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Abstract

As part of a cooperative agreement with the United States Department of Agriculture (USDA), the George Washington University Regulatory Studies Center produced a five-chapter report on regulatory differences between the United States (U.S.) and the European Union (EU) and their effects on agricultural production and productivity. Those chapters are published here as a working paper series with five parts. This chapter reviews the institutions and procedures governing regulatory development in the U.S. and EU, details several notable differences in their respective regulatory approaches towards agriculture, and then presents and compares relevant regulations affecting agricultural production in each jurisdiction. It first provides an overview of the U.S. and EU procedures for developing and implementing regulation and how they differ. It then describes how the jurisdictions approach regulation of the agricultural sector. Finally, it discusses five areas of agricultural policy: (i) agri-environmental regulations, (ii) organic farming, (iii) genetically modified organisms (GMO), (iv) pesticides, and (v) fertilizers. The regulations discussed are initiated at the EU level and the U.S. federal level. The roles of member states (in

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the EU) and states (in the U.S) are outlined wherever applicable, but a complete accounting of the effects of implementation and enforcement present at this level falls outside the scope of this paper.

Regulatory Procedures in the U.S. and EU

Overview of U.S. Regulatory Procedure

The United States and the European Union regulate agriculture in substantively different ways, but both emphasize reducing risks to health and the environment. In the U.S., Executive branch departments and agencies write federal regulations pursuant to authority delegated to them by statutes passed by the two houses of congress and signed by the president. Regulations are constrained by a) authorizing statutory language, b) executive principles for regulatory impact analysis (RIA),³ and c) procedural rules regarding consideration of public comment.⁴ Generally, under the Administrative Procedure Act of 1946, agencies must solicit and consider public comment on draft regulations before they are issued in final form. Once regulations become effective after final publication, it is generally the issuing regulatory agency that is responsible for monitoring and enforcing compliance.⁵

The legislative branch, comprising the U.S. Senate and the House of Representatives, generally passes broad legislation and delegates to regulatory agencies the power to “fill up the details” by issuing regulation.⁶ While legislators can provide oversight over regulatory development (e.g., through hearings, letters and budget restrictions), Congress does not have a role in approving new regulations.^{7,8}

³ Executive Order 12866 “Regulatory Planning and Review.” September 30, 1993 https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf and Executive Order 13563 “Improving Regulation and Regulatory Review.” January 18, 2011 https://www.reginfo.gov/public/jsp/Utilities/EO_13563.pdf

⁴ Administrative Procedure Act (5 U.S.C. Subchapter II) <https://www.archives.gov/federal-register/laws/administrative-procedure>

⁵ Dudley, S., & Wegrich, K. (2015). Achieving Regulatory Policy Objectives: An Overview and Comparison of U.S. and EU Procedures. The George Washington University Regulatory Studies Center, Working Paper March 2015. Retrieved from <https://regulatorystudies.columbian.gwu.edu/achieving-regulatory-policy-objectives-overview-and-comparison-us-and-eu-procedures>

⁶ Wayman v. Southard, 10 Wheat. (23 U.S.) 1, 41 (1825). <https://supreme.justia.com/cases/federal/us/23/1/case.html>

⁷ It has a mechanism for overturning individual regulations, though it is typically only used after presidential transitions.

⁸ Dudley, S. (2015). Improving Regulatory Accountability: Lessons from the Past and Prospects for the Future. *Case Western Reserve Law Review*, 65 (4), 1027-1057. Retrieved from <http://regulatorystudies.columbian.gwu.edu/improving-regulatory-accountability-lessons-past-and-prospects-future>

While some federal statutes, such as the Clean Air Act, envision a role for states in compliance and enforcement, they usually provide federal agencies (e.g., EPA) authority to ensure that their standards are met. Affected parties may seek redress from the judicial branch on final regulations, and courts often remand them to agencies for reconsideration. Judicial review looks to the administrative record developed by the regulating agency,⁹ including its analysis of the facts and its response to public comment.¹⁰ Thus, the administrative record, which includes all supporting documentation and public comment, is an important element of accountability and transparency.¹¹

Overview of EU Regulatory Procedure

In the EU, the European Commission initially drafts legislative acts (comparable to statutory law in the U.S.), and then the political bodies, the European Parliament and European Council, vote to approve them. In practice, these institutions consult informally to reach a policy consensus. The Commission generally must provide an impact assessment (IA) and consult the public and stakeholders before submitting a proposed legislative act to the Parliament and Council.^{12,13}

EU member states are involved through the comitology process, and provide a counterweight to the supranational-oriented Commission. With few exceptions, the Commission is not responsible for implementing EU law; implementation and enforcement are delegated to the member states and their bureaucracies, although the Commission is in charge of overseeing the implementation process.¹⁴ Judicial review is not as important in the EU as in the U.S.

Similarities and Differences

In the U.S., executive branch agencies, accountable to the President, develop and implement regulation pursuant to rulemaking powers delegated by Congress (via legislation). In the EU, regulation is a process driven by the executive (EU Commission) but ultimately decided by the Council and the Parliament. Rulemaking powers are delegated to the European Commission rather than to regulatory agencies. Independent expert bodies such as the European Committee

⁹ Administrative Procedure Act (5 U.S.C. Subchapter II) section 706
<http://www.archives.gov/federalregister/laws/administrative-procedure/>

¹⁰ Parker and Alemanno point out that while this encourages agencies to develop a full and robust record to defend the rule in court, ironically, it may constrain agencies' ability to take international trade impacts into consideration if the enabling statute does not mention those factors. Parker, R., & Alemanno, A. (2014). *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems*. Brussels: European Commission.

¹¹ Dudley, S., & Brito, J. (2012). *Regulation: A Primer*, 2nd ed. (pp. 48-50). Washington, D.C.: The George Washington University Regulatory Studies Center and the Mercatus Center at George Mason University.

¹² Dudley and Wegrich (2015)

¹³ It has increasingly conducted IA and public consultation for non-legislative acts, as well.

¹⁴ For more detail, see Dudley and Wegrich (2015 pp. 28).

for Standardization and the European Telecommunications Standards Institute provide input on technical regulation under broad policy principles defined at EU level.

Stakeholder consultation is an important element of both regimes, however, the mode, timing, and role of consultation differ. In the U.S., consultation is a means of gathering input and increasing the accountability of delegated agency rulemaking to the public. It allows interested parties to voice concerns, and has a long tradition of transparency concerning procedures and the role of comments in decision making and in judicial review. Both regulatory text and supporting analysis are available for review and comment.

In the EU, consultation is a means of gathering input and evidence that politically accountable decision-makers will use to assess policy options. Stakeholder input is solicited earlier in the rulemaking process to develop and support the IA and identify options, but is generally not invited on the IA or regulatory text.

Regulatory Approaches to Agriculture in the U.S. and EU

Approaches to agri-environmental policies, in particular, differ substantially between the two jurisdictions. The U.S. relies more on a voluntary, incentive-based approach to encourage environmental protection efforts in the agricultural sector. In contrast, the EU regulates the environment and agricultural practices mostly through cross-compliance mechanisms within its Common Agricultural Policy (CAP). This section expands on several of these differences before proceeding to compare key components of the agri-environmental policies in both jurisdictions.

Conservation and Agri-Environmental Policies

Agri-environmental policies—a wide range of policies that integrate environmental concerns into agricultural practices—have gained increasing attention in the United States and the European Unions. Agri-environmental policies in both jurisdictions fall into two categories: voluntary incentive-based programs and cross-compliance mechanisms. Voluntary incentive-based programs provide additional financial incentives for farmers to encourage environmentally friendly agricultural practices; cross-compliance mechanisms require farmers to comply with certain regulatory standards as a prerequisite to be eligible for income support and/or other program benefits (e.g. crop insurance).

