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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 Genetically Modified Organisms ("GMO") on the market. Despite this, Germany is home to world-class companies that develop and supply GE seeds globally. Germany's livestock industry is a major consumer of imported GE soybeans for use as animal feed. The next federal election is in September 2017, and GE policy might be subject to change.

Section I. 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 agricultural biotechnology occupies a unique political space. German society remains conflicted regarding agricultural biotechnology and this is reflected in mixed government policies and messaging. Public rejection of genetically engineered (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 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 German agricultural biotechnology. Nevertheless, Germany has given rise to world-class seed companies such as Bayer, BASF, and KWS. In September 2016, Bayer announced its acquisition of Monsanto. The German 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 the United States; Bayer did so in 2004, and BASF followed in 2012. KWS opened its new biotech research center in St. Louis, Missouri in January 2015. This can be seen as 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 more than six million metric tons of soybeans and soy meal for animal feed annually.

There is little public awareness or discussion of GE animals.

Section II. Plant and Animal Biotechnology

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, their production sites are outside of Europe. In the biomedical industry, more than twenty biopharmaceuticals including genetically engineered enzymes, antibodies, and clotting factors are produced in Germany. These products are regulated under German pharmaceutical laws.

b. COMMERCIAL PRODUCTION: There is no commercial production of GE crops in Germany. In addition, 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 outside of Europe. KWS, for example, is a leading supplier of GE sugar beet seeds used by U.S. farmers.

c. EXPORTS: There is no commercial production of GE crops in Germany, and 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 roughly 6.2 million metric tons (MMT) of soybeans and soybean meal in 2016, nearly all of it produced from GE varieties. Soybean imports totaled nearly 3.2 million metric tons in 2016 with over 46 percent coming directly from the United States. Germany imported nearly 3.0 million metric tons of soybean meal in 2016. Here, the U.S. direct market share was below two percent. The main suppliers for soybeans and soybean meal are Argentina, Brazil, and the United States. Soybeans are the largest U.S. agricultural export to Germany.

e. FOOD AID: Germany is not a food aid recipient. The Federal Ministry for Economic Cooperation and Development coordinates a worldwide food aid program under the umbrella of the International Food Aid Convention; Germany provides food aid worth at least 56.24 million euros annually. Germany also supports the assistance provided by the European Union and the United Nations World Food Programme (WFP). Germany pays a basic contribution of 23 million euros to the WFP.

f. TRADE BARRIERS: none

PART B: POLICY

a. REGULATORY FRAMEWORK: Within the EU, GE crops and their products are authorized on a case-by-case basis for the particular 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. (EU-28 Biotechnology Annual 2016 has much more detail on the EU regulatory process.) 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).

The BVL receives a notification of a GE approval request, passes the notification dossier to the European Food Safety Authority (EFSA), checks the completeness and quality of the data supplied in the dossier, evaluates the risk potential, and issues its own statement to the EFSA. 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. The 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, Health, Research, and Environment are also involved in the opinion and decision-making process and need to approve Germany's voting decision in EU committees and councils.

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,' 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. This abstention has become more frequent in recent years due to disagreements between government ministries.

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. The German cabinet approved draft legislation to implement such a bill on November 2, 2016. The German parliament discussed the draft legislation only one time. Disagreements exist within the government as to whether the ban might cover the entire country or be decided individually by each of the German states. As such, the legislation has not yet come into force, and will likely be decided after the September 2017elections. The legislation only affects cultivation and not U.S. exports to Germany.

b. APPROVALS: The German voting patterns on approvals at the EU level in some ways sharply contrasts with its local regulation of GE crops. There have been two German objections in recent years (for EH 92-527-1 potato and TA 45 rapeseed), but Germany abstained from almost every vote since May 2012.

c. STACKED OR PYRAMIDED EVENT APPROVALS: Stacked events are subject to risk assessment on an 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 a) stability, b) expression of the events, and c) potential interactions between the events.

d. FIELD TESTING: Basic plant science research is very strong in German universities, where transgenic 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 few years. In 2007, experimental releases totaled nearly 70 hectares, but by 2017, there were no more field trials.

