Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Bayer Crop Science LP, Petition (20-205-01p) for Determination of Nonregulated Status for Lepidopteran-protected MON 95379 Maize

OECD Unique Identifier: MON-95379-3

Draft Environmental Assessment

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All public comments on this EA must be submitted by the date specified in the Federal Register Notice of Availability for this EA (www.regulations.gov, Docket No. APHIS-2020-113).

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ACRONYMS AND ABBREVIATIONS

a.i.	active ingredient
AOSCA	Association of Official Seed Certifying Agencies
CAA	Clean Air Act
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CO	carbon monoxide
CWA	Clean Water Act
EA	Environmental Assessment
EFSA	European Food Safety Agency
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
FWS	U.S. Fish and Wildlife Service
PGE	plant developed using genetic engineering
HR	herbicide resistant
IR	insect resistant
IRM	insect resistant management
IWM	integrated weed management
lb	pound
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program
NPS	non-point source (pollution)
NRC	National Research Council
NWQI	National Water Quality Initiative
OECD	Organization for Economic Cooperation and Development
PAT	phosphinothricin N-acetyltransferase (enzyme)

ACRONYMS AND ABBREVIATIONS

pat / mo-pat	gene from *Streptomyces viridochromogenes* that encodes the PAT enzyme
PIP	plant-incorporated protectant
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-AMS	U.S. Department of Agriculture- Agricultural Marketing Service
USDA-APHIS or APHIS	U.S. Department of Agriculture-Animal and Plant Health Inspection Service
USDA-ARMS	U.S. Department of Agriculture-Agricultural Resource Management Survey
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USC	U.S. Code
USFWS	U.S. Fish & Wildlife Service
WCR	Western corn rootworm
WPS	Worker Protection Standard (40 CFR part 170)
zm-gos2	a constitutive promotor in corn that drives expression of the *zmm28* gene and ZMM28 protein
zmm28	*zmm28* gene
ZMM28	ZMM28 protein, a transcription factor

1 PURPOSE AND NEED FOR AGENCY ACTION

1.1 Background

In July 2020, Bayer U.S. – Crop Science LP (hereafter referred to as Bayer) submitted a petition to the Animal and Plant Health Inspection Service (APHIS) of the United States Department Agriculture (USDA). The petition seeks a determination of nonregulated status for maize *(Zea mays*) event with OECD Unique Identifier MON-95379-3 developed using genetic engineering (modified maize) for protection against Lepidopteran pests. Bayer requested that MON 95379 maize[1] no longer be considered regulated under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). This petition was assigned the number 20-205-01p and will be referenced as MON 95379 maize or corn in this document. As described in more detail below under 1.4–Requirement to Issue a Regulatory Status Determination, APHIS regulations at 7 CFR part 340 provide that any person may submit a petition to APHIS requesting that an organism developed using genetic engineering should not be regulated, because it is unlikely to pose a plant pest risk.

As part of the evaluation of Bayer's MON 95779 maize, APHIS applied the NEPA-implementing regulations of the USDA and APHIS (7 CFR part 1b and 7 CFR part 372) to prepare this draft Environmental Assessment (EA). USDA deregulation applies nationwide across the U.S., but distribution of MON 95379 corn is restricted based on EPA's registration. (Bayer, 2022).

1.2 Purpose of MON 95379 corn

Bayer is submitting this request to APHIS for a determination of nonregulated status for its biotechnology-derived maize product, MON 95379. MON 95379 maize expresses two insecticidal proteins, Cry1B.868 and Cry1Da_7, which provide protection against damage caused by certain lepidopteran pests. Lepidopterans can influence the development of stalk rot and ear rot diseases in corn. In particular, Fusarium ear rot, caused by F. verticillioides (syn. *F. moniliforme*), *F. proliferatum*, or *F. subglutinans*, and Aspergillus kernel rot, caused by *A. flavus*, are often associated with insect damage to ears or kernels (Munkvold and Hellmich 1999). Developed through genetic engineering, MON 95379 contains traits specifically designed to counteract lepidopteran insect damage. The proteins, Cry1B.868 and Cry1Da_7, are derived from *Bacillus thuringiensis* (hereafter "Bt") and target certain lepidopteran species. In addition, Cry1B.868 is a novel chimeric protein created by combining the genetic sequences of domains I and II from Cry1Be (*Bt*), domain III from Cry1Ca (*Bt* subsp. *aizawai*) and C-terminal protoxin domain from Cry1Ab (*Bt* subsp. *kurstaki*). Neither protein has been previously deregulated by APHIS.

MON 95379 maize line will be commercialized for growers in South America as an additional tool for controlling target lepidopteran maize pests, including fall armyworm resistant to current *Bt* technologies. Bayer has registered MON 95379 with EPA. The registration is restricted to breeding and seed increases only; commercial plantings will not be permitted. The registration is limited to 100 total acres per growing season across three states (Nebraska, Hawaii, and Iowa) (Bayer, 2022). Regardless of APHIS' decision on this petition, EPA registration limits MON 95739 to small-scale breeding, testing, and seed

[1] Maize is the botanical term used globally for the cereal plant Zea mays. In the United States maize is commonly referred to as corn. Both terms are used interchangeably in this document. For consistency with the common plant name and petition APHIS uses the term maize, but also refers to corn in certain instances, such as in reference to food products.

increase nurseries, in the United States, to no more than 100 total acres across NE, HI, and IA. MON 95379 maize was developed to be combined through traditional breeding with other deregulated traits to provide protection against both above-ground and below-ground maize pests. These next generation combined-trait maize products will offer broader grower choice, improved production efficiency, increased pest control durability, and enhanced grower profit potential.

The mechanism by which Cry1B.868 and Cry1Da_7 proteins exert their insecticidal activity has been studied and found to be similar, but not identical, to that which has been described for the *Bt* Cry proteins (Wang et al. 2019; MON 2020). The Cry1B.868 and Cry1Da_7 proteins bind to different receptors in the insect gut (Lee et al. 2003), and the insecticidal activity is limited to species within selected families of the order Lepidoptera. As of May 2023, APHIS has previously granted nonregulated status to 41 petitions for biotechnology-based corn varieties, most of these are insect and/or herbicide resistant *(USDA-APHIS 2020c).*

1.3 Coordinated Framework for the Regulation of Biotechnology

On June 26, 1986, the White House Office of Science and Technology Policy issued the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), which outlined Federal regulatory policy for ensuring the safety of biotechnology products. The primary federal agencies responsible for oversight of biotechnology products are the USDA, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA).

In 2015, the Executive Office of the President issued a memorandum directing the USDA, EPA, and FDA to update the Coordinated Framework to clarify current roles and responsibilities in the regulation of biotechnology products; develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology; and commission an independent, expert analysis of the future landscape of biotechnology products. On January 4, 2017, the USDA, EPA, and FDA released a 2017 update to the Coordinated Framework (USDA-APHIS 2018), and accompanying National Strategy for Modernizing the Regulatory System for Biotechnology Products (ETIPCC 2017).

APHIS is responsible for protecting animal and plant health. APHIS regulates products of biotechnology that may pose a risk to agricultural plants and agriculturally important natural resources under the authorities provided by the plant pest provisions of the Plant Protection Act (PPA), as amended (7 U.S. Code (U.S.C.) 7701–7772) and implementing regulations at 7 CFR part 340.

The purpose of EPA oversight is to protect human and environmental health. The EPA regulates pesticides, including pesticides that are produced in plants developed using genetic engineering, termed plant incorporated protectants, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). The EPA also sets tolerances (maximum limits) for pesticide residues that may remain on or in food and animal feed or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 et seq.). The USDA and EPA monitor tolerances, and FDA enforces tolerances, to ensure the safety of the nation's food supply (US-EPA 2019a; USDA-AMS 2019a). In addition, EPA regulates certain microorganisms produced through genetic engineering (agricultural uses other than pesticides) under the Toxic Substances Control Act (15 U.S.C. 53 *et seq.).*

The purpose of FDA oversight is to ensure human and animal foods and drugs are safe and sanitary. The FDA regulates a wide variety of products, including human and animal foods, cosmetics, human and veterinary drugs, and human biological products under the authority of the FFDCA and Food Safety Modernization Act (FSMA). The FDA created the Plant Biotechnology Consultation Program in the 1992 to cooperatively work with developers of plants developed using genetically engineering to help them ensure foods made from their new plant varieties are safe and lawful (US-FDA 1992, 2006). In this program, the FDA evaluates the safety of food/feed from the new crop developed using genetic engineering before it enters the market. Although the consultation program is voluntary, developers routinely participate in it before bringing a new plant developed using genetic engineering to market. The FDA completed its first plant biotechnology consultation in 1994. Thus far, the FDA has evaluated more than 150 plant varieties developed using genetic engineering through this program.

A more detailed description of the roles and responsibilities of USDA, the EPA, and FDA under the Coordinated Framework can be found on USDA's website[2] (USDA-APHIS 2020a).

1.4 Requirement to Issue a Regulatory Status Determination

Under the authority of the plant pest provisions of the Plant Protection Act (PPA; 7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Movement of Organisms Modified or Produced Through Genetic Engineering," APHIS regulates, among other things, the introduction (importation, interstate movement, or environmental release) of organisms and products modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

Pursuant to the terms in 7 CFR 340.6, any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS must respond to petitioners with a decision to approve or deny the petition. Organism developed using genetic engineering is no longer subject to the requirements of 7 CFR part 340 or the plant pest provisions of the PPA if APHIS determines, through conduct of a Plant Pest Risk Assessment (PPRA), that it is unlikely to pose a plant pest risk.

Consistent with NEPA and the USDA and APHIS NEPA implementing procedures (7 CFR part 1b, and 7 CFR part 372), APHIS has prepared this EIS to consider the potential impacts of a determination of nonregulated status for MON 95379 corn on the human environment.

[2] https://usbiotechnologyregulation.mrp.usda.gov/2017_coordinated_framework_update.pdf

2 SCOPING AND PUBLIC INVOLVEMENT

APHIS seeks public comment on draft EAs through notices published in the *Federal Register*. On March 6, 2012, APHIS announced in the *Federal Register* updated procedures for the way it solicits public comment on petitions for determinations of nonregulated status. APHIS specifies in the preexisting 7 CFR 340.6, as reviewed above in Section 1.4, that APHIS will continue to receive petitions for determination of nonregulated status for corn in accordance with the [legacy] regulations at 7 CFR 340.6. Details on policy and procedures for public participation in the petition review and NEPA process are available in the *Federal Register* notice [3] and on the APHIS website (USDA-APHIS 2020a).

2.1 Public Involvement for Petition 20-205-01p

On March 4, 2024, APHIS announced in the *Federal Register* that it was making Bayer's petition available for public review and comment to help identify potential environmental and interrelated economic issues that APHIS should consider in evaluation of the petition.[4] APHIS accepted written comments on the petition for a period of 60 days, until midnight May 3, 2024. At the end of the comment period APHIS had received five comments on the petition, of which four were opposed to deregulating MON 95379 maize. The National Corn Growers Association, a key stakeholder, supported the petition and submitted a recommendation letter. None of the opposed comments provided any substantive information that contributed to development of this draft EA. A full record of each comment received is available online at www.regulations.gov [Docket No. APHIS–2020–0113].

2.2 Issues Considered in this Draft EA

APHIS developed a list of topics for consideration in this EA based on issues identified in public comments on the petition, public comments submitted for other EAs and Environmental Impact Statements (EISs) evaluating petitions for nonregulated status, prior EAs/EISs for corn varieties produced using genetic engineering, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Zea* and *Tripsacum* species. The following topics were identified as relevant to the scope of the impacts analysis in this EA (40 CFR § 1501.9–Scoping): Agricultural Production: Acreage and areas of corn production, agronomic practices and inputs

- Physical Environment: Soils, water resources, air quality
- Biological Resources: Soil biota, animal communities, plant communities, gene flow and weediness, biodiversity
- Public health and worker safety

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[3] Federal Register, Vol. 77, No. 44, Tuesday, March 6, 2012, p.13258 – Biotechnology Regulatory Services; Changes Regarding the Solicitation of Public Comment for Petitions for Determinations of Nonregulated Status for Genetically Engineered Organisms [http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf]

[4] Federal Register, / Vol. 89, No. 2024-04395 / Monday, March 4, 2024, p. 15542-15543. Bayer U.S.-Crop Science: Availability of a Petition for a Determination of Nonregulated Status for Lepidopteran-Protected Maize [Docket No. APHIS–2020–0113]. Available at https://www.govinfo.gov/content/pkg/FR-2024-03-04/pdf/2024-04395.pdf.

- Animal feed/livestock health and welfare
- Domestic economy and international trade
- Potential impacts on threatened and endangered species
- Compliance of the Agency's regulatory status decision with Executive Orders, and environmental laws and regulations to which the action is subject.

Because the introduced genes in MON 95379 maize confer resistance to lepidopteran pests, which can improve the management of targeted lepidopteran insect pests, the primary focus of this EA is on: (1) insect and insect resistance management (IRM), (2) potential impacts on human and animal (livestock) health, (3) effects on wildlife that may consume MON 95379 maize or MON 95379 maize hybrids, and (4) gene flow and potential weediness of MON 95379 maize hybrids.

3 ALTERNATIVES

Two alternatives to the proposed action are evaluated in this EA: (1) No Action, denial of the petition, which would result in the continued regulation of MON 95379 maize, and (2) Preferred Alternative, approval of the petition, which would result in a determination of nonregulated status for MON 95379 maize in the U. S., however EPA's registration prohibits commercial use of MON 95379 within the United States while allowing breeding and seed increases of no more than100 acres per year across NE, IA, and HI.

3.1 No Action Alternative: Deny the Petition Request

One of the alternatives that must be considered by APHIS is a "No Action Alternative." APHIS must respond to each petition with a regulatory status decision. Thus, for APHIS, No Action in this context means no change in regulatory status. Under the No Action Alternative APHIS would deny the petition request for nonregulated status and MON 95379 maize would remain a regulated article under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would be required for the introduction of MON 95379 maize. Because APHIS concluded in its PPRA that MON 95379 maize is unlikely to pose a plant pest risk (USDA-APHIS 2020c), this alternative would not be an appropriate response to the petition for nonregulated status as it would not satisfactorily meet the purpose and need in providing a science based regulatory status decision to the petitioner, pursuant to 7 CFR § 340.6.