Differing Objectives and Implementation

Although both jurisdictions aim to address environmental concerns while recognizing the important role of agriculture in their respective economies, the U.S. and EU differ substantively in their approach to targeting and implementing their respective policies. Generally, EU agri-environmental policies consist of a broader set of desired outcomes relative to U.S. policy. They focus not only on reducing negative externalities (e.g. environmental harm) but also in

promoting the provision of what Europeans broadly consider to be positive externalities produced by farming such as: extensive tracts of open countryside, and the “scenic value of landscapes [that] make rural areas attractive for the establishment of enterprises, for places to live, and for the tourist and recreation businesses.”¹⁵

Citing a report from the UK’s Ministry of Agriculture, Fisheries and Food, Baylis et al. point out that, relative to the U.S., the EU:

“take[s] a wider view of what constitutes an agricultural externality; in particular, many aspects of traditional farming such as terraces, stone fences...are perceived as being desirable outcomes in and of themselves... EU member states consider it legitimate to offer compensation in return for their provision”¹⁶

Although there are notable exceptions to U.S. agri-environmental policies focused solely on reducing negative environmental externalities, the bulk of U.S. programs do not promote the production of positive externalities related to agriculture.¹⁷ Additionally, EU policies are more prescriptive in promoting certain methods thought to improve environmental outcomes whereas U.S. policies focus more on compensation for the attainment of improved environmental outcomes regardless of the methods employed.¹⁸

Scholars point out that EU efforts to improve environmental outcomes in agriculture may be hampered by several of its approaches related to rural development under CAP.¹⁹ For example, Rickard illustrates that EU policies that sustain the use of traditional, smaller-sized farms with attractive landscapes are not likely to remain competitive compared to more modern, industrialized approaches with regard to either their yield or environmental performance.²⁰

The United States

The major agricultural policy instrument in the U.S.—the Farm Bill²¹—authorizes a number of voluntary conservation programs that address a wide range of environmental issues influenced by agricultural activities such as soil quality, water quality, biodiversity and landscape. The

¹⁵ European Commission. (2017). Agriculture and the Environment: Introduction. Retrieved from https://ec.europa.eu/agriculture/envir_en

¹⁶ Baylis, K., Peplow, S., Rausser, G., & Simon, L. (2008). Agri-environmental policies in the EU and United States: A comparison. *Ecological Economics*, 65 (4), 753-764.

¹⁷ Baylis et al. (2008); Such exceptions include land conservation programs that provide incentives to prevent farmland from being converted to non-agricultural uses; further detailed below on page 6 of this report.

¹⁸ Baylis et al. (2008, pp. 754)

¹⁹ Rickard, S. (2004). CAP Reform, Competitiveness and Sustainability. *Journal of the Science of Food and Agriculture*, 84 (8), 745-756.

²⁰ *Ibid*

²¹ The Farm Bill is a comprehensive omnibus bill that is passed roughly every 5 years by Congress.

major conservation programs can be classified into three categories: land retirement programs, working land conservation programs, and agricultural land preservation programs.²² Additionally, U.S. agriculture policy includes a cross-compliance mechanism known as conservation compliance that targets soil erosion and wetlands.

Land Retirement Programs

Land retirement programs temporarily remove land from agricultural production, usually for a set number of years that range between 10 and 15. Two such programs that apply to row crops are: the Conservation Reserve Program (CRP) and the Conservation Reserve Enhancement Program (CREP). CRP and CREP are administered by the Farm Service Agency of USDA. Introduced in 1985, the CRP is a voluntary, private-land conservation program to improve water quality, reduce soil erosion, and protect habitats for endangered and threatened species. Participants receive an annual payment in exchange for removing environmentally sensitive land from agricultural production and introducing plant species that improve the environment. The program includes specific initiatives such as Bottomland Hardwoods Initiative, Duck Habitat Initiative, Floodplain Wetland Initiative, Highly Erodible Land Initiative, and Longleaf Pine Initiative.²³

The CREP, an enhancement program associated with CRP, is the largest private-land conservation program in the United States. The CREP targets only high-priority conservation issues identified by local, state or tribal government and non-government organizations (NGO). The participants are expected to remove environmentally sensitive land from agricultural production and introduce conservation practices.²⁴ Unlike CRP, the CREP operates as a partnership between federal and state and/or tribal governments. It is worth noting that states often use their portion of the contribution under CREP—typically in the form of an initial lump sum payment—to secure permanent easements longer than the average set-aside (i.e. closer to 30 years than 10 or 15).

²² Bernstein, J., Cooper, J., & Claassen, R. (2004). Agriculture and the Environment in the United States and European Union. In M. A. Normile & S. E. Leetmaa (Eds.), *U.S.-EU Food and Agriculture Comparisons* (pp. 66-77). Agriculture and Trade Report, WRS-04-04. Washington, D.C.: Market and Trade Economics Division, Economic Research Service, USDA.

²³ A complete list of initiatives can be accessed at: <https://www.fsa.usda.gov/programs-and-services/conservation-programs/conservation-reserve-program/index>. Initiatives can vary from year to year and from Farm Bill to Farm Bill.

²⁴ United States Department of Agriculture, Economic Research Service [USDA ERS]. (2014). Conservation Programs. Retrieved from <http://www.ers.usda.gov/topics/natural-resources-environment/conservation-programs.aspx>

Working Land Conservation Programs

The Conservation Stewardship Program (CSP) and Environmental Quality Incentives Program (EQIP) are part of the working land conservation programs to incentivize the adoption and maintenance of conservation practices on agricultural land. These programs are administered by the National Resources Conservation Service (NRCS) within the USDA. CSP provides farmers the opportunity to continue ongoing conservation practices and institute new conservation activities to deal with resource concerns.²⁵ In this incentive-based model, the payment is proportional to the conservation performance of the participants. The land eligible for the program includes private and tribal agricultural land, cropland, grassland, pastureland, rangeland, and non-industrial private forestland. The program is available to producers in all 50 states, the District of Columbia, and Caribbean and Pacific Island areas. In short, this program aims to support farmers that are already involved in conservation practices.

Under EQIP, technical assistance and financial incentives are provided to individuals to improve water and air quality, conserve ground and surface water, reduce soil erosion and sedimentation or improve or create wildlife habitat in agricultural or non-industrial private forestland.²⁶ As part of the program, federal and state governments assist the participant in planning and implementing conservation practices.²⁷ Additionally, EQIP differs from CSP in its method for targeting payments; EQIP payments are tied to a fixed rate per action taken while CSP pays based on the level of achieved benefit.²⁸

Agricultural Land Preservation Programs

The Agricultural Conservation Easement Program is a consolidation of different easement programs with two aims: 1) conserve agricultural land from being converted to non-agriculture uses and 2) protecting wetlands. The first goal of the program aims to sustain agriculture by ensuring availability of productive land for farming. The second aims to conserve wetlands from either agricultural or non-agricultural use. Both provide technical assistance and financial

²⁵ United States Department of Agriculture, Natural Resource Conservation Service [USDA NRCS]. (2017a). Conservation Stewardship Program. Retrieved from <http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/programs/financial/csp/>

²⁶ *Ibid*

²⁷ United States Department of Agriculture, Natural Resource Conservation Service [USDA NRCS]. (2017b). Environment Quality Incentives Program. Retrieved from <http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/programs/financial/eqip/>

²⁸ As of January 2017, USDA's Natural Resources Conservation Service website states that: "CSP participants...receive an annual land use payment for operation-level environmental benefits they produce. Under CSP, participants are paid for conservation performance: the higher the operational performance, the higher their payment" (USDA NRCS, 2017b)

incentives for conservation.²⁹ The program is open to American Indian tribes, state and local governments and NGOs with farmland, rangeland or grassland protection programs. These groups can, in turn, purchase easements from individuals.

Conservation Compliance

The cross-compliance mechanism in the U.S., commonly known as “conservation compliance,” is primarily aimed at protecting highly erodible lands (HEL) and wetlands that are currently or have previously been in production. The use of certain conservation practices on farmed HEL and wetlands is required in order for farmers to be eligible to participate in certain federal agricultural programs provided by the FSA and the Natural Resources Conservation Service (NRCS), such as crop insurance premium subsidies, disaster assistance payments, farm loans, and conservation program payments.³⁰ If a farmer violates the compliance requirements, he or she may be excluded from the farm payments or even required to pay back current or previously awarded benefits.³¹ The USDA protects against soil erosion on HEL through its Sodbuster provisions and prevents the conversion of wetlands into land for agricultural production through its Swampbuster provisions.³²

The European Union

The Common Agricultural Policy (CAP) is the primary policy tool that administers agricultural practices and agri-environmental standards in the European Union. The CAP uses what the EU refers to as the “polluter pays” principle and the “provider gets” principle to integrate environmental goals into agriculture policy. The “polluter pays” principle takes a “sticks” approach to associate the costs of environmental damage to those that cause it.³³ While the “provider gets” principle takes a “carrots” approach and rewards those that go above and beyond the legal, environmental requirements with payments.

