biological questions. However, scientists face a strong incentive to work outside of Germany if they wish to develop new crop varieties using biotechnology. In the past, German companies and universities conducted small field trials of biotech plants, but the number has decreased dramatically over the last years. In 2007, experimental releases totaled nearly 70 hectares. Today there are no field trials. German law requires researchers to publicly publish the exact location of a test plot on the internet. This made it easy for activists to vandalize the plots. Vandalism is a significant barrier to conducting field trials in Germany.
- e) **INNOVATIVE BIOTECHNOLOGIES:** The September 2021 election did not render a clear winner and a coalition of three parties (out of the six parties in German parliament) will have to form the new government. At the time of writing, the Green Party, the Free Democratic Party (FDP), and the SPD agreed to formally enter coalition talks. This means that they will start formal discussions on the make-up of what will likely be Germany's next government. It is expected that these negotiations



will carry on at least until the end of 2021.

In the meantime, the previous government will serve in an acting capacity. This government was formed after September 2017 parliamentary elections and consisted of a coalition of the Christian Democratic Union (CDU), its sister party the Christian Social Union of Bavaria (CSU), and the Social Democratic Party (SPD), as was its immediate predecessor. Their coalition agreement outlined objectives for the following three and a half years. For genetic engineering and innovative biotechnologies, the coalition agreement referred to the, “ECJ [European Court of Justice] decision whether NBT’s [New Breeding Techniques], such as CRISPR/Cas, are to be legally classified as a genetic modification. Then, the coalition will establish rules on the European and/or national level that ensure the application of the precautionary principle and freedom of choice.”

The CJEU decided on July 25, 2018 that genome editing falls under the legislation for GE products. Since then, the decision and its impacts have been discussed in the media. There is disagreement on this issue within the German government between SPD and CDU/CSU. Thus, during the tenure of this ruling coalition, the German Government remained rather passive, waiting for the European Commission to act.

In principle, CDU/CSU acknowledge the great potential of innovative biotechnologies, such as CRISPR/Cas9, for a more efficient, faster, and more cost-efficient plant breeding. Thus, CDU/CSU wanted to develop a "biotechnology agenda" to create jobs and advocated in favor of a process and product-related assessment after the CJEU’s decision. However, the coalition partner SPD is opposed to the use of agricultural biotechnology and advocated for strict regulation of innovative biotechnologies. SPD politicians welcomed the ruling as a clear commitment to the precautionary principle in Europe.

- f) **COEXISTENCE:** Germany's policy of “coexistence” between GE and conventionally grown and organic crops is biased against the use of GE crops. Since there is no GE cultivation in Germany, coexistence regulations are currently theoretical. But in the past, German federal and local governments put into place an assortment of planting bans, buffer zones, and other requirements. For instance, Germany requires a minimum distance of 150 meters – a U.S. football field-and-a-half – between biotech and conventional fields, and a minimum distance of 300 meters between biotech and organic fields.
- g) **LABELING AND TRACEABILITY:** Germany applies EU regulations for labeling GE foods (Regulations EC 1829/2003 and 1830/2003). No foods labeled as “containing genetically modified organisms” are sold in Germany. Under EU rules, foods require a GE-label only if they contain GE-ingredients. There is no required labeling for meat or dairy products coming from animals fed with GE feeds. In May 2008, the German government initiated a voluntary “*Ohne Gentechnik*” (GE-free) labeling program to help consumers better identify products and to standardize the information

consumers receive. The actual national label was introduced by BMEL's predecessor, the Ministry for Food, Agriculture and Consumer Protection (BMELV) in August 2009. Sales under the label generated \$14.4 billion<sup>1</sup> in Germany in 2020, with the vast majority (70 percent) consisting of dairy products, followed by poultry products (17 percent) and eggs (nine percent).