German law requires the researchers publically publish the exact location of a test plot on the internet. This made it easy for activist to vandalize the plots (here is a link to the mapping system). Vandalism is a significant barrier to conducting field trials in Germany.

e. INNOVATIVE BIOTECHNOLOGIES: The German federal election will take place on September 24th, 2017. Depending on the results, German GE policy may change. There is general consent between the different parties to ban the cultivation of GE crops. For innovative biotechnologies, such as genome editing, there is an approach to recognize its great potential with more efficient, faster, and more cost-efficient breeding favoring objective facts-based evaluations. There are parties who reject innovative biotechnologies advocating for a GE regulation. The last elections in 2013 resulted in a grand coalition government between Chancellor Merkel's Christian Democratic Union/Christian Social Union (CDU/CSU) party and the Social Democratic Party (SPD). Their coalition agreement acknowledged the "reservations of the majority of the population towards green biotechnology."

The Federal Ministry of Food and Agriculture started a dialogue series on new breeding techniques (NBTs) in April 2017. From the ministry's point of view, a number of technical and legal as well as societal and ethical issues are emerging. The German government has not yet formed a position on the question of NBT regulation. But the government included an NBT statement in its latest draft legislation to ban the cultivation of GE crops. Here the government ranks the precautionary principle and the innovation principle on the same level of importance as the basis for NBT assessment. The government wants to ensure a balanced discussion that considers the benefits and risks of NBTs.

Neither production nor field trials are taking place in Germany. Cibus, a US-based plant biotechnology company, has approached regulators in Germany and several other Member States seeking permission to sell herbicide-resistant rapeseed varieties produced by oligonucleotide-directed mutagenesis (ODM). In March 2015, the Federal Office of Consumer Protection and Food Safety (BVL) stated the trait does not fall under German biotech legislation since it is a targeted mutation rather than an insertion of foreign DNA. The BVL cited a Central Commission for biological safety (ZKBS) evaluation from 2012, declaring ODM a non-GE technology. Nevertheless, a broad coalition of anti-GE organizations disagreed, arguing that ODM is indeed genetic engineering and therefore requires regulation.

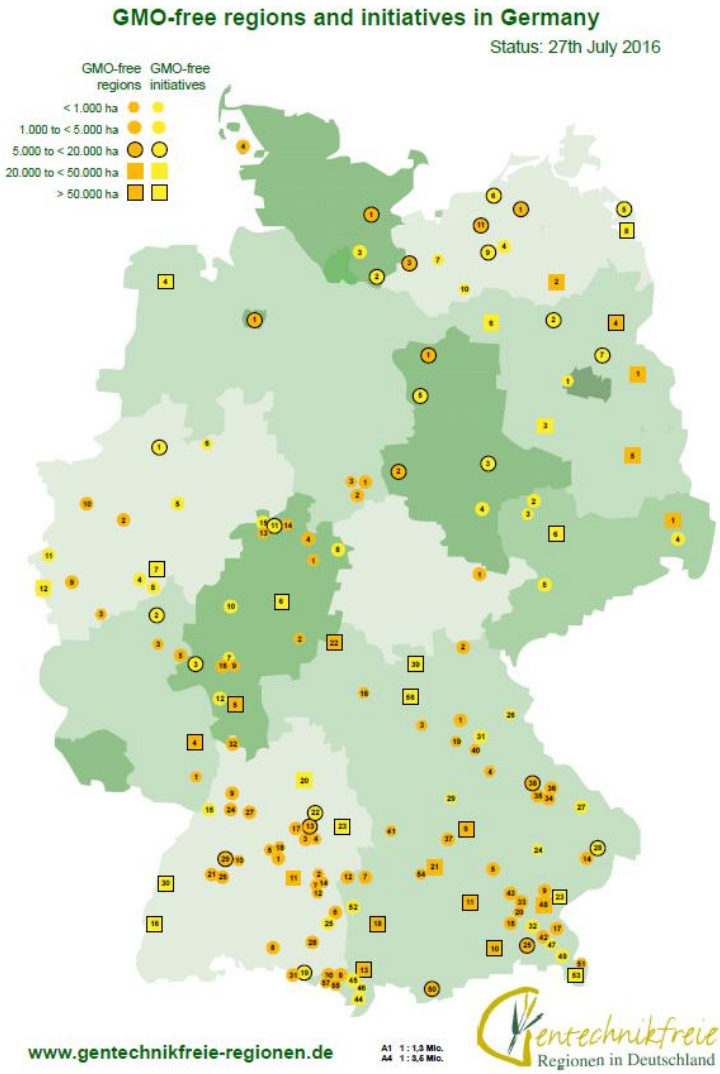
f. COEXISTENCE: Germany's policy of "coexistence" between GE and conventionally-grown and organic crops is biased against the use of GE crops. Since there is no GE cultivation in Germany, coexistence regulations are currently theoretical. But in the past, German federal and local governments put into place an assortment of planting bans, segregation distances, 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 cornfields.