²⁹ USDA NRCS (2017b)

³⁰ United States Department of Agriculture, Natural Resource Conservation Service [USDA NRCS]. (2017c). Highly Erodible Land Conservation and Wetland Conservation Compliance. Retrieved from https://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/alphabetical/camr/?cid=nrcs143_008440

³¹ *Ibid*

³² *Ibid*

³³ European Commission. (2016a). Integrating Environmental Concern into the CAP. Retrieved on April 21, 2016 from http://ec.europa.eu/agriculture/envir/cap/index_en.htm

Environmental Regulations via Cross-compliance

Environmental regulations refer to a set of compulsory standards and requirements that aim to protect the environment from human activities.³⁴ Although the EU has long emphasized the importance of environmental regulations, this cross-compliance mechanism for direct payments was introduced only in 2003 under Council Regulation (EC) No 1782/2003, providing a more flexible means for implementing the “command and control” environmental regulations in the agricultural sector.³⁵ The cross-compliance mechanism includes two components: Statutory Management Requirements (SMRs) and Good Agricultural and Environmental Conditions (GAECs) that operate across three issue areas: (i) environment, climate change, and good agricultural condition of land; (ii) public, animal, and plant health; and (iii) animal welfare. Non-compliance by farmers results in an administrative penalty, which is a reduction in direct payments, decided at the member-state level, based on the provisions listed in Regulation (EU) No 1306/2013 on the financing, management and monitoring of the CAP.

The rules for cross-compliance specify 20 standards and requirements: 13 SMRs and 7 GAECs. The Statutory Management Requirements for the environment, climate change, and good agricultural condition of land are linked to requirements established in three preexisting EU directives. SMR 1 makes it mandatory to comply with the requirements outlined in Council Directive 91/676/EEC, also known as the Nitrates Directive, on the protection of waters against pollution caused by nitrates from agricultural sources.³⁶ SMR 2 and SMR 3 concern Directive 2009/147/EC on the conservation of wild birds and Council Directive 92/43/EEC on the protection of natural habitats and wild flora and fauna.

Regulation (EU) No. 1306/2013 specifies a broad framework for each GAEC. Member states have the flexibility to define national minimum standards for good agricultural practices based on the specific characteristics of the area such as climatic conditions, soil characteristics, land use, and farming practices. In particular, there are seven GAECs regarding water, soil and carbon stock and landscape, which set out legal requirements in addition to SMRs.

Voluntary Agri-Environmental Measures

The EU also uses voluntary programs to reward producers for adopting additional environmentally friendly farming practices, which are called “agri-environmental measures” as a

³⁴ European Commission. (2016b). Cross-Compliance. Retrieved on April 21, 2016 from http://ec.europa.eu/agriculture/envir/cross-compliance/index_en.htm

³⁵ Council Regulation (EC) 1782/2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers [2003] <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003R1782>

³⁶ Regulation (EU) 1306/2013 on the financing, management and monitoring of the common agricultural policy [2013] <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32013R1306>

key element in member states' rural development plans under CAP. The agri-environment measures provide financial incentives for adopting practices across a broad set of policy areas.³⁷ The payments made to farmers cover commitments that are not included as part of the mandatory standards under the cross-compliance mechanism or requirements under the national legislation of the member states. Farmers are required to commit themselves for at least five years.³⁸ These payments are similar to the U.S. EQIP program where producers receive payments to offset the costs of adopting practices that improve the environment.

³⁷ European Commission. (2016c). Agri-environment Measures. Retrieved on April 21, 2016 from http://ec.europa.eu/agriculture/envir/measures_en

³⁸ *Ibid*

Table 1: U.S. and EU Conservation and Agri-Environmental Policies

United States		European Union
Voluntary Incentive-based Programs		
Policy Instrument	<p>Conservation Programs:</p> <ul style="list-style-type: none"> ▪ Land Retirement Programs ▪ Working Land Conservation Programs ▪ Agricultural Land Preservation Programs 	Agri-Environmental Measures
Regulatory Authority	Initially authorized by Farm Bill in different years; all reauthorized in 2014 Farm Bill	Regulation (EU) No 1305/2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)
Administering Institution	USDA’s National Resources Conservation Service (NRCS) & Farm Service Agency (FSA)	Directorate General for Agricultural and Rural Development & Member States
Practices	<ul style="list-style-type: none"> ▪ Retirement of environmentally sensitive land from agricultural production (CRP & CREP) ▪ Adoption and maintenance of conservation practices on agricultural land (CSP & EQIP) ▪ Conservation of agricultural land and wetlands (ACEP) 	<p>Practices vary across member states, which include:</p> <ul style="list-style-type: none"> ▪ Environmentally favorable intensification of farming ▪ Integrated farm management and organic agriculture ▪ Conservation of high-value habitats and biodiversity
Cross-Compliance Mechanisms		
Policy Instrument	Highly Erodible Land Conservation (HELCS) and Wetland Conservation (WC) provisions	<ul style="list-style-type: none"> ▪ Statutory Management Requirements (SMRs) linked to 13 preexisting EU regulations/directives ▪ Good Agricultural and Environmental Conditions (GAECs)
Regulatory Authority	Initially authorized in 1985 Farm Bill, and reauthorized in the consecutive farm bills	Regulation (EU) No 1306/2013 on the financing, management and monitoring of the common agricultural policy
Administering Institution	USDA’s National Resources Conservation Service (NRCS), Farm Service Agency (FSA), & Risk Management Agency (RMA)	Directorate General for Agricultural and Rural Development & Member States
Requirements	<p>Participating farmers shall not:</p> <ul style="list-style-type: none"> ▪ Plant or produce agricultural commodities on a highly erodible land or a converted wetland ▪ Convert a wetland to agricultural land 	<p>Participating farmers must:</p> <ul style="list-style-type: none"> ▪ Comply with 13 SMRs established under preexisting directives/regulations, including the Nitrates Directive, the Birds Directive, and the Habitats Directive; ▪ Comply with 7 GAECs established by member states concerning water, soil and carbon stock and landscape.

Organic Farming

Organic farming has gained popularity in both the United States and the European Union, causing the “Organic” label to have marketing value with consumers, which creates a need for definitional standards. The U.S. and the EU reached an organic certification equivalence agreement in 2012.³⁹ Due to this agreement and trade requirements, there is a growing convergence of organic standards in the U.S and the EU.

United States

In the United States, organic crop production is regulated under the National Organic Program (NOP) by USDA’s Agriculture Marketing Service (AMS). The Organic Food Production Act created the organic program in the United States in 1990.⁴⁰ This act tasked AMS with creating a certifying body for products claiming to be organic, developing organic crop production and livestock standards, and developing standards for labeling, processing, and packaging of organic products.⁴¹

Organic Standards

The NOP establishes the standards required for a product to be labeled as organic.⁴² These rules follow certain farming philosophies defined by USDA as agricultural commodities that are produced using,

“Cultural, biological and mechanical practices that support the cycling of on-farm resources, promote ecological balance, and conserve biodiversity in accordance with the USDA organic regulations. This means that organic operations must maintain or enhance soil and water quality, while also conserving wetlands, woodlands, and wildlife. Synthetic fertilizers, sewage sludge, irradiation, and genetic engineering may not be used”⁴³

³⁹ United States Department of Agriculture, Agriculture Marketing Service [USDA AMS]. (2016a). International Trade Polices: European Union. Retrieved from <https://www.ams.usda.gov/services/organic-certification/international-trade/European%20Union>

⁴⁰ 7 U.S.C. §94 Organic Certification

⁴¹ United States Department of Agriculture, Agriculture Marketing Service [USDA AMS]. (2016b). About the National Organic Program. Retrieved from <https://www.ams.usda.gov/sites/default/files/media/About%20the%20National%20Organic%20Program.pdf>

⁴² 7 C.F.R. §205

⁴³ USDA AMS (2016b)

These concepts are further explained in an agency guidance document titled, the *National Organic Farming Handbook*.⁴⁴ This handbook gives more detailed examples and resources to help producers better understand how to comply with organic standards.