3.2 Preferred Alternative: Approve the Petition–Issue a Determination of Nonregulated Status for MON 95379 Maize

Under this alternative, APHIS would approve the petition for full deregulation, and MON 95379 maize, and progeny derived from it, would no longer be subject to APHIS regulation under 7 CFR part 340. As such, permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 95379 maize anywhere within the U.S. noting that EPA's registration prohibits commercial use of MON 95379 within the United States while allowing breeding and seed increases of no more than100 acres per year across NE, IA, and HI. If Bayer sought to conduct field releases outside of these areas, USDA would not be involved in oversight. Bayer would need to apply to EPA for a change to the registration or an experimental use permit.

On June 1, 2024, the EPA's Ecological Risk Assessment (ERA) determined a "No Effect" finding under ESA for all listed species and their designated critical habitats from the proposed uses of Cry1Da_7 and CryB.868 proteins in event MON 95379 maize (US-EPA 2024). Consequently, it concluded that consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service under ESA § 7(a)(2) is not required. USDA has reviewed the EPA's ERA and agrees with the "No Effect" finding.

Based on the scientific evidence, MON 95379 maize is unlikely to pose a plant pest risk (USDA-APHIS 2020c). This alternative meets the purpose and need to respond appropriately to the petition for nonregulated status pursuant to the requirements of 7 CFR § 340.6, and the Agency's statutory authority under the PPA. Because the agency has concluded that MON 95379 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 95379 is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Under this alternative, growers may have future access to MON 95379 and progeny derived from this event if the developer succeeds in expanding its registration with EPA.

3.3 Alternatives Considered but Rejected from Further Consideration

3.3.1 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 95379 is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.2 Geographical Restrictions

APHIS also considered geographically restricting the production of MON 95379 to those areas where MON 95379 corn was allowed to be grown by EPA. EPA regulates MON 95379 corn under FIFRA. However, as presented in APHIS' plant pest risk assessment for MON 95379, there are no geographic differences associated with any identifiable plant pest risks for MON 95379 (USDA-APHIS 2024). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 95379 does not pose a plant pest risk and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework. Based on the foregoing, the imposition of geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act.

3.4 Summary of the No Action and Preferred Alternative Analyses

Table 3-1 presents a summary of the environmental impacts associated with the No Action Alternative and Preferred Alternative that are evaluated in this draft EA. MON 95379 maize will be cultivated for small-scale breeding, testing, and seed increase activities in Nebraska, Hawaii, and Iowa, with a maximum combined total of 100 acres per growing season. Therefore, the Preferred Alternative in Table 3-1 pertains only to small-scale seed production in these three states. Detailed analysis of the affected environment and environmental impacts is discussed in Chapter 4.

Table 3-1: Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MON 95379 Maize as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for MON 95379 Maize**
Meets Purpose and Need and Objectives	No	Yes
Management Practices		
Acreage and Areas of Corn Production	Denial of the petition would have no effect on the areas or acreage utilized for corn production. Fluctuations in production areas and acreage would be relative to weed, insect pest, and disease pressures, and market demand for corn commodities. Regulated field trials would be conducted on lands allocated for this purpose.	Approval of the petition would not result in corn acreage increase in U.S. EPA registration limits MON 95379 cultivation to small-scale breeding, testing, and seed increase-related activities in three U.S. states including Nebraska, Hawaii, and Iowa with a maximum combined total acreage of 100 acres per growing season.
Agronomic Practices and Inputs	Agronomic practices and inputs used in corn crop production, to include regulated field trials, would be unaffected by denial of the petition.	Agronomic practices and inputs used for MON 95379 corn would be the same as for other corn varieties. EPA registration decision does not allow commercialization of MON 95379 in the United States so there would be no impact on agronomic or cultivation practices used in commercial maize production.
Use of organism produced through genetic engineering Corn	Approximately 80% of the U.S. corn crops are GE herbicide resistant (HR) varieties. Denial of the petition would have no effect on grower choice in the planting of previously deregulated corn varieties developed using genetic engineering. Growers and other parties who are involved in production, handling, processing or consumption of corn would continue to have access to existing deregulated organism produced through genetic engineering as well as conventional corn varieties.	Approval of the petition would provide for an additional tool for controlling target lepidopteran pests for growers in South America. A new registration decision would be needed for commercial use of MON 95379 within the US.
Physical Environment		
Soil Quality	Agronomic practices and inputs associated with corn production potentially impacting soils, to include regulated field trials, would continue along current trends.	The agronomic practices and inputs are the same for both MON 95379 maize and existing corn varieties – potential impacts on soils would be unchanged. MON 95379 maize does not contain herbicide tolerance trait and is therefore no different from other non-herbicide tolerant maize in terms of its effect on soil quality. The Cry proteins expressed in MON 95379 maize have specificity to lepidopteran species and

Table 3-1: Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MON 95379 Maize as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for MON 95379 Maize**
		toxicity studies indicate no effects to soil dwelling organisms.
Water Resources	Denial of the petition would have no effect on water resources in the United States. Regulated field trials are limited on a spatiotemporal scale, and present negligible risks to water resources.	Because MON 95379 maize is agronomically like currently cultivated corn and for a small-scale field trial in three states, approval of the petition would present no potential impacts to water resources as currently cultivated corn varieties. Additionally, the Cry proteins produced by MON 95379 maize are unlikely to impact aquatic species due to their low exposure potential and specific toxicity to lepidopteran species. The small-scale seed increase will occur in fields located away from any water bodies, further minimizing the risk of exposure to aquatic environments.
Air Quality	Emission sources, namely tillage and machinery combusting fossil fuels, and the level of emissions associated with corn production, to include regulated field trials, would be unaffected by denial of the petition.	Because the agronomic practices and inputs used for corn, as well as acreage, would remain unchanged, no changes to emission sources nor any significant changes in the volume of emissions from U.S. corn production, would be expected.
Biological Resources		
Soil Biota	Potential impacts of corn production/regulated field trials on soil biota would continue along current trends. There would be no changes to impacts on animal communities from corn production.	While MON 95379 maize differs from non-biotechnology derived corn varieties only in the protection against lepidopteran pests, these traits are not expected to have significant effects on soil biota or community structures. Effects on soil biota, such as microorganisms and macroinvertebrates, would be the same as under the no action alternative.
Animal Communities	Regulated field trials of MON 95379 maize would present negligible risk to animal communities.	Approval of the petition, and subsequent commercial small-scale seed increase production of MON 95379 maize, would not be expected to affect animal communities adjacent to or within MON 95379 maize cropping systems any differently from that of current corn cropping systems. The two Cry proteins in MON 95379 maize are not toxic to mammals, birds, reptiles, amphibians, non-target organisms, and non-lepidopteran invertebrates. MON 95379 maize is intended to adversely affect lepidopteran larvae that inhabit or are near commercial corn fields planted with the

Table 3-1: Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MON 95379 Maize as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for MON 95379 Maize**
		event if they consume leaves or pollen containing the Cry proteins. Otherwise APHIS expects the impacts on the animal communities to be localized and minimal.
Plant Communities	Regulated field trials of MON 95379 maize would present negligible risks to plant communities in proximity to MON 95379 maize fields.	Because the agronomic practices and inputs that will be used for MON 95379 maize seed production are similar as of other corn varieties, potential impacts on plant communities would be the same as that for other corn varieties currently cultivated. MON 95379 maize is not expected to pose a greater plant pest risk, including weediness, or adverse effects on non-target organisms compared to conventional corn.
Gene Flow and Weediness	*Tripsacum* species are the only sexually compatible plants found in the United States. The potential for corn (*Zea mays*) to hybridize with wild relatives of *Tripsacum* is low; hybridization and successful introgression of *Z. mays* genes into *Tripsacum* is rare (de Wet and Harlan 1972; de Wet et al. 1978; Eubanks 1995). Due to permit requirements, gene flow to *Tripsacum* species during regulated fields trials of MON 95379 maize is highly unlikely.	MON 95379 maize will only be cultivated for small-scale breeding, testing, and seed increase-related activities in three U.S. states including Nebraska, Hawaii, and Iowa with a maximum combined total acreage of 100 acres per growing season. Hence any gene flow is expected to be minimal. (de Wet and Harlan 1972; de Wet et al. 1978; Eubanks 1995).
Biodiversity	As a highly managed landscape biodiversity in and around large-scale cropping systems is limited. The homogeneity of the plants in a crop (monoculture), and frequent disturbance of land through planting, harvesting, cover cropping, tillage, pesticide application, scouting, and related production activities limit the diversity of plants and animals in and around crop fields (Altieri 1999; Landis et al. 2005; Sharpe 2010; Towery and Werblow 2010). Denial of the petition, and further regulated field trials of MON 95379 maize, would not have any impacts on biodiversity different than current canola production.	Because MON 95379 maize is agronomically the same as currently cultivated corn varieties, small scale seed increase production of MON 95379 maize would affect biodiversity no differently than other corn cropping systems. Crops produced through genetic engineering with *Bt* traits have been available on the market since 1994 and the body of evidence in peer-reviewed literature does not suggest any negative effect on biodiversity. The Cry1B.868 and Cry1Da_7, trait proteins are unlikely to present any risks to plant, animal, fungal, or bacterial communities except for local populations of lepidopteran species.
Human and Animal Health		

Table 3-1: Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MON 95379 Maize as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for MON 95379 Maize**
Human Health and Worker Safety	Human health considerations associated with crops produced through genetic engineering are those related to (1) the safety and nutritional value of the crops and their products to consumers, and (2) the potential health effects of pesticides that may be used in association with the crops. Denial of the petition would have no effect on human health. MON 95379 maize would remain regulated and would not be available for food or uses.	Approval of the petition for MON 95379 maize would not present any risks to public health. EPA has issued a tolerance exemption for MON 95379 and the product has cleared food consultations with FDA. (BNF No 000179). Based on the FDA's consultation, laboratory data and scientific literature provided by Bayer (US-FDA 2022), APHIS has concluded that MON 95379 maize would have no anticipated significant impacts on the human environment. The EPA regulation of pesticides, and worker protection standards, would be no different than that of the No Action Alternative.
Animal Health and Welfare	Denial of the petition would have no effect on animal health and welfare. MON 95379 maize would remain regulated and unlikely to be utilized for animal feed.	MON 95379 maize would provide for animal feed products. Bayer consulted with the FDA as to the safety of feed derived from MON 95379 maize, and FDA concludes with "no further questions" determination about the safety, nutrition, and regulatory compliance of human food from MON 95379 corn (US-FDA 2022).
Socioeconomic		
Domestic Economic Environment	Denial of the petition would have no effect on the U.S. domestic corn feed markets.	MON 95379 will not be commercialized in the US under the current EPA registration and therefore is not expected to have an effect on the U.S. domestic economy.
International Trade	Denial of the petition would have no impacts on the trade of corn commodities.	Approval of the petition is unlikely to have a substantial effect on the trade of U.S. corn commodities. It may comprise shipments of corn exported from South America to other nations.
Coordinated Framework		
U.S. Regulatory Agencies	Denial of the petition would have no effect on the roles of the FDA and EPA in the oversight of MON 95379 maize. USDA will continue to regulate the introductions of MON87429 maize.	Bayer completed the FDA consultation process for MON 95379 corn on November 7, 2022, and finalized the consultation with the EPA regarding the registration process and label use requirements on January 3, 2024. The EPA's required ecological risk assessment (ERA) resulted in a "No Effect" finding under the Endangered Species Act (ESA) for all listed species and their designated critical habitats based on the proposed use of the Cry1Da_7 and CryB.868 proteins in MON 95379 maize. The FDA concluded its review with a "no further questions" determination, confirming the

Table 3-1: Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MON 95379 Maize as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for MON 95379 Maize**
		safety, nutrition, and regulatory compliance of human food derived from MON 95379 corn.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Fully compliant	Fully compliant

4 AFFECTED ENVIRONMENT and ENVIRONMENTAL CONSEQUENCES

4.1 Scope of Analysis

Evaluation of the Potential Impacts of Agency Action

An impact would be any change, beneficial or adverse, from existing (baseline) conditions described for the affected environment. Thus, impacts or effects means changes to the human environment that could result from approval of the petition, subsequent commercial production of MON 95379 maize, and market utilization of feed commodities derived from this variety.

Impacts/effects considered are those that are reasonably foreseeable and have a reasonably close causal relationship to the petition decision. Impacts/effects may occur soon after the Agency decision or occur later in time. Potential impacts/effects include ecological (such as the effects on natural resources and on the components and functioning of affected ecosystems), historic, cultural, social, or effects on public health. Economic effects, such as those on employment or markets, may also be considered. Impacts/effects include those resulting from actions that may have both beneficial and detrimental effects.

APHIS has determined in previous NEPA analyses that there are no significant environmental impacts associated with several organisms produced through genetic engineering that express the Cry proteins derived from *Bt (Wraight CL ; Sears et al. 2001; USDA-APHIS 2015b, a).* In considering whether the effects of the proposed action are significant, agencies are to analyze the potentially affected environment, and degree of the effects of the action in relation to the affected environment. Agencies should also consider connected actions. The potentially affected environment (summarized below) is defined by the area(s) potentially impacted by the proposed action (e.g., national, regional, or local), and associated resources (e.g., natural, cultural). In considering the degree of the effects, agencies are to consider the following, as appropriate to the proposed action:

(i) Short- and long-term effects.

(ii) Both beneficial and adverse effects.

(iii) Effects on public health and safety.

(iv) Effects that would violate Federal, State, Tribal, or local law protecting the environment.