- h) **MONITORING AND TESTING:** Germany fully enforces EU rules relating to GE crops. The Rapid Alert System for Food and Feed (RASFF) is used to report food safety issues to consumers, the trade, and other Member States. In the case of biotech crops, Germany's 16 states test for unauthorized GE products and report violations via the RASFF. Germany has a decentralized system for testing and controlling the illegal entry of GE products into Germany. The German states (*Länder*) each have an authority with the competence to ensure that no unauthorized biotech product enters the German retail market. Each state has its own monitoring and sampling plan. Since the experts know the kind of products that potentially contain GE events, they specifically sample for these products. Sampling is primarily done at the wholesale and the processing level.
- i) **LOW-LEVEL PRESENCE (LLP) POLICY:** Germany does not have its own LLP policy. Rather, it fully implements EU Regulation 619/2011, which details official sampling methods and analysis. This "technical solution" threshold is 0.1 percent, which defines zero (as in zero tolerance). The EU "technical solution" is not an actual LLP policy.
- j) **ADDITIONAL REGULATORY REQUIREMENTS:** German farmers producing GE crops must register their fields with the governmental body BVL three months before planting. However, GE cultivation is banned in Germany. However, GE cultivation is de-facto banned in Germany as the country is using the "opt-out" option provided by the EU. Albeit, it has not yet been decided if the opt-out and ultimately the enforcement will be regulated by the federal government or the 16 state governments individually
- k) **INTELLECTUAL PROPERTY RIGHTS:** German intellectual property law mainly consists of the Copyright Act (UrhG), Patent Act (PatG), Trademark Act (MarkenG), Utility Model Act (GebrMG) and Design Rights Act (GeschMG), flanked by some provisions of the Civil Code (BGB) and the Act Against Unfair Competition (UWG). All of these bodies of law have histories dating back to before German membership in the EU but have since been revised and amended several times to implement European Directives and Guidelines or treaties. However, in Germany, the Plant Variety Protection Act protects the intellectual property of new varieties of plants. A breeder can apply for plant variety protection for a new variety at the Federal Office of Plant Varieties (*Bundessortenamt*, BSA). In Germany, plant variety protection is an intellectual property right separate from a patent.
- l) **CARTAGENA PROTOCOL RATIFICATION:** Germany signed the Cartagena Protocol on Biosafety on May 24, 2000. It was ratified in November 2003 and entered into force in February

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<sup>1</sup> Average exchange rate for 2020: 1 Euro = USD1.1422

2004.

- m) **INTERNATIONAL TREATIES/FORUMS:** Germany is a member of several international organizations dealing with plant protection and plant health like the European and Mediterranean Plant Protection Organization, the Organization for Economic Co-operation and Development (OECD), The Food and Agriculture Organization of the United Nations (FAO), and Codex. The Federal Republic of Germany is the host country for a subsidiary body of the Codex Alimentarius Commission, the Codex Committee on Nutrition and Foods for Special Dietary Uses. Germany does not actively participate in discussions related to GE plants.
- n) **RELATED ISSUES:**  
For the past several years the German Green Party has been supported by a range of non-governmental organizations (NGOs), and introduced policy proposals to end the importation of GE soybeans into Germany. Several proposals aim at replacing soy imports with domestically produced pulses and other protein crops. However, based on European growing conditions and competing land use for other crops, a full replacement of imported protein feeds does not appear to be a realistic option in the near term.

## PART C: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Years of controversy have produced a large number of polling studies on German and European attitudes toward GE crops. Findings from studies and polls relative to the marketing of U.S. agricultural products include: Though opposition to GE foods might vary in polls, opposition in general remains high and steady over time. For consumers, maintaining the precautionary principle is very important as well as labelling of GE foods. In general, the public demands that societal concerns take precedence over economic interests.
- b) **MARKET ACCEPTANCE:** For a generation, German consumers have been exposed to consistent messaging from NGOs that biotech crops are dangerous, a product of exploitive capitalism and even immoral. As a result, the use of biotech crops in foods is a highly contentious and politicized issue. Since biotech crops were first introduced in the mid-1990s, attempts to educate consumers and opponents about the benefits of biotech crops and about the science in general have proven ineffective. German public opposition to GE foods has run steadily in the 80 percent range.

According to the German Food Federation, an estimated 60-80 percent of all food in German supermarkets has been exposed to biotechnology in some form. GE-microorganisms such as bacteria and fungi are increasingly used for the commercial production of a diversity of enzymes that are tailored to specific food processing conditions, such as the production of calf chymosin for cheese making with GE microorganisms. The Union of German Academies of Science has concluded that objections to biotech in agriculture lack any scientific basis, and agricultural biotech tends to find