Certification of Producers

To be a certified organic producer, one must be certified by a USDA accredited third-party certifier.⁴⁵ Individuals must present organic production or processing plans to the certifier for review and must submit their production or handling operation to a full inspection. USDA accredited third-party certifiers may issue an organic certification if an operation meets all of the standards laid out in the regulation or if only minor noncompliance issues need to be resolved. In the latter case, the certifier would give the certified operation a time limit for coming into compliance with organic standards.⁴⁶ Certified operations are listed in the USDA Annual List of Certified Organic Operations and maintained in an online database called the Organic INTEGRITY Database.⁴⁷

Prohibited Substances

To specify the synthetic and non-synthetic substances that can be used in an organic operation, the NOP created the National List of Allowed and Prohibited Substances (The National List or the list). It lists substances that are disallowed in an organic operation, but also identifies some synthetic materials that can be used in the production or processing of organic products.⁴⁸ Substances can refer to any product applied to a crop including but not limited to, pesticides, herbicides, compost, and pheromones.⁴⁹ The synthetic substances on the National List may be allowed for specific uses, situations, or for a pre-determined time limit. General guidelines for when a synthetic substance may be allowed include: if there are no organic substitutes; if it does not adversely affect the environment; if the substance or its breakdown product does not harm

⁴⁴ United States Department of Agriculture, Agriculture Marketing Service [USDA AMS]. (2015). *National Organic Farming Handbook* (pp. D1-D14). Washington, D.C.: U.S. Department of Agriculture. Retrieved from <https://policy.nrcs.usda.gov/OpenNonWebContent.aspx?content=37903.wba>

⁴⁵ United States Department of Agriculture, Agriculture Marketing Service, National Organic Program. (2015). *Accreditation Policies and Procedures* (pp. 5-16). Washington, D.C.: U.S. Department of Agriculture. Retrieved from <https://www.ams.usda.gov/sites/default/files/media/General%20Accreditation%20Policies%20and%20Procedures.pdf>

⁴⁶ 7 C.F.R. §205

⁴⁷ United States Department of Agriculture, Agriculture Marketing Service [USDA AMS]. (2016c). U.S. Organic Integrity Database. Retrieved on April 26, 2016 from <https://apps.ams.usda.gov/integrity/>

⁴⁸ United States Department of Agriculture, Agriculture Marketing Service [USDA AMS]. (2016d). The National List. Retrieved on April 26, 2016 from <https://www.ams.usda.gov/rules-regulations/organic/national-list>

⁴⁹ Coleman, P. (2012). *Guide for Organic Crop Producers* (pp. 37-41). Washington, D.C.: U.S. Department of Agriculture, Agriculture Marketing Service. Retrieved from <https://www.ams.usda.gov/sites/default/files/media/Guide-OrganicCropProducers.pdf>

human health and is generally recognized as safe by the Food and Drug Administration (FDA); if it is not primarily a preservative; and in cases where the substance is essential for organic handling.⁵⁰

Labeling

USDA accredited agents certify organic products or farms.⁵¹ There is an exemption for producers whose total income from sales of organic products is below \$5,000 per year. These producers may claim organic status without going through certification; this allows producers to use the term “organic” but not the official USDA Organic logo. NOP regulations specify when and how the word “organic” can be used on the front panel or information panel of a product. There are four categories of labeling:⁵²

1. “100 percent organic” can only be used for products that contain only organic ingredients.
2. “Organic” may be used for products that contain a minimum of 95 percent organic ingredients. The non-organic ingredients must not be commercially available in organic form.
3. “Made with Organic ____” may be used for products that have at least 70 percent organic ingredients. The non-organic ingredients must still meet certain standards.
4. Organic ingredients can be listed as such on the information panel if a product contains less than 70 percent organic ingredients.

European Union

The Directorate General for Agricultural and Rural Development implements Council Regulation (EC) No. 834/2007 for organic farming. In 1991, the EU first introduced Regulation (EEC) No 2092/91 on organic farming and labeling for organic farm produce and foods, and animal products. Subsequently, a new organics program was created in 2007 with Council Regulation (EC) No. 834/2007 “on organic production and labeling of organic products and repealing regulation (EEC) No. 2092/91.”⁵³ The aims of the legislation were to create an organic farming environment that uses, “sustainable cultivation systems, a variety of high-quality products, a greater emphasis on environmental protection, more attention to biodiversity, consumer confidence, and protecting consumer interests.”⁵⁴ The aforementioned policies

⁵⁰ 7 C.F.R. §205.600

⁵¹ 7 C.F.R. §205.400

⁵² Coleman, 2012

⁵³ Council Regulation (EC) No 834/2007 on organic production and labelling of organic products [2007] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:189:0001:0023:EN:PDF>

⁵⁴ European Commission. (2016d). EU Law on Organic Production: An Overview. Retrieved on May 4, 2016 from http://ec.europa.eu/agriculture/organic/eu-policy/eu-legislation/brief-overview/index_en.htm

generally encourage closed systems that use internal inputs rather than external inputs.⁵⁵ The regulation applies to living or unprocessed products, processed foods, animal feed and seeds, and propagating material.

Organic Standards

The EU organics regulation determines specific standards and accepted practices for organic production.⁵⁶ Rules for plant production can be organized into four categories: the life of the soil, crop rotation, prevention of pests and disease, and the collection and use of wild plants. The standards require that plant production should “maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.”⁵⁷ The regulation specifies that one way to preserve and improve the soil is through intentional crop rotation and the application of other organic materials from compost or animal refuse. To prevent pests and disease, producers can use approved fertilizers and soil conditioners along with the “protection by natural enemies, the choice of species and varieties, crop rotation, cultivation techniques and thermal processes.”⁵⁸ Finally, the regulation specifies when and how wild plants can be used in commercial production.

Certification of Producers

In the EU, the process for certification of producers is decentralized. The producers of organic goods must go through either a private or public control body in their country to be certified. Each member-state is required to designate a private control body, a public entity that regulates organic certification, or both. Authorities in each member-state supervise these control bodies. To be certified, producers must notify the control body of their intent to produce under an organic label, and the control body conducts an audit of their operation.⁵⁹ Certified operations are listed in online databases by each individual certifier. In the case of non-compliance, producers are not allowed to label or advertise their production as organic.

⁵⁵ *Ibid*

⁵⁶ Council Regulation (EC) 834/2007

⁵⁷ *Ibid*

⁵⁸ Council Regulation (EC) 834/2007

⁵⁹ European Commission, Directorate General for Agriculture and Rural Development. (2011). Working document of the Commission Services on Official Controls in the Organic Sector, Version 8. Retrieved on May 9, 2016 from https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/docs/body/controls-working-document-20110708_en.pdf

Prohibited Substances

Commission Regulation (EC) No 889/2008 specifies the list of substances allowed in organic production and processing.⁶⁰ Only substances mentioned in the annex of the regulation can be used for organic farming. The substances contained in the regulation include fertilizers, pesticides, products and substances for use in production such as food additives and processing aids, and products for cleaning and disinfection. In 2011, the EU convened an Expert Group for Technical Advice on Organic Production (EGTOP) to review the substances listed in the regulation. This group of scientific experts used a combination of evidence-based practice and precautionary risk assessments to evaluate whether certain additives and non-organic ingredients should be allowed in organic production.⁶¹ Based on the recommendation of EGTOP, Commission Regulation (EC) No 889/2008 has been amended to include additional substances.⁶²

Labeling

The labeling requirements are set out in Council Regulation (EC) No. 834/2007 and Commission Regulation (EC) No 889/2008. In the EU, the term organic is sometimes interchangeable with the words ‘eco’ short for ecological or ‘bio’ short for biodynamic. Items labeled as any organic, bio, or eco, that use the EU organic logo must satisfy the requirements established in the regulation. The organic items must have ingredients that are at least 95% organic by weight and that only include approved additives. Products labeled as organic must also be free of GMO. Further, the label needs to include a code referencing the appropriate control body and place of origin. Member states are charged with enforcing labeling requirements but the EU regulation mandates an annual verification.⁶³

⁶⁰ Commission Regulation (EC) 889/2008 on laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control [2008]. <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R0889>

⁶¹ European Commission, Directorate General for Agriculture and Rural Development. (2013). Expert Group for Technical Advice on Organic Production (EGTOP): Final Report III. Retrieved on May 9, 2016 from https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/docs/body/2013_05_19_permanent_group_egtop_food_mandate_3_en.pdf

⁶² Commission Implementing Regulation (EU) 2016/673 on organic production and labelling of organic products with regard to organic production, labelling and control [2016] <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=uriserv%3AOJ.L.2016.116.01.0008.01.ENG>

⁶³ European Commission, Directorate General for Agriculture and Rural Development, 2011