Potentially Affected Environment

The potential environmental impacts of a biotechnology-derived crop occur within the context of agriculture's general contribution to environmental change (NRC 2010a). Crop production has historically converted biologically diverse natural grasslands, wetlands, and native forests into less diverse agroecosystems to produce food, feed, fiber, and fuel (NRC 2010a). Potential effects on the environment depend on the intensity of scale of crop production over time, the agronomic inputs applied (e.g., fertilizers, pesticides, irrigation water), the effective management of inputs, pests, and weeds, and tillage. There are around 185 million acres of the land area in the United States planted to corn, soybean, and cotton (principle crops of which there are biotechnology-derived varieties) (USDA-NASS 2019d), thus, the scale of potential impacts, namely in an aggregate sense, requires integration of crop production with sustainability and mitigation practices—for both biotech and non-biotech crops. In general, tillage, crop monoculture, and fertilizer and pesticide inputs can have adverse effects on topsoils, water quality, and biodiversity (NRC 2010a). Agriculture is a leading cause of water-quality impairment in the United States (EPA 2015). No-tillage systems, crop rotations, integrated pest and weed management, and other environmentally beneficial management practices can help prevent some of the adverse impacts, although a tradeoff between agricultural production food, feed, fiber, and fuel, and some degree of environment impacts, will always remain (NRC 2010a; NAS 2016b). Due to the scale of crop production in the United States, developing and implementing environmentally sound, sustainable agricultural management practices is a primary goal of federal and state programs (e.g., (US-EPA 2017b; USDA-NIFA 2017; USDA-NRCS 2019c, 2020d), and others).

Gene flow, movement of a transgene to sexually compatible species, has also been a topic of concern, more so in terms of potential economic, as opposed to ecological, impacts. For corn, gene flow to wild relative species has not been an issue to date because sexually compatible relatives of corn do not exist in the United States. However, gene flow of approved biotechnology-derived traits in corn into non-biotech corn varieties, or other is a concern for farmers and markets that depend on adhering to strict non-biotech trait presence and identity preservation standards for certain food and feed commodities. Such gene flow can result in adverse economic impacts to the biotech trait-sensitive market.

It is within this context that APHIS evaluates the potential impacts of MON 95379 maize on the human environment. When it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Some impacts of this product and its cultivation will not differ between the alternatives. As indicated in the preferred alternative, MON 95379 corn is not registered by EPA for commercial use. The registration limits MON 95379 to small-scale seed increase plantings in Nebraska, Hawaii, and Iowa, with a maximum total acreage of 100 acres per growing season. APHIS will limit its environmental analysis to areas currently used for MON 95379 corn seed production and the surrounding regions. To identify corn production areas, APHIS relied on national agricultural statistics data, confirming Nebraska, Hawaii, and Iowa as the targeted locations for these plantings, with a maximum of 100 acres per growing season (USDA-NASS 2020). As MON 95379 lacks an herbicide resistance trait, weed management and herbicide use is outside the scope of analysis for this EA. For the purposes of this EA, it is assumed that the only potential impacts that could derive from production and marketing of MON 95379 maize (that could be considered unique as compared to other corn varieties), are relative to the trait genes and gene products summarized below.

4.1.1 Cry Proteins

A Cry protein is a parasporal inclusion (crystal) protein, produced during the late exponential growth phase of *Bacillus thuringiensis* (*Bt*) bacteria in an inactive form (Wu et al. 2007) . A Cry protein encoded by a *cry* gene which is selectively toxic against a wide variety of insects and pests (Naveenarani M. and Chinnaswamy C. 2019). Activation of Cry protein occurs after the target insect eats plant material expressing the Cry protein and the Cry protein subsequently is exposed to the alkaline pH in the insect's gut. The activated Cry protein lyses the epithelial cells of the gut which leads to the death of the insect (Romeis and Meissle 2011). Cry proteins are highly specific to their target insect (e.g., Lepidoptera vs. Coleoptera), are innocuous to humans, vertebrates and plants (OECD 2003; Wu et al. 2007). Cry proteins are completely biodegradable (Chen et al. 2011; Naveenarani M. and Chinnaswamy C. 2019). When the

Cry proteins are ingested by insects, they are solubilized in the alkaline environment of the insect gut, releasing their constituent Cry proteins as protoxins. Midgut subsequently converts the protoxins into biologically active toxins by proteolytic enzymes (Bravo 1997). These activated toxins then bind to specific receptors on the surface of the midgut epithelial cells and insert into the cell membranes followed by destruction of the epithelial cells (Wu et al. 2007). Crops producing Cry proteins are also known as *Bt* crops. The specificity of Cry proteins allows a grower to select a corn variety containing a Cry protein specific to an insect pest. Therefore, the introduction of Cry proteins from *B. thuringiensis* into corn is a viable alternative for the control of insect pests in agriculture.

4.1.1.1 MON 95379 Maize Cry1B.868 and Cry1Da_7 proteins

MON 95379 maize produces two insecticidal Cry proteins, Cry1B.868 and Cry1Da_7, which protect against feeding damage caused by lepidopteran species (Table 4-1). Cry1B.868 is a chimeric protein comprised of domains I and II from Cry1Be (*Bt*), domain III from Cry1Ca (*Bt* subsp. *aizawai*) and C-terminal protoxin domain from Cry1Ab (*Bt* subsp. *kurstaki*) (MON 2020). Cry1Da_7 is a modified Cry1Da protein derived from *Bt* subsp. *aizawai.*

Table 4-1. Summary of Genetic Elements in MON 95379 Maize

Gene Introduced	Gene Source	Product	Function
Cry1B.868	*Bacillus thuringiensis*	domains I and II from Cry1Be *(Bacillus thuringiensis, Bt),* domain III from Cry1Ca *(Bt* subsp. *aizawai)* and C-terminal protoxin domain from Cry1Ab (*Bt* subsp. *kurstaki*)	chimeric protein protects against feeding damage caused by targeted lepidopteran insect pests
Cry1Da_7	*Bacillus thuringiensis*	*A* modified Cry1Da protein derived from *Bt* (*Bt* subsp. *aizawai*)	A modified Cry1Da protein confers resistance to lepidopteran insects by selectively damaging their midgut lining

The activity of MON 95379 maize appears to be limited to the order Lepidoptera. The two Cry proteins in MON 95379 maize were not toxic to the coleopteran species western corn rootworm (*Diabrotica virgifera virgifera*), southern corn rootworm (*Diabrotica undecimpunctata howardi*), Colorado potato beetle (*Leptinotarsa decimlineata*), or Mexican bean beetle (*Epilachna varivestis*), or hemipteran species of western tarnished plant bug (*Lygus hesperus*) and neotropical brown stink bug (*Euschistus heros*) at the highest dose tested. The advantage of this target specificity is that the grower can then avoid the application of broad-spectrum insecticides (Brookes and Barfoot 2010), allowing corn growers to reduce insecticide applications (Brookes and Barfoot 2010; Brookes and Barfoot 2013). This provides benefits to growers and the environment from the reduction of exposure to insecticides and a corresponding reduction in costs to the grower associated with insecticide purchases and applications (Koch et al. 2015a; US-EPA 2019i).

4.2 No Action Alternative: Deny the Petition

Under the No Action Alternative, MON 95379 maize would remain regulated, requiring APHIS authorization for any importation, interstate movement, or environmental release. Bayer would need to apply for a permit or submit a notification to APHIS before conducting field trials. Once approved, EPA inspects trial sites to ensure compliance and assess potential risks such as pollen drift or seed escape. Post-trial monitoring is required to confirm no GE plants, or their progeny persist or spread unintentionally.

Under the No Action Alternative, U.S. maize production trends would remain unchanged, with commercial cultivation continuing primarily in the Corn Belt (USDA-NASS 2019f). APHIS approval would be required for any field testing or interstate movement of MON 95379 maize, either through a permit or an acknowledgment of notification under 7 CFR part 340. The notification process is a streamlined alternative to permits, provided the biotechnology-derived plants meet specific eligibility criteria, and the proposed introduction adheres to pre-defined performance standards[5]. APHIS reviews notifications to ensure these criteria are met and that the proposed activity, whether importation, interstate movement, or environmental release, can be conducted in compliance with the regulations. If all regulatory requirements are satisfied, APHIS authorizes the notification through a process called "acknowledgment," allowing the applicant to proceed under the conditions outlined in the notification.

For both permits and notifications, APHIS Biotechnology Regulatory Services establishes criteria and conditions to ensure the regulated organism remains contained within the trial site and does not persist in the environment. Applicants must provide documentation, such as design protocols, that detail how these conditions will be met during the field trial or release.

If a regulated organism does not qualify for notification due to potential risks, such as the ability to establish or persist in the environment, a more stringent permit process is required[6]. This applies to organisms related to wild or weedy plants, insects, or microorganisms. Permit applicants must not only meet the information requirements for notification but also describe field testing measures that ensure confinement of the organism to the trial site and its elimination after the field test is complete. The permitting provisions in 7 CFR part 340 outline the information required, standard permit conditions, and administrative procedures. APHIS can impose additional conditions as necessary to mitigate any risks.

The regulation of MON 95379 maize would not affect the acreage used for U.S. corn production or alter current farming practices and inputs. Denial of the petition would similarly have no impact on the physical environment, biological resources, human or animal health, or domestic and international corn markets. Actions taken by APHIS on permit applications and notifications are subject to NEPA. APHIS ensures compliance of permits issued and notifications acknowledged with NEPA, and USDA implementing regulations.[7] Issuance of permits and acknowledgement of notifications are usually considered to be confined releases which are typically authorized under a categorical exclusion from the requirement to conduct an EA or EIS, consistent with APHIS' NEPA implementation regulations (7 CFR

[5] On April 5th, 2021, the notification process is terminated under APHIS' new SECURE rule and only permits will be issued as described in § 340.5.
[6] On April 5th, 2021, applicants begin following the new permitting process under the SECURE rule described in § 340.5.
[7] USDA regulations implementing NEPA at 7 CFR part 1b; and APHIS regulations at 7 CFR part 372.

part 372). APHIS conducts EAs or EISs for permits as applicable to the permit request. This process complies with USDA regulations for implementing NEPA.

There are no anticipated impacts on the human environment that would derive from denial of the petition. To the extent individuals comply with APHIS notification and permit requirements, EPA requirements for pesticide use, and ESA requirements, there would be little risk of harm to wildlife or natural resources because of APHIS authorized field testing of MON 95379 maize. Interstate movement of MON 95379 maize would present negligible environmental risks.

4.3 Preferred Alternative – Approve the Petition

4.3.1 Overview of U.S. Corn Production

4.3.1.1 Acreage and Area of U.S. Corn Production

There are three primary varieties of corn cultivated in the United States: Dent (or field) corn (*Zea mays* var. *indenata*), sweet corn (*Zea mays* var. *saccharata*), and popcorn (*Zea mays* var. *everta*). To a lesser extent flour (*Zea mays* var. *amylacea*) and waxy corn (*Zea mays* var. *ceratina*) varieties are produced. Dent corn, at maturity, has an obvious depression (or dent) at the crown of the kernels—thus its name.

The most recent USDA data on U.S. dent corn production indicates that for the 2024 season, corn production is estimated at around 15.1 billion bushels, an increase from the previous year (USDA-NASS 2024b). This rise is driven by increased acreage and favorable weather conditions in key growing areas like the Midwest. Dent corn, which makes up the bulk of U.S. corn production, is predominantly used for animal feed, ethanol production, and various industrial purposes. MON 95379 maize is a dent corn variety.

In 2024, usage patterns for corn remain steady. A significant portion (about 38%) is allocated to livestock feed, particularly for cattle, hogs, and poultry. Additionally, ethanol production consumes roughly 35-40% of the total U.S. corn supply, supporting the renewable fuel sector (USDA-ERS 2023b). Exports also account for a notable share, with major destinations being Mexico, Japan, and China. The demand for U.S. corn exports is expected to remain stable due to competitive pricing (Figure 4-1). For more detailed and updated insights, including feed usage and export trends, you can refer to the USDA Feed Outlook report for September 2024 (USDA-NASS 2024b).

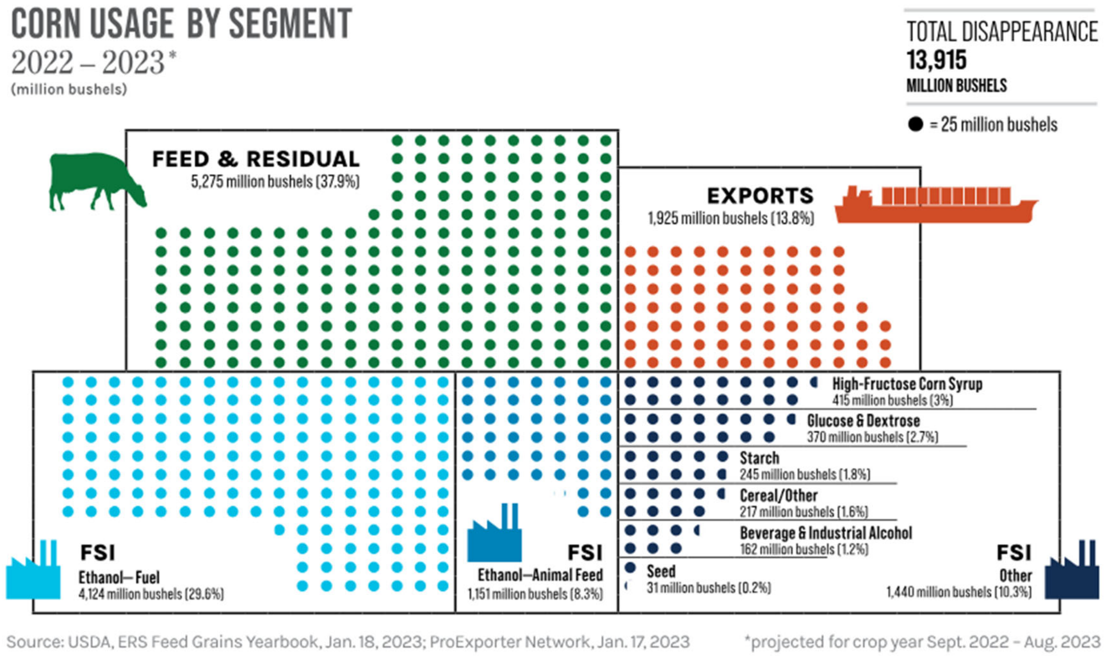


Figure 4-1. Corn Uses in the United States
Source: (NCGA 2023; USDA-ERS 2023a).