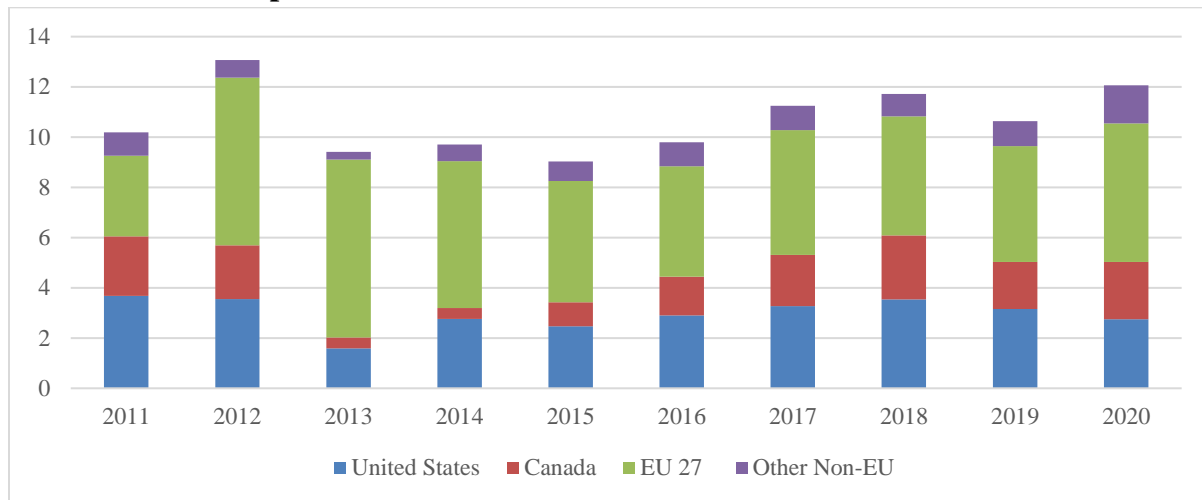
stronger support among consumers with postgraduate degrees.

Although the EU has approved numerous biotech plants that would theoretically be legal to sell in Germany, practically no labeled biotech foods are on the market. One contributing factor is the concentration of the food retail sector and its vulnerability to narrowly focused consumer activists. The German retail food sector is dominated by four large retail groups, which combined had more than 74 percent of the market in 2020 (70 percent in 2019). Germany also has the highest market share of the world's discount retail food stores. Within this low-margin and concentrated industry, anti-biotech NGOs would likely target any retailer offering GE-labeled products. This presents an unacceptable brand risk that hinders the introduction of GE-labeled foods.

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** In Germany, research into GE animal biotechnology and cloning is mainly located at the Friedrich Loeffler Institute (FLI) in its Animal Genetics unit. This research is conducted in “closed system” laboratories. There is no production of cloned animals in Germany.
- b) **COMMERCIAL PRODUCTION:** There is no commercial production of GE animals and cloning in Germany.
- c) **EXPORTS:** As there is no commercial production, there are no exports.
- d) **BIOTECHNOLOGY IMPORTS:** There are no known imports of GE animals or cloned animals for agricultural purposes into Germany. However, Germany has most likely imported semen and embryos from cloned animals as well as from offspring from clones as part of normal herd improvement programs, particularly in the dairy sector. The specific quantity of these imports is not available. The United States is the second largest single country supplier of bovine semen to Germany after the Netherlands, with an average market share of 28 percent in value over the past ten years.

**Chart: German Imports of Bovine Semen in \$ Million**

Source: FAS/Berlin based on data from Trade Data Monitor, LLC

- e) **TRADE BARRIERS:** Most GE-related trade barriers in Germany have their origins in EU regulation.

## PART E: POLICY

- a) **REGULATORY FRAMEWORK:** Germany implements the EU Regulation on animal biotechnology. Please see EFSA GE animal website:  
<https://www.efsa.europa.eu/en/topics/topic/gmanimals>
- b) **APPROVALS:** There is no GE animal approved or registered in Germany for use.
- c) **INNOVATIVE BIOTECHNOLOGIES:** There are no known current or pending German regulations of these technologies in animals. The EU has guidance and EFSA published guidance for food and feed derived from GE animals and a guidance on environmental risk assessment. Please see  
<https://www.efsa.europa.eu/en/efsajournal/pub/2501>  
<https://www.efsa.europa.eu/en/efsajournal/pub/3200>
- d) **LABELING AND TRACEABILITY:** No policy.
- e) **INTELLECTUAL PROPERTY RIGHTS (IPR):** German intellectual property law mainly consists of the Copyright Act (UrhG), Patent Act (PatG), Trademark Act (MarkenG), Utility Model Act (GebrMG) and Design Rights Act (GeschMG), flanked by some provisions of the Civil Code (BGB) and the Act Against Unfair Competition (UWG). All of these bodies of law have histories dating back to before German membership in the European Union (EU) but have since been revised

and amended several times to implement European Directives and Guidelines or treaties.