Table 2: U.S. and EU Organic Farming Regulations

	United States	European Union
Regulatory Authority	USDA organic regulations established under the National Organic Program (NOP), authorized by the Organic Food Production Act	Regulation (EC) No. 834/2007 on organic production and labeling of organic products (repealing Regulation (EEC) No 2092/91) Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Regulation (EC) No 834/2007
Administering Institution	USDA's Agriculture Marketing Service (AMS)	Directorate General for Agricultural and Rural Development
Organic Standards	Organic farming is defined as plant production practices that: <ul style="list-style-type: none"> i. support the cycling of on-farm resources ii. promote ecological balance iii. conserve biodiversity 	Organic farming is defined as plant production practices that: <ul style="list-style-type: none"> i. maintain or increase soil organic matter ii. enhance soil stability and soil biodiversity iii. prevent soil compaction and soil erosion
Certification of Producers	An organic producer must: <ul style="list-style-type: none"> i. be certified by a USDA accredited third-party certifier ii. submit organic production or processing plans to the certifier for review iii. submit production or handling operation to a full inspection 	An organic producer must: <ul style="list-style-type: none"> i. be certified by either a private or public control body designated by member states ii. notify the intent to produce under an organic label to the control body iii. accept an audit of operation conducted by the control body
Prohibited Substances	The National List of Allowed and Prohibited Substances specifies substances that are disallowed in an organic operation, and synthetic materials that can be used in production or processing of organic products.	Regulation (EC) No 889/2008 specifies substances that can and cannot be used for organic farming.
Labeling	<ul style="list-style-type: none"> ▪ Products labeled as "100% organic" must: <ul style="list-style-type: none"> i. contain only organic ingredients ▪ Products labeled as "Organic" must: <ul style="list-style-type: none"> i. contain at least 95% organic ingredients ii. contain non-organic ingredients only if they are not commercially available in organic form ▪ Products labeled as "Made with organic ____" must: <ul style="list-style-type: none"> i. contain at least 70% organic ingredients ii. contain non-organic ingredients only if they meet certain standards 	<ul style="list-style-type: none"> ▪ Products labeled as "Organic," "Eco," or "Bio" must: <ul style="list-style-type: none"> i. contain at least 95% organic ingredients by weight ii. contain only approved additives iii. be free of GMO iv. include a code referencing the appropriate control body and place of origin

Genetically Modified Organisms

Over time, GMO regulations in the European Union have become more restrictive in comparison to the United States. Public opinion in the EU has led to stringent controls on GMOs, whereas the United States has a relatively tolerant approach towards this newer technology. This section highlights the divergent approaches followed in the U.S. and the EU towards GMO crops.

The United States

GMO crops are not regulated under a specific federal legislation in the United States. In the 1986 “Coordinated Framework for Regulation of Biotechnology,” the Office of Science and Technology Policy (OSTP), under the Executive Office of the President, indicated that the U.S. would approach regulating GMO’s through existing federal law.⁶⁴ Therefore, GMOs are regulated under legislation concerning health, safety, and environmental issues.⁶⁵ The framework characterizes U.S. policy towards GM production as one that focuses on the end product of genetic modification and not the development process.⁶⁶ A recent review of the coordinated framework has updated some aspects of it, but retained its original principles.⁶⁷

Current federal regulation covering GM crops falls under the jurisdiction of three primary agencies: USDA’s Animal Plant Health Inspection Service (APHIS), The Environmental Protection Agency (EPA), and the FDA.⁶⁸

APHIS is responsible for implementing the Plant Protection Act (PPA). Under this legislation, APHIS regulates the entry of pests and noxious weeds through importation, transportation, or introduction of new crops and seeds.⁶⁹ GM crops are regulated under this federal legislation because they are introduced to the environment and interact with other plants and insects. Under

⁶⁴ Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23, 302 (June 26, 1986). Retrieved from http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

⁶⁵ Acosta, L. (2014, March). Restrictions on Genetically Modified Organisms: United States. *Library of Congress*. Retrieved from <https://www.loc.gov/law/help/restrictions-on-gmos/usa.php>

⁶⁶ Pew Initiative on Food and Biotechnology. (2001, September). Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products. Pew Research Trust. Retrieved from http://www.pewtrusts.org/~media/legacy/uploadedfiles/wwwpewtrustsorg/reports/food_and_biotechnology/hhsb_iotech0901pdf.pdf

⁶⁷ Barbero, R., Boling, T., Doherty, J., Goldstein, M., & Kim, J. (2016, September 16). Building on 30 Years of Experience to Prepare for the Future of Biotechnology. Retrieved on September 31, 2016 from <https://www.whitehouse.gov/blog/2016/09/16/building-30-years-experience-prepare-future-biotechnology>

⁶⁸ *Ibid*

⁶⁹ 7 U.S.C. § 7712(a) (2012) <http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section-7712&num=0&edition=prelim>

PPA, APHIS grants permits for the sale of GM crops and through that permitting oversees the containment of those crop varieties.⁷⁰

FDA is responsible for implementing the Federal Food, Drug and Cosmetic Act (FFDCA). Through this act, FDA evaluates whether food products are safe for human consumption.⁷¹ In 1992, foods derived from GMOs were deemed to be “generally recognized as safe” (GRAS) and therefore do not have to be approved for each use unless a new variety “differs significantly in structure, function, or composition from substances found currently in food.”⁷²

EPA is responsible for implementing the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA),⁷³ and the National Environmental Policy Act (NEPA).^{74, 75} Under FIFRA, EPA regulates pesticide manufacture, sale, and use. GM Crops that are engineered to produce pesticide products (called plant-incorporated protectants) are covered under this regulation. EPA also has jurisdiction to regulate GM crops through TSCA. TSCA regulates chemicals that pose an unreasonable risk to human health or the environment. Finally, NEPA regulations require agencies to submit Environmental Assessments or Environmental Impact Statements for any federal action that is likely to have a significant impact on the environment. Agencies that register GM crops may have to prepare these assessments as a part of their approval process.⁷⁶

Labeling and Traceability

Products that contain genetically modified ingredients are not currently required to be labeled in the U.S. In November 2015, FDA published a guidance document detailing ways to label non-GMO products. The voluntary labeling practices suggested by FDA aim to help industry better understand how to distinguish non-GMO products for consumers without misleading the

⁷⁰ Acosta (2014)

⁷¹ Acosta (2014)

⁷² United States Food and Drug Administration [US FDA]. (1992, May 29). Guidance to Industry for Foods Derived from New Plant Varieties. *Statement of policy - foods derived from new plant varieties*. Retrieved from <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/%20Biotechnology/ucm096095.htm>

⁷³ The Toxic Substances Control Act was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, signed by President Obama on June 22, 2016. The new act provides new risk-based safety standard, increased public transparency, and consistent source of funding for EPA (see footnote 74).

⁷⁴ United States Environmental Protection Agency [US EPA]. (2016). The Frank R. Lautenberg Chemical Safety for the 21st Century Act. *Assessing and managing chemicals under TSCA*. Retrieved from <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>

⁷⁵ Acosta (2014)

⁷⁶ Acosta (2014)

public.⁷⁷ On July 29, 2016, President Barack Obama signed the National Bioengineered Disclosure Law, amending the Agricultural Marketing Act of 1946. The legislation authorizes the USDA AMS to develop a “national mandatory bioengineered food disclosure standard” for GMO disclosure and labeling.⁷⁸ The related rulemaking process is expected to be finalized within two years. A few states had introduced legislation requiring labeling of GMOs at the state level prior to the law’s passage. These include Vermont, Maine, and Connecticut. At least 13 other states have proposed bills to require labeling, but have yet to enact them.⁷⁹ The recently passed legislation will preempt any state labeling standards.

European Union

Four key regulations set out the rules for GMO production, labeling and use in the European Union: Directive 2001/18/EC (deliberate release of GMOs in the environment), Regulation (EC) 1829/2003 (authorization and release of GMOs for feed and food), Directive (EU) 2015/412 (member states’ right to restrict GMOs), Directive 2009/41/EC (contained use of GM microorganisms), and Regulation (EC) 1830/2003 (traceability and labeling).⁸⁰ GMO legislation in the EU has four stated goals:

1. “To protect human and animal health and the environment by introducing safety assessment of the highest possible standards at EU level before any GMO is placed on the market.”
2. “Put into place harmonized procedures for risk assessment and authorization of GMOs that are efficient, time-limited and transparent.”
3. “Ensure clear labeling of GMOs placed on the market in order to enable consumers as well as professional to make an informed choice.”
4. “Ensure the traceability of GMOs placed on the market”⁸¹

Regulation (EC) 1829/2003 and Regulation (EC) 1829/2003 establish procedures for GMO authorization for cultivation, feed, and food. This legislation requires strict testing and approval processes before a product is approved for cultivation and sale. Member states may submit

⁷⁷ United States Food and Drug Administration [US FDA]. (2015, November). Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants. Retrieved on May 10, 2016 from <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm>

⁷⁸ United States Department of Agriculture, Agricultural Marketing Services [USDA AMS]. (2016e). GMO Disclosure & Labeling. Retrieved on May 16, 2016 from <https://www.ams.usda.gov/rules-regulations/gmo>

⁷⁹ Center for Food Safety. (2016). 2016 State Labeling Legislation. Retrieved on May 10, 2016 from <http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives#>

⁸⁰ European Commission. (2016e). GMO Legislation. *Genetically Modified Organisms*. Retrieved from http://ec.europa.eu/food/plant/gmo/legislation_en