The 2024 National Corn Growers Association Corn Production Report estimates U.S. corn production at 15.2 billion bushels, down 1% from last year (USDA-NASS 2024). The forecast yield per acre is at a record high of 183.6 bushels, 6.3 bushels higher than in 2023. While the total area planted to corn remains steady at 90.7 million acres, the area harvested for grain is expected to decrease by 4% (Hanrahan 2024; USDA-NASS 2024b). About 65% of the crop is rated in good or excellent condition, a significant improvement over last year. USDA-NASS also forecasts record-high yields in key states, including Iowa, Illinois, and Indiana, as well as other states like Louisiana, Michigan, and Nebraska. Biotech varieties now account for 94% of all corn acres planted in the U.S., up from 93% in 2023 (USDA-NASS 2024b) (

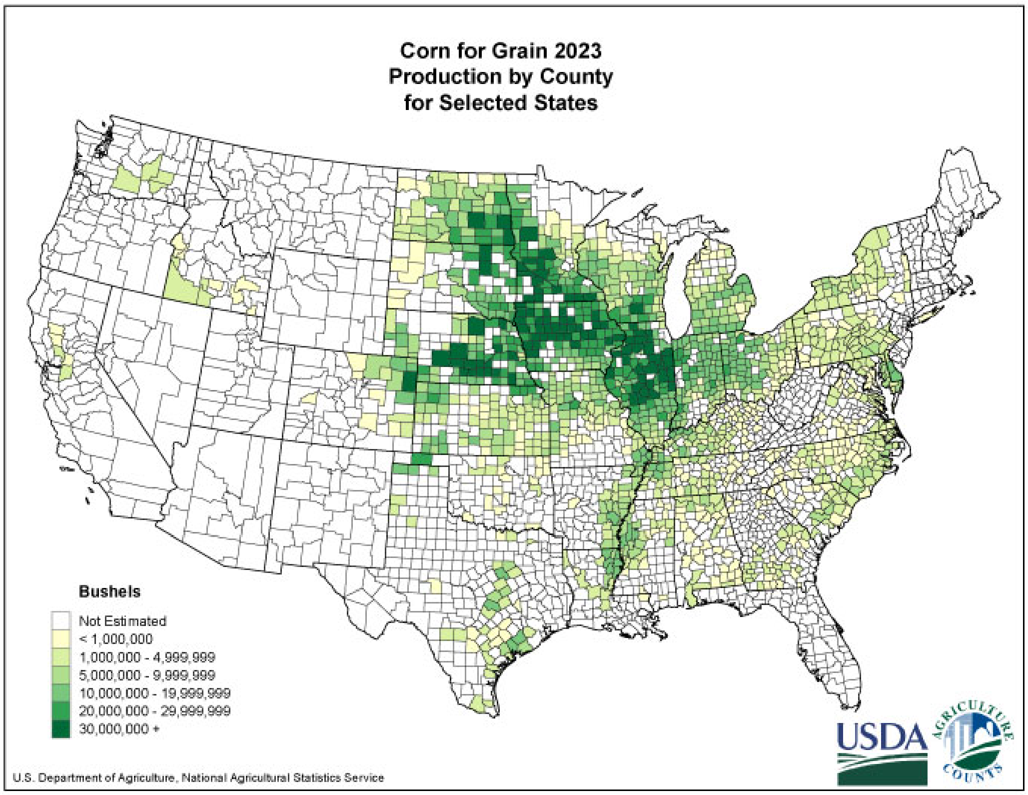


Figure 4-2).

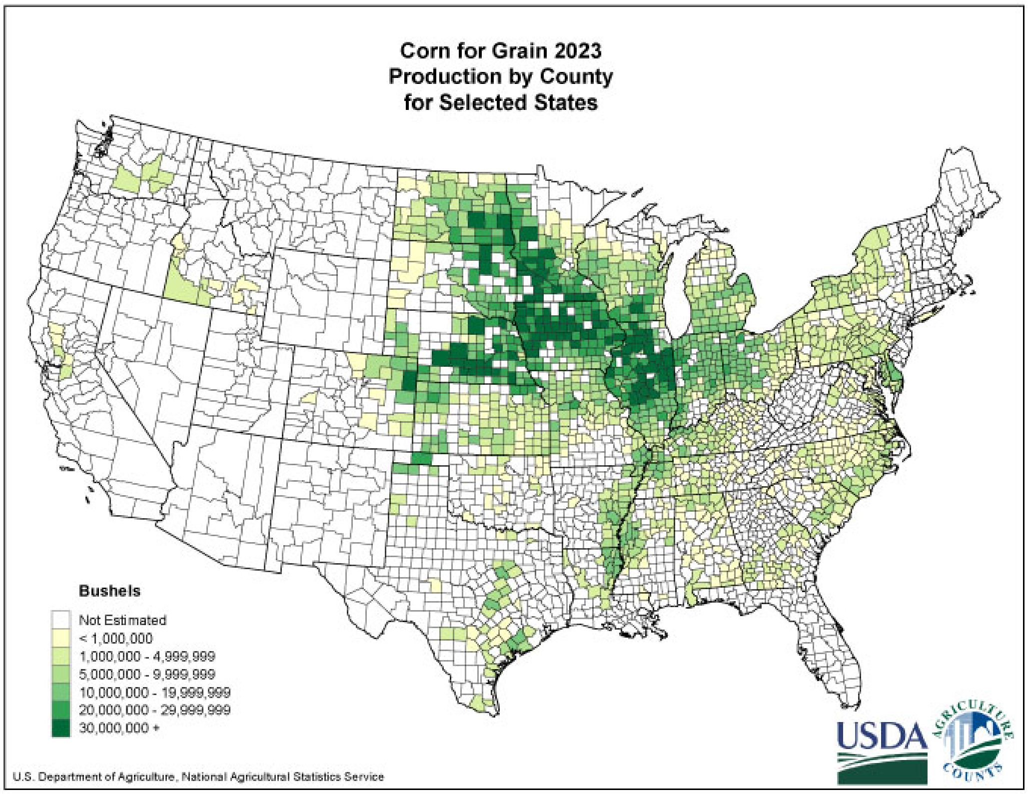
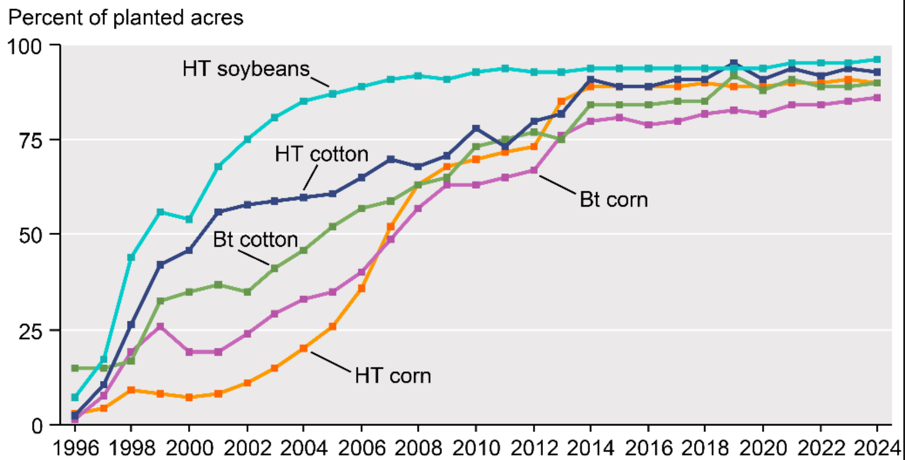


Figure 4-2. Corn Cultivation in the United States by County, 2023
Source: (USDA-NASS 2024b)

Around 94% of the corn produced in the United States in 2024 is derived from biotechnology varieties, which remains predominantly dent/field corn (

Adoption of genetically engineered crops in the United States, 1996–2024

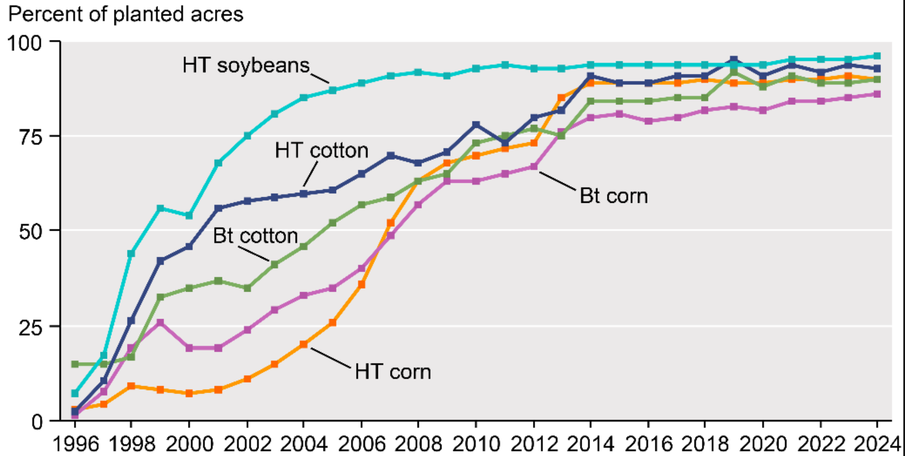


Note: HT indicates herbicide-tolerant varieties; Bt (Bacillus thuringiensis) indicates insect-resistant varieties (containing genes from the soil bacterium Bt). Data for HT/Bt corn and cotton are not mutually exclusive, as HT and Bt categories include those varieties with overlapping (stacked) HT and Bt traits.
Source: USDA, Economic Research Service using data from the 2002 ERS report, Adoption of Bioengineered Crops (AER-810) for 1996–99 and National Agricultural Statistics Service, (annual) June Agricultural Survey for 2000–24.

Figure 4-3). Sweet corn represents a small share, about 1% of total corn production, with only around 10% of that acreage comprising biotech varieties. As in previous years, there are still no biotech varieties for popcorn, flour, or waxy corn.

Most biotech corn varieties continue to have stacked traits, combining herbicide-resistant (HR) and insect-resistant (IR) properties. In 2024, 82% of planted corn acreage featured stacked traits, slightly up from 2019 (USDA-NASS 2024b). Single HR traits make up around 8% of corn crops, while single IR traits account for 3%. In 2024, of the approximately 91.5 million corn acres planted, around 7 million acres remain non-biotech (USDA-ERS 2023a; USDA-NASS 2024b) (

Adoption of genetically engineered crops in the United States, 1996–2024



Note: HT indicates herbicide-tolerant varieties; Bt (Bacillus thuringiensis) indicates insect-resistant varieties (containing genes from the soil bacterium Bt). Data for HT/Bt corn and cotton are not mutually exclusive, as HT and Bt categories include those varieties with overlapping (stacked) HT and Bt traits.
Source: USDA, Economic Research Service using data from the 2002 ERS report, Adoption of Bioengineered Crops (AER-810) for 1996–99 and National Agricultural Statistics Service, (annual) June Agricultural Survey for 2000–24.

Figure 4-3).

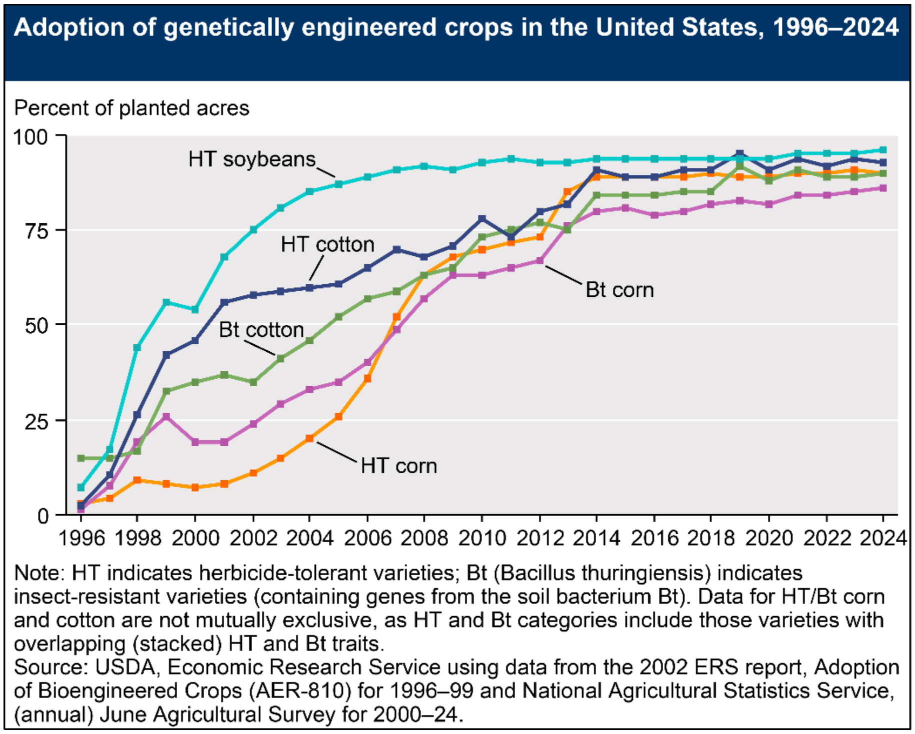


Figure 4-3. Biotechnology-Derived Corn Traits Planted in the United States, 2024
Source: (USDA-NASS 2024b).

4.3.1.2 Agronomic Practices and Inputs

Corn production utilizes a variety of agronomic practices and inputs that aim to achieve optimal yield, product quality, and grower net returns. These include the occasional or regular application of manure or synthetic fertilizers; pesticides; tillage; crop rotation; and cover crops. Organic farming systems are required to exclude certain inputs, such as use of synthetic pesticides. Some of these practices (e.g., tillage) and inputs (e.g., fertilizers, pesticides) can, when applied in excess or improperly, or as a result of aggregate effects, present environmental challenges in maintaining air, soil, and water quality. Pesticide and fertilizer use can also present risks to wildlife and human health. The relationship between these practices and inputs and air, soil, and water quality, biological resources, human health, as well as the socioeconomic aspects of corn production, are discussed in the subsequent sections of this chapter.