Some state-level governments in Germany have also declared themselves biotech-free. Of the 16 German states (laender), the states of Baden-Württemberg, Bavaria, Bremen, Hamburg, Hesse,

Lower Saxony, North Rhine-Westphalia, Rhineland-Palatinate, Saarland, Schleswig-Holstein, and Thuringia all support biotech free to some degree. Governing coalitions of political parties have 'biotech free' in their coalition agreements, and in some states growing biotech crops on state-owned land is prohibited. The Green Party is the main driver for laender governments to join the EU-wide network of GE-free regions. The Greens form a governing coalition in most of the laender with the exception of Bavaria, Brandenburg, Mecklenburg-Western Pomerania, North Rhine-Westphalia, Saxony, and Saarland.

There are 215 initiatives and self-declared 'biotech-free zones' in Germany. The first biotech-free region in Germany was founded in 2004. Biotech-free areas are formed by voluntary agreement among farmers to not plant biotech crops in the region. There is no legal enforcement mechanism connected to the declaration. In part, these declarations are used to help promote a regions image and attract tourism. Biotech-free areas are especially popular in the southern state of Bavaria. The total area covered by these biotech-free zones in 2016 amounts to nearly 1.2 million hectares of arable land with over 31,000 participating farmers. This is equivalent to about 7 percent of Germany's farmland (arable land and grassland).

Germany's influential Catholic and Protestant churches have also taken strong anti-biotech positions. Biotech crops are generally not allowed on church-owned lands, which is important because churches have significant agricultural holdings in Germany. Land rental contracts usually forbid farmers from growing biotech crops on church-owned land, even if only a portion of the land the farmers work is church-owned.



Source: www.gentechnikfreie-regionen.de

g. LABELING: Germany applies EU regulations for labeling GE foods (Regulations EC 1829/2003 and 1830/2003). No foods labeled as containing 'GMO' are sold in Germany. Under EU rules, foods require such a label only if GE crops are used as an ingredient. There is no required labeling for meat or dairy products coming from animals fed with GE feeds.

In May 2008, the German government created a voluntary "Ohne Gentechnik" (GMO-free) labeling program. In August 2009, the Ministry for Food, Agriculture and Consumer Protection introduced a national label to help consumers better identify products and to standardize the information consumers receive. This label is administered by the Verband Lebensmittel Ohne Gentechnik (VLOG—organization for food without genetic engineering) and promoted to the public by the Ministry of Agriculture.

Food manufacturers can use an official label on their products only if they comply with strict documentation requirements. Eggs and cheese are the most popular products sold under this

labeling scheme. The label may not be used for products for which no biotech varieties exist, for example products such as oranges, wheat or basmati rice. The administration of this program is largely entrusted to the VLOG. The Association represents more than 450 members and licensees. So far most licensees are from Germany. Combined annual sales exceed 214 billion euros.

h. MONITORING AND TESTING: Germany has a decentralized system for testing and controlling the illegal entry of GE products into Germany. The German laender each have the authority with the competence to ensure that no unauthorized biotech product enters the German retail market. The laender each have their own monitoring and sampling plans. 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.