⁸¹ *Ibid*

applications to the European Food Safety Administration which conducts risk assessments. These risk assessments and approval processes are an example of the EU's use of the precautionary principle for regulation; this philosophy that requires the EU and its member states to do everything possible to prevent harm to human health and the environment.⁸² No member-state can use GMOs unless authorized under EU legislation. During the process of authorization and following approval, GMOs are listed in the "EU Register of GM Food and Feed." This database provides the name, company, a unique identifier, and the relevant genetic information for the product along with whether it is approved for food, feed, or both.⁸³

Though GMOs are registered by the European Commission, individual member states can restrict the cultivation of GMOs they consider a risk, even if they are in the database of approved products.⁸⁴ In 2015, the European Commission passed a directive to allow member states to restrict GMO production within their countries. This directive was introduced to accommodate disparate policy preferences of member states within the EU. Per Directive (EU) 2015/412, member states can decide to restrict cultivation within their respective region during an EU-wide authorization process by asking to restrict the geographic scope of the GMO authorization application. Additionally, a member state can continue its ban on the cultivation of a GMO within their borders by citing environmental policy, socio-economic impact or public policy concerns. When this Directive was introduced in April 2015, the EU Parliament and the Council allowed member states to request geographic amendments to GMO authorizations granted prior to April 2015.⁸⁵ As of October 2015, Austria, France, Germany, Greece, Luxembourg, Bulgaria and Hungary have decided to ban cultivation of Monsanto's MON810 corn. Nevertheless, the member states cannot restrict the sale of GMO products—a proposal recommending the use of import bans was rejected by the EU parliament in 2015.⁸⁶ At present, corn is the only GM crop that is cultivated commercially in the EU, and there are 58 GMO varieties approved for sale for corn, cotton, rapeseed, sugar beet and soybean.

⁸² Papademetriou, T. (2014, March). Restrictions on genetically modified organisms: European Union. *Library of Congress*. Retrieved on May 10, 2016 from <https://www.loc.gov/law/help/restrictions-on-gmos/eu.php>

⁸³ European Commission. (2016f). EU Register of authorized GMOs. *Genetically Modified Organism*. Retrieved from http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

⁸⁴ Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory, at 3, COM (2010) 375 final (July 13, 2010); European Commission (2016g). *Genetically Modified Organisms*. Retrieved from http://ec.europa.eu/food/plant/gmo_en

⁸⁵ Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory Text with EEA relevance [2015] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_068_R_0001

⁸⁶ European Parliament News. (2015, October 13). Environment MEPs oppose national GMO import bans proposal [Press Release]. Retrieved from <http://www.europarl.europa.eu/news/en/news-room/20151012IPR97161/environment-meeps-oppose-national-gmo-import-bans-proposal>

Labeling and Traceability

The identification of products that contain GMO ingredients and the ability of officials and companies to trace those ingredients are major goals of EU legislation. Traceability refers to the capacity of professionals to know which products contain GMO ingredients so that they can properly label them and the ability of officials to monitor environmental risks and make effective recalls when necessary. To ensure that each GMO ingredient can be distinguished, each is given a unique numeric or alphanumeric identifier. According to Regulation (EC) 1830/2003, food containing or produced from GMO ingredients must specify the presence of GMO and include the assigned unique identification number for traceability. The labeling requirements include a specific provision of adding “This product contains genetically modified organisms or [name of the organism].”⁸⁷ These terms must be clearly visible in or near the list of ingredients. Products that contain 0.9 percent or less of GMO ingredients are exempt from this labeling requirement.⁸⁸

⁸⁷ Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms [2003] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF>

⁸⁸ *Ibid*

Table 3: U.S. and EU GMO Regulations

United States		European Union
GM Plant Cultivation (Release to the Environment)		
Regulatory Authority	Plant Protection Act (PPA)	Directive 2001/18/EC on the deliberate release of GMOs into the environment (repealing Directive 90/220/EC); Regulation (EC) 1829/2003 on GM food and feed; Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for member states to restrict or prohibit the cultivation of GMOs in their territory
Administering Institution	USDA Animal and Plant Health Inspection Service (APHIS)	European Commission authorizes GMO cultivation; Member States have the freedom to restrict or prohibit the cultivation of GMOs in their territory.
Scope of Application	Importation, interstate movement, and field testing of GE plants and organisms that are or might be plant pests.	Commercial use of a GM plant (that is able to reproduce); release into the environment involved with growing the plant or importing plant material.
Food and Feed (Release to the Market)		
Regulatory Authority	Federal Food, Drug and Cosmetic Act (FFDCA) Public Health Service Act (PHSA)	Regulation (EC) 1829/2003 on GM food and feed
Administering Institution	Food and Drug Administration (FDA)	European Food Safety Authority assesses risks; Standing Committee on the Food Chain and Animal Health accepts the proposal; European Commission adopts the proposal.
Scope of Application	Food, animal feed additives, and human and animal drugs, including those from biotechnology.	GMOs used in food or in animal feed; food or animal feed containing GMOs; food or feed made with or containing ingredients made using GMOs.
Contained Use of GM Microorganisms (GMMs)		
Regulatory Authority	Toxic Substances Control Act (TSCA)	Directive 2009/41/EC on the contained use of GMMs (repealing Directive 90/219/EEC)
Administering Institution	Environmental Protection Agency (EPA)	Member States
Scope of Application	Use of GMMs for chemical purposes requires EPA notification.	Use of GMMs requires an examination of the containment and protection measures taken, in order to avoid a release.
Use of GM Pesticides		
Regulatory	Federal Insecticide, Fungicide, and	Directive 2001/18/EC on the deliberate release

Reference	Rodenticide Act (FIFRA)	of GMOs into the environment (repealing Directive 90/220/EC) Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market
Administering Institution	Environmental Protection Agency (EPA)	European Commission authorizes the use of GM pesticides; Member States have the freedom to restrict or prohibit them under Directive (EU) 2015/412.
Scope of Application	Use of all pesticides, including those genetically engineered into plants (plant-incorporated protectants (PIPs))	Placing on the market and use of pesticides containing a GMO
Traceability and Labeling		
Regulatory Authority	National Bioengineered Disclosure Law, amending the Agricultural Marketing Act of 1946	Regulation (EC) 1830/2003 concerning the traceability and labeling of GMOs and the traceability of food and feed products produced from GMOs
Administering Institution	USDA Agricultural Marketing Service (AMS) is responsible for the rulemaking under the new law.	Member States carry out inspections and enforcement; European Commission gives technical guidance and keeps a central register.
Scope of Application	Rulemaking for “a national mandatory bioengineered food disclosure standard” is in progress.	GMOs and products containing GMOs or produced from GMOs are all subject to compulsory labeling and/or traceability; only food or feed containing less than 0.9% GMOs may be exempted.

Pesticides

The United States

Both federal and state laws govern the production and use of pesticides in the United States. At the federal level, the key statutes governing pesticides include the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), the Food Quality Protection Act (FQPA), the Pesticide Registration Improvement Act (PRIA), the Clean Water Act, and the Endangered Species Act (ESA). The FQPA and PRIA amended the FIFRA and FFDCA to include provisions for pesticide registration. EPA regulates and approves pesticides but the FDA, USDA, the Department of Interior's Bureau of Land Management and U.S. Fish and Wildlife Service, as well as state agencies work with EPA to ensure food and environmental safety and compliance.⁸⁹ Although EPA establishes pesticide regulations, a state government may set rules that are more stringent than federal regulations and standards for pesticide use.⁹⁰ Each state has its own set of pesticide regulations but works in close collaboration with EPA to ensure compliance with the federal standards.

Manufacturing, Distribution and Labeling

Under FIFRA, EPA must approve all pesticides that are sold or distributed in the United States. EPA conducts risk assessments aimed at both ecological risks and human health hazards. This risk assessment process is performed both before a pesticide enters the market and no less than every 15 years.⁹¹ Despite the federal approval, states have the right to restrict the use of a pesticide if they deem it to be harmful.

Application to the Land

EPA also regulates the information that must be included on pesticide labels and the safety procedures that must be included in pesticide handling instructions. In the U.S., allowable uses for a pesticide are determined at the federal level. States are tasked with enforcing compliance with pesticide labeling requirements.⁹² Farms must comply with EPA pesticide labeling instructions, which place limits on application rates to the land.