4.3.1.2.1 Agronomic Practices

Growers employ several practices for the management of pests and weeds, summarized below (Table 4-2), such as scouting for weeds, crop rotation, and maintaining ground cover or mulching. Tillage is the primary practice that can have environmental impacts, and this topic, in relation to MON 95379 maize, is discussed in more detail below.

Table 4-2. Top Practices in Pest Management, 2018 Crop Year	
	% of Corn Acres
Monitoring: Scouted for weeds	94
Avoidance: Rotated crops during last three years	84
Prevention: Used no-till or minimum till	65
Suppression:	45

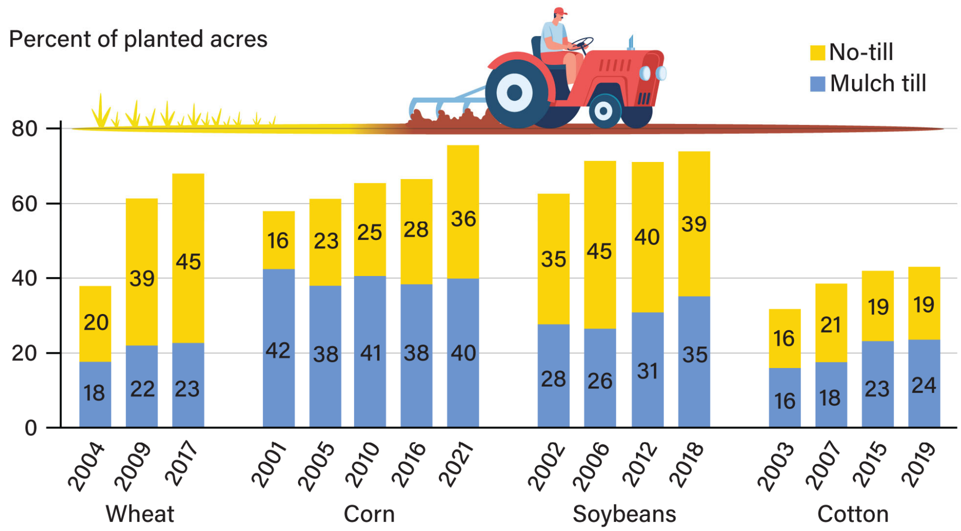
The USDA-NASS survey asked growers in 18 states that accounted for 93% of the planted corn acreage to report on the practices they used to manage pests, defined as weeds, insects, or diseases. Corn growers reported practices in four categories: prevention, avoidance, monitoring, and suppression. Only the top practice in each category is shown. Source: (USDA-NASS 2019a)

4.3.1.2.1.1 Tillage

Tillage is used to control weeds and soil-borne pests and disease and prepare the seedbed. Tillage types are classified as conventional, reduced, and conservation tillage (e.g., no-till and mulch-till), which are characterized in part by the amount of plant material left on the field after harvest and the degree of soil disturbance they cause. Conventional tillage involves intensive plowing leaving less than 15% crop residue in the field; reduced tillage leaves 15% to 30% crop residue; conservation tillage, such as mulch-till, involves leaving at least 30% of crop residue. No-till systems leave all crop residue on the field (Claassen et al. 2018; OSU 2019).

Decisions concerning the amount, timing, and type of tillage to employ involve consideration of a wide range of interrelated factors such as the variety and extent of weeds and crop pests present, soil erosional capacity, fuel and other input costs, anticipated weather patterns, and potential air and water quality issues. Over the long-term conventional tillage reduces soil quality, and results in soil erosion and runoff that can adversely affect surface waters (Wallander 2015). Conservation tillage systems are the least intensive and, as the name implies, aim to conserve top-soil and soil quality. Conservation tillage provides a variety of agronomic and economic benefits, such as preservation of soil organic matter, reductions in soil erosion and water pollution, as well as reductions in fuel use and crop production costs (Fernandez-Cornejo et al. 2012; Claassen et al. 2018). However, conservation tillage, especially no-till, can also cause production problems such as increased soil compaction, perennial weeds or weed shifts, buildup of plant pathogens or pests in crop residue, and slow early crop growth due to cooler soil temperatures (Roth 2015). A systematic use of crop rotations can improve the success of conservation tillage by eliminating some of these stresses observed in continuous no-till corn (Roth 2015).

The use of conservation tillage increased steadily throughout the 1980s and 1990s and continues to do so. While approximately 33% of corn acres were produced using conservation tillage systems in 1990, 65% of corn acres were produced using conservation tillage systems in 2016 (Claassen et al. 2018). No-till accounted for around 42% of conservation tillage on U.S. corn acres in 2016 (27% overall) (Figure 4-4). An increase in conservation tillage has been facilitated by the availability of post-emergent herbicides (since the 1980s), which can be applied over crops throughout the growing season—not just before planting, as had previously been the case (Fernandez-Cornejo et al. 2012). Another factor has been the implementation of soil conservation programs that began in the mid-1980s, which encourage/incentivize implementing conservation tillage practices (USDA-NRCS 2006). Continued increases in conservation tillage since the late 1990s have also been attributed to, in part, the use of herbicide resistant crops, which can facilitate effective weed management and reduce the need for mechanical weed control (Towery and Werblow 2010; USDA-ERS 2012).



Notes: By not tilling (**No-till** acreage), producers leave soil and crop residue from the previous harvest undisturbed. **Mulch tilling** involves using instruments such as a chisel or a disk with low soil disturbance. Conservation tillage is the sum of no-till and mulch till acreage. Differences in years reported by crop are related to differences in years the crop was included in the USDA, Agricultural Resource Management Survey (ARMS).

Figure 4-4. Conservation Tillage Practices in Corn, 2001 – 2021
Source: (USDA-NASS 2022).

4.3.1.2.2 Agronomic Inputs

In addition to the agronomic practices described, chemical inputs for control of insect pests, nematodes, pathogens, weeds, and the addition of plant nutrients to soils are an integral part of corn production, biotech and non-biotech cropping systems alike. These inputs are used to maximize yield, product quality, and grower net returns. Agronomic inputs relative to MON 95379 maize production are discussed following.

4.3.1.2.2.1 Fertilizers

Soils in many areas of the United States where corn is produced are naturally deficient in nitrogen, phosphorus, and other nutrients, requiring fertilizer inputs, to include manure, to produce crops efficiently, and the yields necessary, to meet market demand. Given the importance of nutrient availability to corn growth, fertilization with nitrogen, phosphorus, and potassium is practiced widely in the United States.

Since 1975, approximately 94% to 99% of corn acreage continues to be treated with nitrogen, with the average rate of application now increasing to around 155 lbs/acre in 2024, up from the 149 lbs/acre average in 2018 (USDA-ERS 2024). Phosphate use remains consistent, fluctuating between 78% and 85% of treated acreage, with an average application rate now ranging from 58 to 62 lbs/acre. Potash usage has seen a slight decrease, with around 63% to 81% of corn acreage treated in 2024, and application rates averaging 70 to 89 lbs/acre (USDA-ERS 2024). These fertilizer application trends reflect a modest but steady increase in nutrient use, particularly nitrogen, as farmers work to optimize yields while managing environmental concerns. Inputs for the 2018 crop year (latest data) are provided in Table 4-3.

While nitrogen and phosphorus are important agricultural inputs in crop production, the introduction of amounts exceeding recommended thresholds can have a number of undesirable impacts on water and air quality (discussed in the following relevant sections).

Table 4-3: Fertilizer Applied to Corn Acres, 2024 Crop Year

Fertilizer	% of Planted Acres	Avg. Rate for Year (lbs/acre)	Total Applied (billion lbs)
Nitrogen (N)	97	146	12.7
Phosphate (P2O5)	80	56	4.1
Potash (K2O)	63	40	2.3
Sulfur (S)	43	15	0.6

Source: (Quinn 2023; USDA-NASS 2024b).

4.3.1.2.2.2 Manure

Manure is widely used as a crop fertilizer and soil amendment. It contains not only nutrients—such as nitrogen, phosphorus, and potassium—but can improve soil quality by neutralizing acidity, increasing organic matter, decreasing compaction, and increasing water-holding capacity. Manure is used as a substitute for commercial fertilizers relative to pricing, proximity of a crop field to sources of manure production, and cost of transport (MacDonald et al. 2009). The option to use manure is primarily limited by the cost of transport, which can be expensive for even short distances (MacDonald et al. 2009).

As of 2025, the most recent comprehensive data on manure application for seven major U.S. field crops (corn, soybeans, wheat, cotton, oats, peanuts, and barley) was published in 2020, showing that manure was applied about 7.7% of the 240.9 million acres planted with this crops. (USDA-NASS 2023). While beneficial to crop production manure can pose environmental and human health risks when stockpiled or applied in excessive amounts (discussed further in subsequent sections on the physical environment, biological resources, and human health). Most manure producing operations store manure prior to application, in pits and lagoons, which can pose environmental risks from seepage, flooding, or catastrophic failure of containment structures (MacDonald et al. 2009). Manure from crop fields, animal feeding operations, and storage sites can also be transmitted to surface waters through the runoff, carrying nutrients, organic matter, and potentially, pathogens. Leaching of nutrients and enteric bacteria to ground water, and volatilization of gases and odors to the atmosphere, can also occur (MacDonald et al. 2009; Davis 2018a). Because manure can present risks to water and air quality, federal, state, and local authorities regulate manure production facilities and manure storage. The EPA's Clean Water Act regulations discussed further in 4.3.2.2–Water Resources, prohibits discharges from certain animal feeding operations to waters of the United States without a National Pollutant Discharge Elimination System (NPDES) permit. Federal and state regulations also require many large operations to develop and implement nutrient management plans (NMPs) as a part of manure production and application (MacDonald et al. 2009; US-EPA 2019i).

4.3.1.2.2.3 Pesticides

Pesticides contribute to higher yields, optimal product quality, and grower net returns by controlling weeds, insects, nematodes, and plant pathogens. However, some pesticides may be potentially harmful to humans and wildlife, as well as other crops, when not properly used. Common corn pests include *Coleoptera* species (beetles), *Lepidoptera* species (moth and butterfly larvae), pathogenic fungi (e.g., corn leaf blight), bacteria (e.g., stalk rot), and viruses (e.g., dwarf mosaic virus). There are around 50 species of weeds that occur among U.S cornfields, requiring annual control (Jhala et al. 2014). Weeds have been and will remain a problem in corn crop production; they are difficult to manage, competitive, and use up resources — soil moisture, nutrients, access to sunlight — that would otherwise be available to the corn plant. In corn production, herbicides are the most widely used, followed by fungicides and insecticides (Figure 4-5), exemplary of the significance of weed control in corn production.

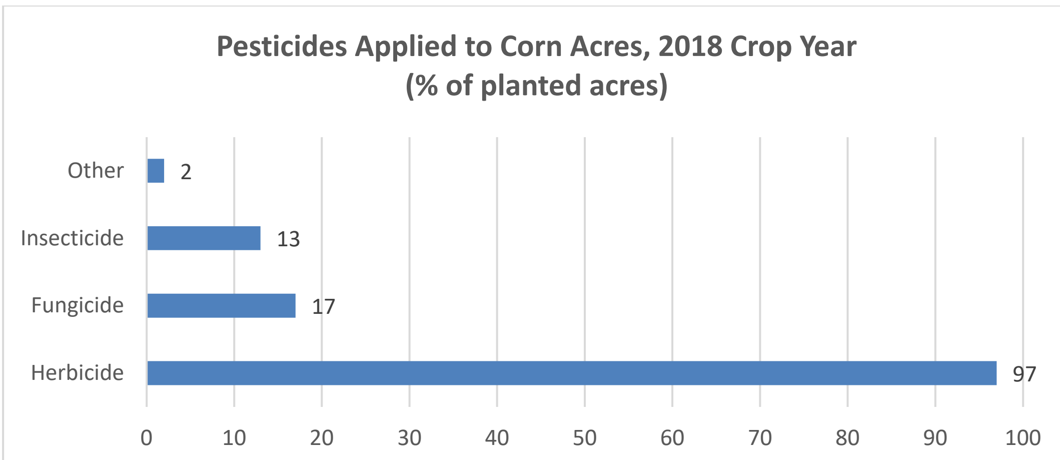


Figure 4-5. Pesticides Applied to Corn, 2018
Source: (USDA-NASS 2019a)

4.3.1.2.2.4 Fungicides

Fungicide, usually combined with an insecticide, is used to treat seeds. This practice varies by grower preferences and regional disease distribution (Ruhl 2008; MI-Extension 2022). Some of the common fungal diseases on corn include anthracnose leaf blight (*C. graminicola*), common rust (*Puccinia sorghi*), eyespot (*K. zeae*), gray leaf spot (*C. zea-maydis*), northern corn leaf blight (*Exserohilum turcicum*), corn leaf spot (*Bipolaris zeicola*), and seed rot caused by fungi and bacteria (AR-Extension 2015). Historically, foliar applications of fungicides were not common, and fungal disease management was focused on selection of disease-resistant hybrids, crop rotation to break the disease cycle, and tillage to encourage decomposition of crop residues that were reservoirs for the disease. Continuous cultivation and conservation tillage practices have increased disease risk in some areas.

4.3.1.2.3 Insect and Insect Resistance Management (IRM)

Corn is susceptible to attack by a variety of insects throughout its life cycle. In addition to direct damage caused by feeding on plant tissue, the corn insect pests are known in the transmission and dissemination of pathogenic organisms during corn development (Alegbeleye et al. 2018). Insect control options available to corn growers include conventional insecticide applications, microbial insecticide applications, crop rotation, and planting of insect resistant cultivars. Before the introduction of corn varieties modified through genetic engineering, the corn growers had difficulty controlling insects.

Domestic *Bt* corn use grew from about 8% of corn acreage in 1997 to 19% in 2000, before climbing to 82% in 2020 (USDA-ERS 2020). Prior to the introduction of rootworm-protected *Bt* varieties in 2003, an estimated 14 million acres were treated annually with conventional insecticides to control corn rootworms, which accounted for the largest single use of insecticides in the United States (James 2014; Brookes and Barfoot 2018a). In 2013, 76% of the total U.S. corn acreage was planted in a stacked variety containing at least one *Bt* trait (USDA-NASS 2014). As of 2018, with 80% of U.S. corn acres were planted, only 13% of corn acres were treated with insecticides (USDA-ERS 2019b; USDA-NASS 2019b).