- f) **INTERNATIONAL TREATIES/FORUMS:** As a member of the EU, Germany is a member of the Codex Alimentarius. Germany is also a member of the World Organization for Animal Health (OIE). Germany does not actively participate in discussions related to GE plants or animals.
- g) **RELATED ISSUES:** As elaborated in the previous section, a new coalition government is currently being formed after the September 2021 election. The former coalition government (CDU/CSU and SPD) rejected the use of cloning. The German Parliament unanimously voted against the cloning of animals on May 8, 2015. The motion includes cloning of animals for food production and labeling of cloned animals, their offspring, and products derived therefrom. With its motion, the German parliament challenges an EU proposal, which prohibits cloning in food production but not the import of offspring of clones and their meat or milk.

## PART F: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Animal biotechnology is currently not high on the political agenda, and there is currently no high-profile lobbying for or against the use of livestock cloning or GE animals. However, public views on cloning are widely believed to be similar to those held for GE crops. Past EU-level debates on the regulation of cloning have not received positive media coverage. There has been limited media coverage of cloning in the context of endangered or extinct species. That coverage was fairly balanced.
- b) **MARKET ACCEPTANCE/STUDIES:** There is little awareness of GE animals or cloning among the German public. Post is not aware of studies specific to Germany on the marketing GE animals or clones.

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

### PART G: PRODUCTION AND TRADE

- a) **COMMERCIAL PRODUCTION:** German companies commercially produce food ingredients derived from microbial biotechnology. In Germany, microbial biotechnology falls under the superordinate term “industrial biotechnology”, and it is difficult to estimate the share of microbial biotechnology within the sector. This is because the component of biotechnology in large groups of the food, nutrition, chemical, and pharmaceutical industries is not specifically listed and is therefore not recorded statistically. According to the German Association of Biotechnology Industries (DIB), sales of industrial biotechnology amounted to over \$300 million in 2019.

- b) **EXPORTS:** There are no official statistics nor estimates on exports with microbial biotechnology products. The only microbial biotech-derived food ingredients exported by Germany are those traditionally used in the production of alcoholic beverages, dairy products, and processed products. Likewise, Germany exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.
- c) **IMPORTS:** There are no official statistics nor estimates on imports of microbial biotechnology products. The only microbial biotech-derived food ingredients imported by Germany are those traditionally used in the production of alcoholic beverages, dairy products, and processed products. Likewise, Germany imports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.
- d) **TRADE BARRIERS:** In general, most biotechnology related trade barriers in Germany have their origins in EU regulation. There is no information on any additional biotechnology-related trade barriers that negatively affect U.S. exports of microbial biotech-derived food ingredients or processed food products containing microbial biotech-derived food ingredients.

## PART H: POLICY

- a) **REGULATORY FRAMEWORK:** The Federal Office for Consumer Protection and Food Safety (BVL) is the national competent authority. According to EU Directive 2001/18/EC, the BVL coordinates the exchange of information between consent holder, the public, and the authorities involved in the approval procedure. The BVL is also involved in developing policies and organizational structures for monitoring products of genetic engineering. Holders of authorization to use specified GE products (placing on the market) are under the obligation to monitor these products. This obligation is based on EU Directive 2001/18/EC on the release of “GMOs” into the environment, and EU regulation 1829/2003/EC on genetically modified food and feed, both of which are transposed into German law in § 16c of the Genetic Engineering Act (GenTG).
- b) **APPROVALS:** No national policy specific to microbial biotechnology.
- c) **LABELING AND TRACEABILITY:** No national policy specific to microbial biotechnology.
- d) **MONITORING AND TESTING:** No national policy specific to microbial biotechnology.
- e) **ADDITIONAL REGULATORY REQUIREMENTS:** In general, most biotechnology related trade barriers in Germany have their origins in EU regulation. There is no information on any additional biotechnology-related regulatory requirements that negatively impact U.S. exports of microbial biotech-derived food ingredients

- f) **INTELLECTUAL PROPERTY RIGHTS (IPR):** German intellectual property law mainly consists of the Copyright Act (UrhG), Patent Act (PatG), Trademark Act (MarkenG), Utility Model Act (GebrMG) and Design Rights Act (GeschMG), flanked by some provisions of the Civil Code (BGB) and the Act Against Unfair Competition (UWG). All of these bodies of law have histories dating back to before German membership in the European Union (EU) but have since been revised and amended several times to implement European Directives and Guidelines or treaties.

## PART I: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Microbial biotechnology has never been high on the political agenda, and there is currently no high-profile lobbying for or against its use in food. In general, the public is not aware that microbial biotechnology is an essential part of today's food production. Media coverage of the issue is limited.
- b) **MARKET ACCEPTANCE/STUDIES:** There is little awareness of microbial biotechnology in food production within the German public.

### **Attachments:**

No Attachments