⁸⁹ National Pesticide Information Center. (2016a, February 22). Federal Pesticide Regulation. Retrieved from <http://npic.orst.edu/reg/regfed.html>

⁹⁰ National Pesticide Information Center. (2016b, February 22). State Pesticide Regulation. Retrieved from <http://npic.orst.edu/reg/regstate.html>

⁹¹ United States Environmental Protection Agency. (2016a, October 17). Overview of Risk Assessment in the Pesticide Program. Retrieved on May 12, 2016 from <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>

⁹² United States Environmental Protection Agency. (2011). *Label Review Manual*. Washington, D.C.: US EPA. Retrieved from <https://www.epa.gov/sites/production/files/2015-08/documents/lrm-chap1-18-aug-2015.pdf>

Food Tolerance Levels

Section 408 of FFDCA tasks EPA with setting tolerance levels for pesticides—limits on the amount of pesticides that may remain in or on foods—while the FDA is responsible for the enforcement of tolerances.⁹³ The tolerance level is established based on the toxicity of a pesticide and “its break-down products, aggregate exposure to the pesticide in foods and from other sources of exposure, and any special risks posed to infants and children. Some pesticides are exempted from the requirement to have a tolerance”.⁹⁴ EPA is required to state a tolerance level or tolerance exemption when a pesticide is registered with the agency.

Further, in compliance with the ESA, EPA implements the Endangered Species Protection Program (ESPP) under the authority of FIFRA. The ESPP sets limits for pesticide applications in certain areas and time periods with the intent of protecting threatened or endangered species and their habitats from potential harms related to pesticide use. These limitations are specified in Endangered Species Protection Bulletins, which are referenced on pesticide labels.

Since pesticides are a potential pollutant to waters of the U.S., certain pesticide applications are also regulated by the National Pollutant Discharge Elimination System (NPDES) permitting program, pursuant to section 402 of the Clean Water Act. As of 2011, farms applying biological and chemical pesticides that will lead to point source discharges to U.S. waters must apply for NPDES Pesticide General Permits (PGPs). Within the 47 states and territories authorized by EPA to administer NPDES permits, state environmental protection regulatory agencies issue PGPs.⁹⁵ In other areas, EPA is the PGP permitting authority. The PGP requires eligible entities to minimize pesticide discharges by implementing pesticide management measures.

The European Union

The European Union has a multilayer approach to pesticide authorization and risk assessment. Three key laws governing pesticides are (i) Regulation (EC) 1107/2009 on placing on the market of Plant Protection Products, (ii) Directive 2009/128/EC on the sustainable use of pesticides, and (iii) Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.⁹⁶

⁹³ United States Environmental Protection Agency. (n.d.). About Pesticide Registration. Retrieved on May 12, 2016 from <https://www.epa.gov/pesticide-registration/about-pesticide-registration#laws>

⁹⁴ *Ibid*

⁹⁵ United States Environmental Protection Agency. (2016b, October). Pesticide Permitting – 2016 PGP. *National Pollutant Discharge Elimination System*. Retrieved from <https://www.epa.gov/npdes/pesticide-permitting-2016-pgp>

⁹⁶ European Commission. (2016h). EU legislation on MRLs. Retrieved on May 10, 2016 from http://ec.europa.eu/food/plant/pesticides/max_residue_levels/eu_rules_en

Manufacturing, Distribution and Labeling

Pesticides, commonly referred to as Plant Production Products (PPPs) in the EU, are made of several ingredients, but the key component used against pests/plant diseases is termed the “active substance.” Based on the distinction between active substances and PPPs, an independent registration process is followed. The European Commission and the member states are jointly responsible for approval of each active substance, in accordance with Regulation (EC) 1107/2009.⁹⁷ The member state carries out the initial risk evaluation of the substance, and submits the draft assessment report to the European Food Safety Authority (EFSA) for peer review. EFSA, in consultation with the public, provides its conclusions to the Commission concerning its opinion that the substance should either be approved or disapproved. The Commission makes its final decision based on the result of votes cast by the Standing Committee for Food Chain and Animal Health. Initial approval is given for 10 years, and subsequent renewals are valid for 15 years.

The new EU chemicals legislation—Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)—requires manufacturers and importers of substances to submit a registration to the European Chemicals Agency for each chemical substance manufactured or imported into the EU. However, REACH provides exemptions from the general obligation for a number of substances that are considered adequately controlled under pre-existing EU legislation. Active substances included in Regulation (EC) 1107/2009 fall into this category. Article 15 of REACH articulates that “active substances and co-formulants manufactured or imported for use in plant protection products only ... shall be regarded as being registered and the registration as completed.”⁹⁸

PPPs (compounds of active substances and other ingredients) are authorized at the member-state level. This provision rests on the idea that member states have a better understanding of the environmental needs of their localities.⁹⁹ Regulation (EC) No 1107/2009 lays out standard procedures for member states to consider and approve PPPs. Furthermore, Commission Regulation (EU) No 547/2011 (implementing Regulation (EC) No 1107/2009 as regards labelling requirements for PPPs) sets the information required on pesticide labels.¹⁰⁰ The required information includes safety and usage information as well as toxicological information.

⁹⁷ Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market [2009] <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=ENb>

⁹⁸ Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency [2006] <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

⁹⁹ European Commission (2016h)

¹⁰⁰ Commission Regulation (EU) No 547/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labeling requirements for plant protection products [2011] <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0547&from=EN>

The regulation specifies standard phrases to be used to identify safety risks to human or animal health or the environment. Since the allowed pesticide products are determined at the member state level, labels may differ from one to the next.

In addition, the EU requires each pesticide to have a Maximum Residue Level (MRL) (equivalent to the U.S. tolerance level), which is established under Regulation (EC) No 396/2005.¹⁰¹ To set a MRL for a pesticide, an application needs to be submitted to the EU along with information on use (quantity, frequency, etc.) of pesticide on the crop, expected residue when the pesticide is applied, and toxicological data.¹⁰² The Commission adopts MRLs based on risk assessments for residues conducted by EFSA.

Application to the Land

Regulation (EC) No 1107/2009 concerning the placing of PPPs on the market prescribes the conditions for pesticide use. The use of pesticides in any manner other than that instructed on the product package label is prohibited. To ensure compliance with these provisions, the directive is linked to the SMR requirements of the cross-compliance rules in CAP.

To promote the sustainable use of pesticides, the EU introduced Directive 2009/128/EC, which sets out the general principles of integrated pest management to be followed when using pesticides. In particular, the legislation charges member states with developing a national action plan to set up their quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides. These targets may cover different areas of concern, for example worker protection, protection of the environment, residues, use of specific techniques or use in specific crop.¹⁰³

Articles 8 and 9 of the directive require member states to inspect pesticide application equipment and to prohibit aerial spraying of pesticides, although they allow for certain exemptions.

¹⁰¹ European Commission. (2016i). Maximum Residue Levels. Retrieved on May 10, 2016 from http://ec.europa.eu/food/plant/pesticides/max_residue_levels/index_en.htm.

¹⁰² European Commission. (2016j). How are EU MRLs set?. Retrieved on May 10, 2016 from http://ec.europa.eu/food/plant/pesticides/max_residue_levels/application_en

¹⁰³ Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides [2009] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0071:0086:en:PDF>

Table 4: U.S. and EU Pesticide Regulations

United States		European Union
Introducing pesticides to the market		
Regulatory Authority	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	Regulation (EC) No 1107/2009 on the placing of plant protection products (PPPs) on the market (repealing Directive 79/117/EEC and 91/414/EEC)
Administering Institution	EPA	Directorate General for Health and Food Safety
Scope of Application	<ul style="list-style-type: none"> ▪ All pesticides sold or distributed in the U.S. must be registered by EPA; ▪ States may ban the sale or use of any federally registered pesticides; ▪ States may register a new pesticide for general use, or a federally registered product for an additional use, if there is “special local need.” 	<ul style="list-style-type: none"> ▪ The Regulation specifies a list of approved substances that are allowed in pesticides at EU level; ▪ Pesticides must be authorized by member states before they can be placed on the market; ▪ Member states may ban the listed active substances at national or local level.
Application of pesticides on farmland		
Regulatory Authority	Endangered Species Act; Clean Water Act	Directive 2009/128/EC on the sustainable use of pesticides
Administering Institution	EPA	Directorate General for Health and Food Safety & Member States
Scope of Application	<ul style="list-style-type: none"> ▪ EPA sets limitations on pesticide application for protection of endangered species and their habitats; ▪ Farms applying pesticides that will lead to discharges to U.S. waters must apply for NPDES Pesticide General Permits. 	<ul style="list-style-type: none"> ▪ Member states are required to adopt National Action Plans (NAPs) that set objectives and timetables to reduce risks and impacts of pesticide use.
Pesticide Maximum Residue Level (Tolerance)		
Regulatory Authority	Federal Food, Drug and Cosmetic Act (FFDCA)	Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (amending Directive 91/414/EEC)
Administering Institution	EPA establishes tolerance levels; FDA enforces tolerances.	Directorate General for Health and Food Safety
Scope of Application	<ul style="list-style-type: none"> ▪ EPA sets pesticide tolerances for all pesticides used in or on food (several exemptions apply). 	<ul style="list-style-type: none"> ▪ The Regulation sets MRLs for 315 fresh agricultural products intended for food or feed; ▪ Where a pesticide is not listed, a general default MRL of 0.01 mg/kg applies.