Studies conducted by USDA-ERS (Fernandez-Cornejo et al. 2014a; Fernandez-Cornejo et al. 2014b), the National Academy of Sciences (NAS 2016a), and others (Osteen and Fernandez-Cornejo 2016; Fleming et al. 2018) have found that insecticide use has declined in corn production due in part to the adoption of *Bt* corn (Figure 4-6). Growers are attracted to the convenience of *Bt* maize hybrids because they will be handling and applying fewer chemical insecticides, which has both human health benefits and important environmental benefits. As a result, insecticide use with corn, which peaked in the late 1970s and 1980s at an average 0.35 – 0.45 pounds per acre, declined throughout the 1990s and 2000s to an average of under 0.03 pounds per planted acre in 2018 (USDA-NASS 2019d).

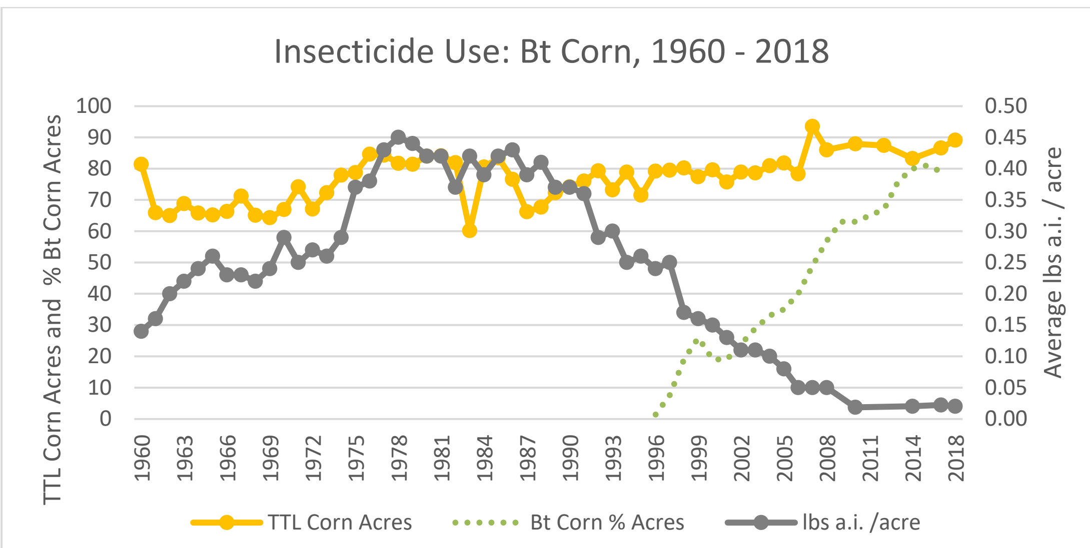


Figure 4-6. Insecticide Use in Bt Corn Production
Source: (Fernandez-Cornejo et al. 2014c; USDA-NASS 2019d).

Environmental damage from insecticide overuse is a major concern, particularly for conservation of "good" insects such as pollinators that ensure stable production of food crops. However, insecticides are also necessary for farmers to manage pests and thus, a more holistic view of crop management needs to account for the proper balance between the beneficial and detrimental aspects of pesticides (Pecenka et al. 2021). Integrated pest management (IPM) is a central organizing principle to optimize pesticide inputs and preventing overuse via practices. Although IPM has been a mainstay in agriculture for over 50 years, technological changes in farming practices over recent decades have made this well-accepted and effective approach more efficient (Peterson et al. 2018; Pecenka et al. 2021).

In areas where cultivation of *Bt* corn is high, the use of *Bt* crop varieties has also been associated with reduced insecticide use in adjacent cropping systems cultivating non-*Bt* varieties, a result of the area-wide suppression of insect pest populations (NAS 2016a). For example, several studies have found that the use of *Bt* corn and *Bt* cotton are positively associated with the area-wide suppression of European corn borer and pink bollworm, respectively (Dively et al. 2018). A combination of use of integrated pest management (IPM) strategies and *Bt* crops led to a significant reduction in the number of insecticide applications. In general, peer review literature and other reports indicate that cultivation of *Bt* crops can potentially-provide tangential benefits to adjacent farms by tempering the prevalence of certain insect pest populations, reducing the need for insecticide use in nearby cropping systems (NAS 2016a)(USDA-ARS 2010). The study attributes the collateral benefits enjoyed by non-Bt farmers to areawide suppression of corn borers stemming from long-term plantings of Bt-protected crops (USDA-ARS 2010).

Insect Resistant (IR) Management (IRM) in IR Crops Produced through Genetic Engineering

As with herbicide resistant (HR) weeds, continued exposure of insect pests to insecticides can result in the development of resistant insect populations. This is an important issue for crop plants produced through genetic engineering that have insecticidal traits. The beneficial attributes of IR cropping systems considered, the potential for development of insect populations resistant to IR trait proteins is ever present and has occurred in some areas. For example, resistance of *Helicoverpa zea* (corn earworm) to several *Bt* toxins has emerged in the eastern and central corn Belt (Dively et al. 2016). Field-evolved resistance by CRW to organism produced through genetic engineering Cry3Bb1 corn, mCry3A corn, and eCry3.1Ab corn has been documented in multiple Midwestern states (Gassmann et al. 2016; Jakka et al. 2016). Additionally, cross-resistance among Cry3Bb1, mCry3A, and eCry3.1Ab has been reported (Jakka et al. 2016). Consequently, implementation of IRM practices in cultivation of *Bt* crops is required to protect and effectively steward *Bt* crop technologies for longevity (Tabashnik BE et al. 2013; US-EPA 2019e). While insects are capable of developing resistance to most all insecticides, for PIPs this risk may be heightened by the fact that:

- Insecticidal proteins are expressed at high levels in most or all plant tissues;
- the proteins are produced by the plant continually during the growing season (i.e., throughout the lifespan of the plant); and
- some of the major target pests, such as European corn borer, corn rootworm, and pink bollworm, feed almost exclusively on corn or cotton.

These factors can increase insect exposure to the insecticidal protein and thereby increase selection pressure for development of resistant populations. For example, the cases of pest resistance to certain *Bt* Cry proteins produced by transgenic crops increased from 3 in 2005 to 16 in 2016 (Tabashnik and Carriere 2017). These 16 cases represent resistance of some populations of seven major pests in five countries to each of the nine Cry toxins produced by widely grown *Bt* crops: Cry1Ab, Cry1Ac, Cry1A.105, Cry1Fa, Cry2Ab, Cry3Bb, mCry3A, eCry3.1Ab, and Cry34/35Ab. Both corn earworm (Jakka et al. 2016) and corn rootworm (Gassmann et al. 2016; Jakka et al. 2016) have developed resistance to multiple Cry toxins (e.g., Cry3Bb1, mCry3A, and eCry3.1Ab). For the 16 cases of resistance that have been documented, the average time for evolution of resistance was only 5.2 years (Tabashnik and Carriere 2017). In contrast with the 16 cases of resistance documented, global monitoring data also show 17 cases where no significant decrease in pest susceptibility occurring, after 1 to 19 years of exposure to *Bt* crops (Tabashnik and Carriere 2017). Results from resistant insect bioassays, disabled insecticidal protein bioassays, and cell-based assays using insect cell lines expressing individual receptors indicate that Cry1B.868 and Cry1Da_7 utilize receptors that are distinct from each other as well as other commercialized *Bt* proteins (MON 2020).

IRM in *Bt* crops remains a key concern and will continue to be an essential aspect of IR crops produced through genetic engineering systems (Tabashnik and Carriere 2017). Several strategies, such as the use of multiple Cry proteins/toxins, spatial and temporal refuges, and high or ultrahigh doses of Cry, are employed to prevent the development of insect resistance to PIPs. A major principle of management of resistance to insecticidal proteins is the use of combinations of different Cry proteins, proteins that have different receptors or different modes of action. The IRM strategy that has received the most attention involves a "high dose/refuge" (HDR) concept (Bates et al. 2005; Siegfried and Hellmich 2012). With this approach, insects that feed on *Bt* crops are exposed to a high dose of toxin. This is complemented with a refuge, a non-*Bt* crop variety or other plant hosts, which supports a population of unexposed insects, thereby eliminating selection pressure on those insect populations. Resistant insect pest populations that develop as a result of exposure to Cry toxins, instead of mating with each other, are able to mate with individuals among a large number of non-resistant pests from the refuge. This process essentially dilutes resistance genes in populations, and sustains populations of susceptible insects (Bates et al. 2005; Siegfried and Hellmich 2012).

To help counter the development of resistance, the EPA has mandated the implementation of an IRM plan for each commercially registered *Bt* Cry protein (US-EPA 2019e). The goal of an IRM plan is to prevent or delay the development of resistant insect populations. In 2017, the EPA issued PRN 2017-1, *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling* (US-EPA 2017a) for all conventional pesticides and resistance management.

Plant-incorporated protectants (PIPs) are pesticidal substances produced by genetically modified plants. The EPA regulates PIPs as pesticides under FIFRA, overseeing their expressed proteins and genetic material, but not the plants themselves (EPA 2024b). Under FIFRA, registrants must report any additional information on unreasonable adverse effects on the environment as per section 6(a)(2) (EPA 2024a). The EPA also has the authority to issue stop-sale orders for products in violation of FIFRA. In 2018, the USDA updated its National Road Map for Integrated Pest Management, guided by the Federal Integrated Pest Management Coordinating Committee (FIPMCC).

4.3.1.3 Potential Effects on U.S. Corn Production

Acreage and Area of Corn Production

Approval of MON 95379 maize is not expected to change U.S corn acreage under the intended use. MON 95379 maize will not be commercialized in the U.S. but is intended to be cultivated in small-scale breeding, testing, and seed increase nurseries to develop seed for future products in South America. The small acreage breeding/seed increase nurseries and agronomic testing trials of MON 95379 maize will be subject to an EPA seed increase registration.

Agronomic Practices and Inputs

The agronomic practices and inputs used for MON 95379 maize production would be similar to/same as that for other field corn varieties (MON 2020). MON 95379 maize has no herbicide traits, thus, herbicide use on this crop will be similar to that used on conventional corn. Corn growers implement production practices and select pesticide inputs based on weed/HR weed populations, insect/resistance-insect populations, and disease pressures present; the efficacy of pesticides; costs of pesticide inputs; worker safety considerations; and ease and flexibility in management of pests and weeds. APHIS did not identify any significant changes to agronomic practices or inputs that would have effects on plant diseases, insect pests, or their management.

4.3.2 Physical Environment

4.3.2.1 Soil Quality

Overview

Relative to crop production, concerns regarding soils are the potential for agronomic practices and inputs to affect soil fertility; erosional capacity; off-site transport of topsoil (sediments), pesticides, and fertilizers; and disturbance of soil biodiversity. Tillage, cover crops, crop rotation, and pesticide and fertilizer inputs can influence the biological, physical, and chemical properties of soil and have a substantial impact on soil fertility, crop yield potential, and erosion (Baumhardt et al. 2015a). Soil quality loss occurs through declines in soil organic matter (SOM), minerals (e.g., magnesium, calcium), essential nutrients (e.g., nitrogen, phosphorus, potassium), soil biota, and physical alteration of soil structure (compaction).

Soil Erosion on U.S. Croplands

Due to the rate of soil formation, which is on the order of millimeters per year, soil is considered a nonrenewable resource that requires conservation for sustainable crop production. Soil erosion not only increases fertilizer requirements and production costs, it leads to impaired air and water quality (USDA-NRCS 2010; Baumhardt et al. 2015b). Excessively eroding cropland soils are concentrated in the Midwest, Southern High Plains of Texas, and Northern Plain States, to include the Corn Belt (Figure 4-7).

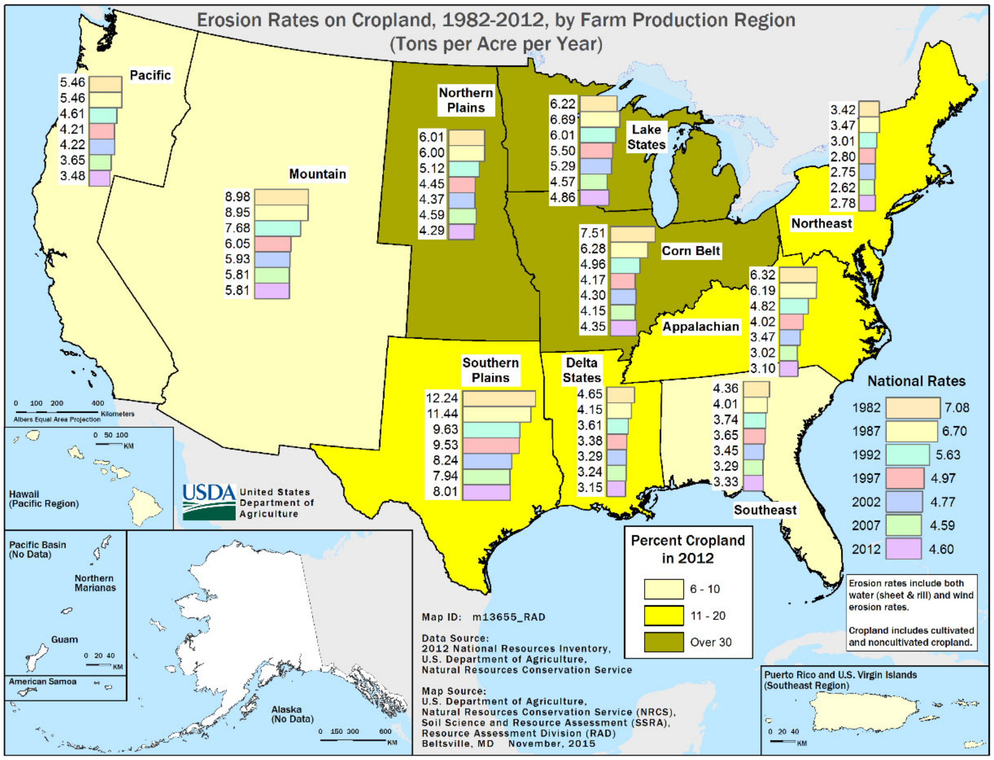


Figure 4-7: Locations and Status of U.S. Croplands Subject to Water and Wind Erosion
Source: (USDA-NRCS 2018a)

Since 1985, conservation programs have specifically targeted highly erodible lands in the United States; as conservation tillage and cover cropping practices increased, soil erosion has declined (USDA-NRCS 2010, 2018b). In 1982, total annual water erosion (sheet and rill) on cultivated cropland was 3.82 tons per acre per year, versus 2.71 in 2015 (USDA-NRCS 2010, 2018b). For wind erosion, erosion rates reduced from 3.21 to 1.91 tons per acre over the same time period (USDA-NRCS 2010, 2018b). Any decrease in erosion of cropland soils carries with it a corresponding decrease in run-off and introduction of non-point source pollution (NPS) pollutants such as sediments, fertilizer, and pesticides into surface waters.