   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 laender test for unauthorized GE products and report violations via the RASFF.

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.

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 (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 on February 2004.

m. INTERNATIONAL TREATIES/FORA: Germany is a member of several international organizations dealing with plant protection and plant health like the European and Mediterranean Plant Protection Organization, the Organisation for Economic Co-operation and Development, The Food and Agriculture Organization of the United Nations, 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.

n. RELATED ISSUES*:*
The German company Bayer AG was successful in its bid for Monsanto, the world's largest seed company, with Monsanto's Board agreeing to a $66 billion purchase price; both companies signed a binding agreement on September 14, 2016. The merger would make Bayer the world's largest agrochemical company. Bayer CEO Werner Baumann responded to concerns about Monsanto's use of GMOs and its perceived market dominance by saying, "It is not our plan or our ambition or our intent to prevent farmers from having a choice." In initial reactions, environmental groups and politicians from the opposition called on the German government and the German Cartel Office to stop the deal. However, the responsibility lies with the EU Commission; The German Cartel Office can advise the EU Commission.

For the past several years, the German Green Party, supported by a range of non-governmental organizations (NGOs), has introduced policy proposals to end the importation of GE soybeans into Germany. Under several proposals, soy imports would be replaced by domestically produced pulses and other protein crops. However, a full replacement of imported protein feeds does not appear to be a realistic option in the near term. (For more information see Germany Finances Protein Strategy and New Protein Initiative in Lower Saxony).

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. A very comprehensive study comes from the European Commission/Eurostat and is titled Europeans and Biotechnology – Winds of Change (2010). Four findings from this study relative to the marketing of U.S. agricultural products include: 1) opposition to GE foods is high and steady over time; 2) the level of support for GE foods is declining; 3) familiarity with the technology or science does not improve attitudes; and 4) educating consumers does not increase GE crop acceptance (implying that messaging is more important than facts).

b. MARKET ACCEPTANCE: For nearly 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 Federation of Food Law and Food Science, an estimated 60-80 percent of all food in German supermarkets has come in contact with biotech products in some way. 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. Because there are broad exceptions to EU labeling requirements for food enzymes produced from GE microorganisms, many German consumers do not know there are biotech foods on the market.

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 five large retailers, which have more than 90 percent of the market. 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 is mainly at the Friedrich Loeffler Institute (FLI) in its Animal Genetics unit. This is conducted in "closed system" laboratories.

b. COMMERCIAL PRODUCTION: There is no commercial production of GE animals 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 for agricultural purposes into Germany. Germany has imported unknown numbers of genetics and offspring from clones as part of normal herd improvement programs, particularly in the dairy sector.

e. TRADE BARRIERS: Most GE-related trade barriers in Germany have their origins in EU regulation, especially the slow EU approval process for GE plant varieties commonly planted outside of Europe. Germany strictly enforces EU directives, testing guidance, and other import rules relating to the presence of unapproved events in food and feed.

PART E: POLICY

a. REGULATION: Germany implements the EU Regulation on animal biotechnology. Please see EFSA GE animal website: https://www.efsa.europa.eu/en/topics/topic/gmanimals

b. 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 also 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)

c. LABELING AND TRACEABILITY: There is no policy for the traceability and labeling of livestock clones. In discussion, officials and representatives express the desire for traceability in the United States.

d. 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.

e. INTERNATIONAL TREATIES/FORA: As a member of the EU, Germany is a member of Codex Alimentarius. Germany is also a member of the World Organization for Animal Health (OIE).

f. RELATED ISSUES: The elections in fall 2013 resulted in a grand coalition government between Chancellor Merkel's CDU/CSU party and the SPD. The coalition agreement pledges to work on the European level to prohibit the use of animal cloning and the import of cloned animals and their meat. In addition, the coalition calls for the labeling of the offspring of cloned animals and their meat as well as other products derived from offspring. The German federal election will take place on September 24th, 2017. In general, German policy on animal biotechnology is not likely to change.

   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. 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 among the German public. There are no known studies specific to Germany on the marketing GE animals or clones.