Fertilizer

Fertilizers are primarily composed of three essential plant nutrients (nitrogen, phosphorous and potash) but may also contain micronutrients¹⁰⁴ and other macronutrients.¹⁰⁵ Regulations covering fertilizers establish standards for manufacturing, labeling, and the application of commercial fertilizers (chemical and organic). Biosolids (treated sewage sludge) and livestock manure used in agriculture also fall within the regulatory framework.

The United States

Manufacturing, Distribution and Labeling

The registration, labeling, handling, and risk assessments of fertilizers are mostly regulated at the state level. State regulations define fertilizer standards (i.e. limits of nutrients or chemicals used in their composition), and specify the prerequisites for registration and labeling.

At the federal level, the Emergency Planning and Community Right-to-Know Act requires disclosure and reporting of environmental and safety hazards posed by toxic chemicals. Under the act, the public has access to information on chemicals at individual facilities and their potential impact on the neighboring environment if released.

Application to the Land

Given the environmental concerns for water and air due to fertilizer use, fertilizer application for farmland is controlled under environmental regulations. Federal legislation such as the Clean Water Act (CWA) and the Clean Air Act (CAA) authorize EPA to establish regulations to reduce water and air pollutants from various sources.

The CWA, administered by the EPA, governs the pollutants released into U.S. waters and provides guidance for states to establish surface water quality standards. Fertilizer use in agriculture is a leading cause of water pollution due to the excess nutrients in the soil entering into the surrounding water, mostly through surface runoff. The policy approach of the CWA to address nonpoint source pollution¹⁰⁶ is primarily accomplished through voluntary programs and grants. A key component is the Section 319 Nonpoint Source Management Program established by the 1987 amendment of CWA that provides grant money to states to support nonpoint source

¹⁰⁴ Micronutrients used in commercial fertilizer include copper, iron, zinc, manganese, and molybdenum.

¹⁰⁵ In addition to Nitrogen, Phosphorous and Potash, nutrients such as calcium, magnesium and sulphur is used.

¹⁰⁶ Nonpoint sources refer to diffuse sources of pollution caused by land runoff, soil erosion, or leaching, etc. In contrast, point sources apply to identifiable sources of pollution such as fertilizer manufacturing units.

solutions such as nutrient management practices.¹⁰⁷ The Farm Bill conservation programs, introduced in section 1, also encourage farmers to implement nutrient management to optimize fertilizer use. While there are no limits on fertilizer application rates established at the federal level, states may set regulatory standards based on local soil conditions and environmental objectives.

Biosolids are treated sewage sludge applied to land; they are nutrient-rich organic materials used as an alternative to commercial fertilizer. The use and disposal of biosolids is regulated under EPA Part 503 Biosolids Rule,¹⁰⁸ as authorized by Section 405 of the CWA. The regulation specifies general requirements, pollutant limits, management practices, and operational standards for biosolids applied to the land, in addition to those for sewage sludge used for other purposes or disposed in other ways.¹⁰⁹

The European Union

The European Union regulates fertilizers via Regulation (EC) No 2003/2003 relating to the introduction of fertilizers on the market, but the use of fertilizers is covered under environmental legislation—the Nitrates Directive in particular.

Manufacturing, Distribution and Labeling

Regulation (EC) No 2003/2003 frames the standards for fertilizers in the European Union. Member states have to adhere to EU-level standards. A member state is allowed to prohibit a fertilizer only if there is a risk to the environment or health. If such a claim was made, the European Commission would undertake a study on the fertilizer and temporarily ban the product. The regulation establishes minimum requirements for nutrient fertilizers containing nitrogen, phosphorus, and potash.

Regulation (EC) No 2003/2003 also harmonizes the rules on labeling and packaging for fertilizers in the EU. In particular, fertilizer packages are required to have labels printed at a visible position, which include details on the nutrient or micro-nutrients, information about the manufacturer, and information regarding blends.

Fertilizer labeled as “EC Fertiliser” allows for free circulation on the EU market. Member states can conduct inspections for compliance of fertilizer labeled “EC Fertiliser” according to the

¹⁰⁷ For more details on policy approaches addressing nutrient pollutions in the U.S and EU, please refer to chapter 5 of this report.

¹⁰⁸ United States National Archives and Records Administration (1993). *Code of Federal Regulations*. Title 40, Part 503. Standards for the Use or Disposal of Sewage Sludge.

¹⁰⁹ United States Environmental Protection Agency (2016c, July 26). Biosolids Laws and Regulations. Retrieved on May 10, 2016 from <https://www.epa.gov/biosolids/biosolids-laws-and-regulations>

provisions of Regulation (EC) No 2003/2003. However, checks can be carried out only by designated laboratories in each member state and must follow the procedure set out within the Regulation. Member states set penalties for any infraction related to the labeling of fertilizers.

Contrary to the registration of active substances in pesticides, fertilizer ingredients do not have a separate registration process. Fertilizer manufactures and importers in the EU are therefore subject to REACH requirements that obligate them to collect and report information on the properties and uses of all the chemical substances involved.

Application to the Land

Fertilizer use and soil nutrient content are primarily regulated under the Nitrates Directive¹¹⁰ introduced to protect water quality from agricultural activities. The Nitrates Directive requires member states to monitor nitrate concentrations in surface and ground water, designate Nitrate Vulnerable Zones (NVZs), and establish “Action Programmes” to be implemented by farmers on a mandatory basis within NVZs as well as Codes of Agricultural Practice to be implemented on a voluntary basis outside NVZs. Member states have the freedom to establish specific requirements of Action Programmes; however, the Nitrates Directive specifies some minimum measures that must be included in the national Action Programmes, such as application prohibition periods, minimum storage capacity for livestock manure, and maximum manure application rate (170 kg N/ha/year).¹¹¹

Member states are expected to report every four years on: (i) nitrate concentrations in groundwater and surface waters; (ii) eutrophication¹¹² of surface waters; (iii) assessments of the impact of Action Programmes on water quality and agricultural practices, and (iv) revisions of NVZs and Action Programmes that include estimations of future trends in water quality.

The use of biosolids in agriculture is regulated under the Sewage Sludge Directive 81/278/EEC. It aims to encourage the use of biosolids while preventing the negative effects on soil, vegetation, animals, and human beings. The requirements include the prohibition of the use of untreated sludge on agriculture land, and limit the application of sludge to specified vegetables and fruits.

¹¹⁰ Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources [1991] <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31991L0676>

¹¹¹ Chapter 5 of this report discusses details on the Nitrates Directive.

¹¹² Eutrophication refers to the enrichment of a water body in nutrients.

Table 5: U.S. and EU Fertilizer Regulations

United States		European Union
Placing of fertilizers on the market		
Regulatory Authority	Regulated by states	Regulation (EC) No 2003/2003 relating to fertilizers
Administering Institution	U.S. States	European Commission
Scope of Application	<ul style="list-style-type: none"> ▪ State regulations cover registration, labeling, handling, application, and consumer protection of fertilizers. 	<ul style="list-style-type: none"> ▪ The Regulation specifies the definition, traceability, markings, labelling, packaging for different types of fertilizers; ▪ It lists “EC fertiliser” that may circulate freely on the European market; ▪ Member states may not prohibit or limit “EC fertiliser” on the market unless the fertilizer represents a danger for health or a risk to the environment.
Application of fertilizers on the farmland		
Regulatory Authority	Regulated through environmental regulations (e.g. Clean Water Act), Farm Bill conservation programs	Directive 91/676/EEC (Nitrates Directive) on the protection of waters against pollution caused by nitrates from agricultural sources
Administering Institution	EPA & USDA	Directorate General for Environment & Member states
Scope of Application	<ul style="list-style-type: none"> ▪ Under CWA, Section 319 Nonpoint Source Management Program provides grant money to states to support voluntary nonpoint source management practices; ▪ Conservation programs encourage farmers to take nutrient management practices that prevent nutrient runoff from farmland; ▪ States set maximum fertilizer application rates based on local conditions and environmental objectives (e.g. water quality criteria). 	<ul style="list-style-type: none"> ▪ Member states are required to designate Nitrates Vulnerable Zones (NVZs) for the water bodies with nitrate concentration exceeding 50 mg/l; ▪ Farmers within NVZs must comply with the Action Programmes established by member states, which must include: <ol style="list-style-type: none"> i. Application prohibition periods; ii. Minimum storage capacity for livestock manure; iii. Maximum manure application rate (170 kg N/ha/year), etc.