A 2017 survey conducted by the Sustainable Agriculture Research and Education (SARE) program and the Conservation Technology Information Center (SARE/CTIC 2017) found that 41% of surveyed farmers who were cover-crop users applied continuous no-till practices, 14% rotational no-till, 27% reduced tillage, 4% vertical tillage (a type of conservation tillage), with only 14% using conventional tillage. A 2017 USDA-NASS survey showed that overall, surveyed farmers applied reduced tillage on 97.7 million acres, conventional tillage on 80 million acres, and no-till on 104.5 million acres (Table 4-4). In addition, farmers are adopting the use of cover crops primarily to conserve soils and soil quality (SARE/CTIC 2017). An increase in conservation tillage has been facilitated by the availability (since the 1980s) of post-emergent herbicides (Fernandez-Cornejo et al. 2012), which can be applied over crops throughout the growing season—not just before planting, as had previously been the case. The increasing use of conservation tillage is also attributed to an increased use of HR crops, which provide for effective chemical means of weed control, and can reduce reliance on tillage for control of weeds (Fernandez-

Cornejo et al. 2014b). However, the availability of biotechnology-derived HR crops is not the only driving factor in adoption of conservation tillage practices, as many growers adopted conservation tillage well before biotech HR varieties were introduced to the market (Givens et al. 2009).

Table 4-4: Tillage Practice on U.S. Cropland, 2012 – 2017

	Total Harvested Cropland	Cropland with reduced tillage, excluding no-till	Cropland with no-till practices	Cropland with intensive tillage practices	Cropland planted to a cover crop (excluding CRP)
2017	320,041,858	97,753,854	104,452,339	80,005,292	15,390,674
		30.54%	*32.64%*	*25.00%*	*4.81%*
2012	314,964,600	76,639,804	96,476,496	105,707,971	10,280,793
		24.33%	*30.63%*	*33.56%*	*3.26%*

Source: (USDA-NASS 2014, 2019c)

All growers producing crops on highly erodible land are required to maintain and implement a soil conservation plan that substantially reduces soil loss and is approved by the USDA National Resources Conservation Service (NRCS). These plans are prepared by the grower pursuant to the Food Security Act of 1985 (P.L. 99-198, Farm Bill), which included a number of provisions designed to conserve soil and water resources and minimize erosion. The 2014 and 2018 Farm Bills have continued the requirement that producers adhere to conservation compliance guidelines to be eligible for conservation programs administered by USDA-FSA and USDA-NRCS. State agencies likewise provide assistance in development and implementation of soil conservation plans.

4.3.2.1.1 Potential Effects on Soils

Agronomic Practices and Inputs

MON 95379 maize differs only in the trait genes and gene products; modified levels of Cry1B.868 and Cry1Da_7 proteins expression of PMI, which are unlikely to affect soil quality. Thus, any potential impacts on soil quality resulting from MON 95379 maize cultivation would be the same or similar as for other corn varieties. Furthermore, MON 95379 maize is not expected to be commercialized in the U.S so any exposure to MON 95379 and impacts to soil quality will be negligible. Water Resources

Agronomic inputs, and in many areas' tillage and irrigation, are necessary for efficient crop production. These practices and inputs can, however, lead to the impairment of surface waters through runoff of pesticides, fertilizers (nutrients), and soil sediment (Bricker et al. 2008; CENR 2010). Groundwater can also be impacted by agronomic inputs via leaching, as well as through irrigation withdraw. In many areas of the Midwest corn yields has come from the expansion of irrigation, which has the potential to impact local and regional corn production. Irrigated corn accounts for 58% of total annual corn production (Grassini et al. 2011).

While pollutants come from various sources, the National Water Quality Assessment indicate that agricultural nonpoint source (NPS) pollution is a leading cause of impairment of surveyed rivers and streams, the third largest source for lakes/ponds, the second largest source of impairments to wetlands, and a major contributor to contamination of surveyed estuaries, coastal areas, and ground water (US-EPA 2019j). The most common NPS contaminants in agricultural run-off are sediment, nutrients such as nitrogen and phosphorus, and pesticides (Table 4-5), all of which can adversely affect aquatic ecosystems.

Table 4-5: Causes of Impairment in Assessed Waters, 2019								
	Rivers, Streams		**Lakes, Reservoirs, Ponds**		**Bays, Estuaries**		**Wetlands**	
	Miles	Rank	Acres	Rank	Miles	Rank	Acres	Rank
Nutrients	118,831	3rd	3,943,395	2nd	18,279	2nd	67,849	6th
Sediment	138,874	2nd	502,200	12th	400	18th	1,237	15th
Pesticides	18,069	16th	412,672	13th	7,543	8th	202	21st

Shown are national water quality data reported by the States to EPA under Section 305(b) and 303(d) of the Clean Water Act. The data shown is the most current available, which varies widely among states, spanning the years from 2004 to 2016. The EPA lists around 34 different factors that are the cause impairment of U.S. waters. For rivers and streams, the EPA lists sediments as the second most frequent cause of impairment, nutrients third, and pesticides sixteenth. For lakes, reservoirs, and ponds, nutrients are second, sediments twelfth, and pesticides thirteenth. For bays and estuaries, nutrients are second, sediments eighteenth, and pesticides 8th. For wetlands, nutrients are sixth, sediments fifteenth, and pesticides twenty-first. Source: (US-EPA 2019j)

Excess sediment in runoff can adversely affect aquatic ecosystems by covering fish breeding substrates, increasing turbidity, and impairing growth of aquatic plants. Nutrient runoff (e.g., nitrogen and phosphorus) from agricultural fields can contribute to eutrophication of surface waters. Nearly two-thirds of the U.S. estuaries have moderate to high levels of eutrophication. Eutrophic conditions cause impairments to human uses and living resources as a result of harmful algal blooms and hypoxic/anoxic conditions,[8] which lead to fish kills, fish consumption warnings (to prevent human health problems), declines in tourism, and impacts on fisheries (Bricker et al. 2008; CENR 2010). Based on a U.S. Geological Survey (USGS) study (Munn et al. 2018) some the most impaired streams, as assessed by algae or invertebrate conditions, are in those areas with the greatest agricultural land use—primarily in the central United States, to include the Corn Belt (Figure 4-8). Watersheds with a high potential to discharge nitrogen and phosphorus from agriculture to estuaries are located in the Heartland, Mississippi Portal, and Southern Seaboard regions (Wiebe and Gollehon 2006; CENR 2010; US-EPA 2020d).

[8] Hypoxia means low dissolved oxygen concentrations. Anoxia means a total depletion of dissolved oxygen. Both conditions are harmful to aquatic biota.

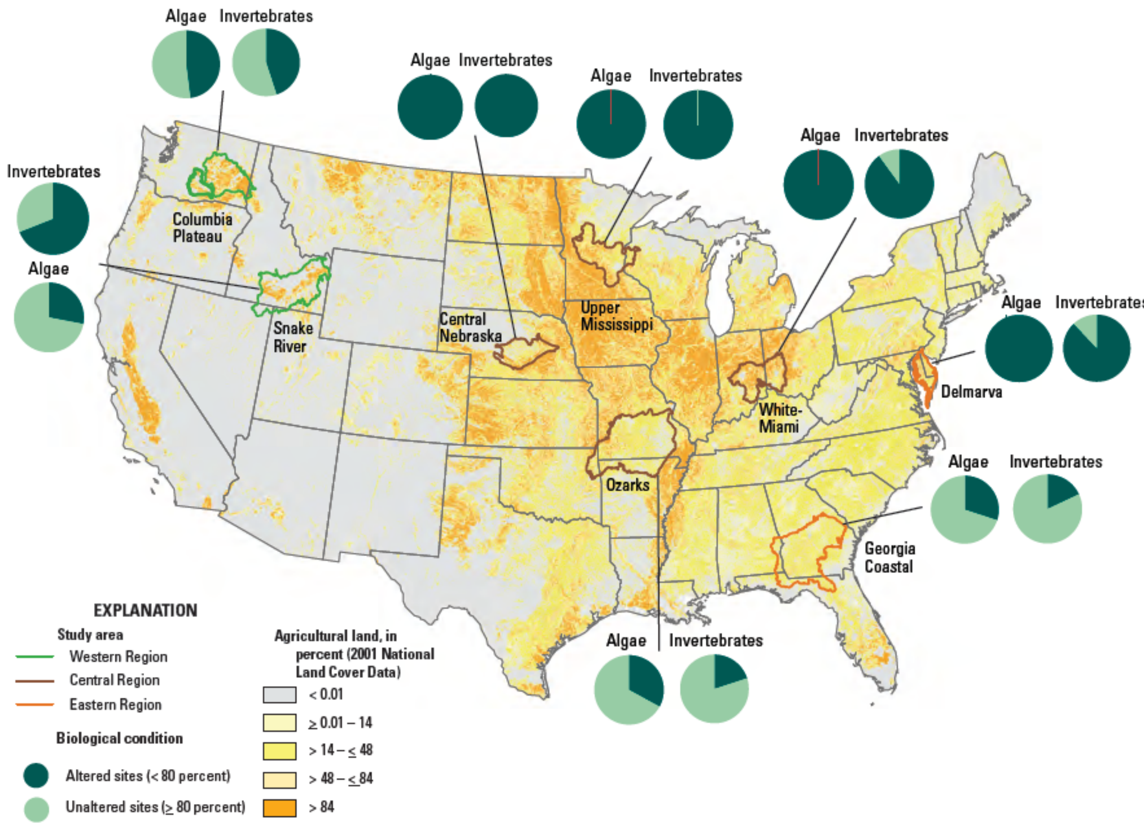


Figure 4-8. Impaired Rivers and Streams in the United States
Based on USGS surveys conducted from 2003 to 2011. Biological conditions in streams decreases as agricultural intensity increases in a watershed. Generally, biological condition was highest in the Western Region where the agricultural intensity is the lowest; conversely, biological conditions were lowest in the Central Region where agricultural intensity is highest. Assessing biological condition involves comparing the observed number of taxa at a site to the number of taxa expected based on a set of regional reference sites. A stream with a score greater than 80 percent implies an unaltered stream, whereas a stream with a score less than 80 percent implies an altered biological condition. Source: (Munn et al. 2018).

Human uses impacted by impaired surface waters include commercial and recreational fishing, shellfish harvesting, fish consumption, swimming, aesthetics, and tourism (CENR 2010). The overall top four causes of these use impairments were listed as agriculture (crops and animal operations), wastewater treatment plants, urban runoff, and atmospheric deposition (Bricker et al. 2008; Boesch 2019). Excess nutrients have a major economic impact—causing an estimated $2.2 billion per year in damages related to recreational water usage, waterfront real estate, and drinking water treatment (Dodds et al. 2009). In all regions except for the North Atlantic, controlling non-point sources remain a primary focus (CENR 2010).

Over the last 50 years the Midwest has been re-engineered with tile drainage systems that allow farmers to control subsurface water levels, which can increase yields. Tile drainage systems can however negatively affect water quality by facilitating run-off of water and its solutes—such as nitrogen, phosphorus, pesticides, and sediment—into streams and rivers without allowing natural attenuation of run-off to occur (CENR 2010; Ribaudo et al. 2011). Use of tile drainage for corn can greatly contribute to nitrogen loss. USDA-ARMS data indicate that nearly 26% of treated cropland is tiled, most of this in corn production (Ribaudo et al. 2011).

The U.S. corn belt lies within the Mississippi River Basin, which spans 1,245 million square miles across 31 states. Agricultural sources contribute around 70% of the nitrogen and phosphorus delivered to the Gulf of Mexico, versus 9% to 12% contribution from urban sources (Alexander et al. 2008). Corn, specifically, accounts for about 45% of U.S. crop acreage receiving manure, and 65% of the 8.7 million tons of nitrogen fertilizer applied by farmers each year (Ribaudo et al. 2011). Nitrogen run-off from cornfields in the Mississippi River Basin is the single largest source of nutrient pollution to the Gulf of Mexico's "dead zone" (Figure 4-9). The most heavily tile-drained areas are also the largest contributing source of nitrate to the Gulf of Mexico, leading to seasonal hypoxia (David et al. 2010).

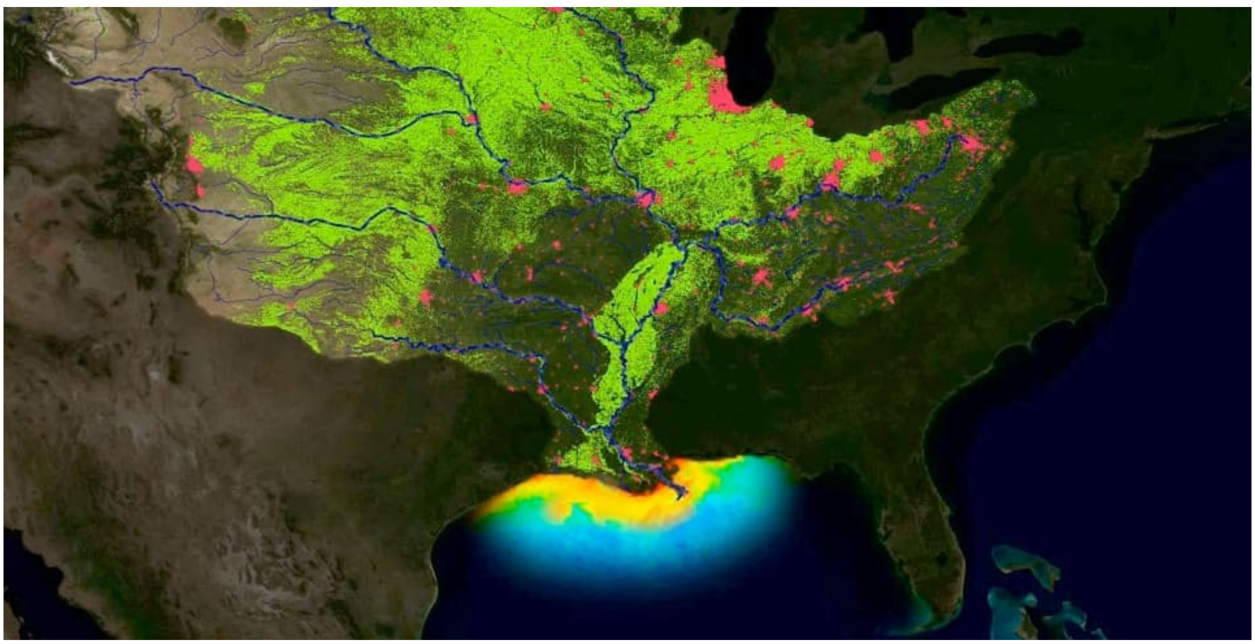


Figure 4-9. Agricultural Run-Off: Mississippi River Watershed
This image from a NOAA Environmental Visualization Lab animation illustrates how run-off from farms (green areas) and cities (red areas) drains into the Gulf of Mexico (GOM). This run-off contains nutrients from fertilizers, wastewater treatment plants, and other sources, which leads to hypoxic "dead zones" on an annual basis; areas in the GOM where the oxygen concentration is so low that aquatic biota can suffocate and die. The largest hypoxic zone in the United States, and the second largest hypoxic zone worldwide, forms in the northern Gulf of Mexico near New Orleans. Source: (NOAA 2019).

4.3.2.1.2 Water Quality Regulation

Point and Non-Point Source Discharges

Impacts on water resources derive from point source and NPS pollutants. NPS pollution represents the most significant source of pollution, overall (US-EPA 2020b). NPS contaminants in runoff originate from sources such as construction sites (e.g., residential and commercial development, construction of roads/highways), impervious surfaces (parking lots, roads/highways, rooftops), and crop fields and livestock rearing facilities. NPS pollutants include fertilizers and pesticides applied to residential, commercial, and agricultural sites, and sediments from the built environment and croplands, as well as unmanaged landscapes. The most common NPS contaminants in agricultural run-off are sediment, nitrogen and phosphorus, and pesticides.

Point source pollutants are discharged from any identifiable, singular source, such as a pipe, drain, or vessel. Factories and sewage treatment plants are examples of point sources. Factories, such as oil refineries, pulp/paper mills, and chemical manufacturers typically discharge one or more pollutants in EPA regulated effluents. Livestock rearing facilities (e.g., dairy and beef cows, hogs, chickens) are other sources of point source pollution (e.g., nutrients, microbial pathogens, pharmaceuticals) (Burkholder et al. 2007).

The Clean Water Act (CWA) established the National Pollutant Discharge Elimination System (NPDES) for regulation of point sources (US-EPA 2019g). Under the NPDES program, factories, certain livestock rearing facilities (concentrated animal feeding operations (CAFOs)), sewage treatment plants, and other point sources must obtain a permit from the state and EPA before they can discharge their waste or effluents into any body of water. Prior to discharge, the point source must use the latest technologies available to treat its effluents and reduce the level of pollutants.

NPS pollution, which is the primary type of discharge from cropping systems, is not regulated under the CWA/NPDES permit program, rather, it is left largely to voluntary controls implemented by states and local authorities. Thus, most crop production activities do not require a Section 404 permit. To be exempt, the farming activity must be part of an ongoing farming operation, cannot be associated with bringing a wetland into agricultural production, or converting an agricultural wetland to a non-wetland area. While the CWA does not provide for direct regulation of nonpoint sources, Section 319 of the CWA created a federal grant program that provides money to states, tribes, and territories for developing and implementing NPS management programs.

Pesticides

The EPA determines use requirements for pesticides that are intended to be protective of water quality, including drinking water, and to protect aquatic life (US-EPA 2019h, d). The EPA provides label use restrictions and guidance for product handling intended to prevent impacts to surface and groundwater.

4.3.2.1.3 Potential Effects on Water Resources

The potential impacts of crop production on water quality primarily derive from the collective/aggregate inputs from crop fields into surface waters. Impacts on surface waters are generally temporal and minor as evaluated from an individual commercial corn cropping system. However, certain pesticides—depending on mobility and persistence characteristics—can leach into groundwater at sites where the pesticide is mixed or applied. Collectively, runoff of nutrients, pesticides, and topsoils from croplands can have significant impacts on surface waters and nearshore coastal waters. Because the agronomic practices and inputs utilized for MON 95379 maize production would not substantially differ from other corn varieties, the sources of potential impacts on water resources, namely NPS pollutants in agricultural run-off, would not substantially differ (e.g., sediments, fertilizers, insecticides, herbicides, fungicides).

Based on the non-target organism toxicity studies, as well the spectrum of activity studies, the Cry1Da_7 and Cry1B.868 proteins are specific to lepidopteran species. Due to expectation of negligible exposure levels and due to MON 95379 maize small scale seed production only in three states, toxicity would not be expected in freshwater fish and invertebrates. Therefore, a determination of nonregulated status of MON 95379 maize is unlikely to change the current use of water resource.

Mitigating Factors

Due to the potential impacts of agriculture on water resources, there are various national and regional efforts to reduce NPS contaminants in agricultural runoff, and runoff itself, such as the EPA's Mississippi River/Gulf of Mexico Hypoxia Task Force (US-EPA 2017b) and USDA-NRCS National Water Quality Initiative (NWQI) (USDA-NRCS 2017). Through the NWQI, the NRCS and partners (e.g., local and state agencies, nongovernmental organizations) work with producers and landowners to implement voluntary conservation practices that improve water quality. The NWQI program is in its 8th year and extended through 2023. It provides funding for financial and technical assistance for conservation practices, and in 2018 the NRCS invested $30 million in targeted assistance to help farmers and ranchers improve water quality in high priority streams and rivers. State water quality agencies and other partners contribute additional resources for watershed planning, program implementation, and for monitoring efforts to track water quality improvements over time.

Several other statutory drivers also influence how Federal agencies work on coastal water quality including the Food, Conservation, and Energy Act ("Farm Bill"); the Energy Independence and Security Act of 2007; the Coastal Zone Management Act, and The Harmful Algal Bloom and Hypoxia Research and Control Act. Responsibility for resolving hypoxia spans several Federal agencies (USDA, USGS, EPA, and National Oceanic and Atmospheric Administration), which oversee research and management/control programs. States play a critical role in monitoring and managing eutrophication (CENR 2010).

4.3.2.2 Air Quality

National Ambient Air Quality Standards

Air pollution can adversely affect human health and the environment and maintaining and improving air quality is a primary U.S. regulatory goal. The EPA establishes National Ambient Air Quality Standards (NAAQS) pursuant to the Clean Air Act (CAA) that are intended to protect public health and the environment (US-EPA 2019b). NAAQS are established for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and particulate matter (PM). In addition to criteria pollutants, the EPA regulates 187 hazardous air pollutants, such as ammonia and hydrogen sulfide, as well as greenhouse gas emissions. To help regulate emissions the EPA has categorized primary emissions sources into point, mobile, biogenic, and area. Point sources include major industrial facilities such as chemical plants, oil refineries, and power plants. Mobile sources include cars, trucks and buses and off-road equipment such as ships, airplanes, and agricultural and construction equipment. Area sources are defined as smaller operations such as dry cleaners and gas stations. Biogenic sources are comprised of vegetation, soils, and animals.

All areas of the United States are classified as to their consistency with the NAAQS; for example, having attained NAAQS, or not. While the EPA establishes NAAQS, the standards do not set emission control requirements for any particular industry, including agriculture. States enforce the NAAQS through creation of State Implementation Plans (SIPs), which are designed to achieve EPA-established NAAQS. The EPA designates a region as being in attainment for a criteria pollutant if atmospheric concentrations of that pollutant are below the NAAQS or being in nonattainment if criteria pollutant concentrations violate the NAAQS.

Crop production practices can generate air pollutants that can contribute to challenges in maintaining regional NAAQS. Agricultural emission sources include smoke from agricultural burning (PM); fossil fuel combustion associated with equipment used in tillage, pesticide application, and harvest (CO_2, NO_x, SO_x); soil particulates from tillage (PM); soil nitrous oxide (N_2O) emissions from the use of fertilizers/manure; and atmospheric emissions through the volatilization of pesticides, and gases from manure (Aneja et al. 2009; US-EPA 2019f).

While the EPA establishes NAAQS, the standards do not set emission control requirements for any particular industry, including agriculture.[9] The USDA and EPA provide guidance for regional, state, and local regulatory agencies, and farmers, on how to best manage agricultural emissions sources (USDA-EPA 2012). These measures allow stakeholders flexibility in choosing which measures are best suited for their specific situations/conditions and desired purposes. EPA has also developed USDA-approved measures to help manage air emissions from cropping systems to help satisfy State Implementation Plan requirements. The EPA recommends that in areas where agricultural activities have been identified as a contributor to a violation of NAAQS, USDA-approved conservation systems and activities be implemented to limit emissions. The USDA Environmental Quality Incentives Program Air Quality Initiative provides financial and technical assistance to help farmers and ranchers limit air pollution (USDA-NRCS 2020c).

Pesticides

Apart from NAAQS emissions, spray drift, and volatilization of pesticides from soil and plant surfaces, can result in the introduction of constituent chemicals into the air; which can present human health risks, and risks to nearby crops. Thus, drift and volatilization of pesticides can be a source of concern to both farmers and the general public in regard to potential environmental and human health effects.

Volatilization is dependent on pesticide chemistry, exposed soil structure and wetness, dew, humidity, and temperature (US-EPA 2020c). Drift is dependent on wind conditions, topography, the type of crop sprayed, and applicator practices, to include application equipment features such as nozzle size (US-EPA 2015).

The EPA's Office of Pesticide Programs, which regulates the use of pesticides, introduced initiatives to help pesticide applicators minimize off-target pesticide drift. The EPA's voluntary Drift Reduction Technology Program was developed to encourage the manufacture, marketing, and use of spray technologies that reduce pesticide drift. The EPA is also working with pesticide manufacturers through

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[9] Many types of stationary engines exist and are found on farms, including diesel engines, spark ignited engines, and reciprocating internal combustion engines. Air quality requirements vary for stationary engines, depending on whether the engine is new or existing, where the engine is located, and what type of ignition system is used. The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Reciprocating Internal Combustion Engines (RICE) are outlined in the Code of Federal Regulations under 40 CFR 63 Subpart ZZZZ.

the registration and registration review programs on improvements to pesticide label instructions to reduce drift and volatilization (US-EPA 2015, 2020c).

4.3.2.2.1 Potential Effects on Air Quality

Agricultural production of corn may affect air quality in direct and indirect ways. Primary sources of emissions associated with crop production include exhaust from motorized equipment, such as tractors and irrigation equipment; suspended soil particulates from tillage and wind-induced erosion; smoke from burning of fields; drift from sprayed herbicides and pesticides; nitrous oxide emissions from the use of nitrogen fertilizer. Fertilizers, herbicides, and pesticides applied to soil and plant surfaces may also introduce chemicals into the air that drift and affect all living species, including humans. Drift is defined by EPA as "the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application" (US-EPA 2000).

Since EPA's registration limits MON 95379 production to no more than 100 acres per growing season in Nebraska, Hawaii, and Iowa, expected changes to emission sources, such as tillage, fossil fuel-burning equipment, or the application of fertilizers and pesticides, to the overall volume of emissions from U.S. corn production are expected to be negligible.

Mitigating Factors

Pollution from agricultural sources, such as dust from tilling; drift/diffusion/volatilization of farm chemicals; exhaust emissions from mechanized farm equipment, have declined as mitigating agronomic practices increase in the U.S. Practices to improve air quality include conservation tillage, residue management, wind breaks, road treatments, burn management, shredding of prunings, feed management, manure management, integrated pest management, chemical storage, nutrient management, fertilizer injection, chemigation and fertigation (i.e., inclusion of chemicals in irrigation), conservation irrigation, scrubbers, and equipment calibration (USDA-NRCS 2006). The nonregulated status in whole to MON 95379 Maize use, or air quality, is expected to continue to provide improvements in air quality due the potential for continued reduction in use of more hazardous chemical pesticides. (USDA-EPA 2012; US-EPA 2015; USDA-NRCS 2020c).

4.3.3 Biological Resources

4.3.3.1 non-target species

APHIS evaluated the potential impact of MON 95379 maize and its products on non-target species, including birds, mammals, aquatic species, terrestrial invertebrates, and both terrestrial and aquatic plants. Compositional analyses of MON 95379 grain and forage showed no significant unintended changes due to the introduction of Cry1B.868 and Cry1Da_7 proteins. These proteins act similarly to previously commercialized Cry proteins, following the same general process of ingestion, solubilization, oligomerization, and the formation of selective ion channels. Bayer confirmed that the composition of MON 95379 maize is equivalent to that of conventional maize in terms of key nutrients and anti-nutrients in both grain and forage (MON 2020).

Bayer followed the EPA framework for laboratory tests of nontarget species using exposure levels representing at least 10x the highest expected environmental concentration (EEC) of Cry1B.868 and Cry1Da_7 proteins expressed in MON 95379 maize (MON 2020). The ratio of the median lethal concentration (LC_{50}) values to the calculated EEC values gives the margin of exposure (MOE) and characterizes risk to nontarget species. The lower the MOE (margin between the toxicity effect level and the exposure dose), the more likely a chemical is to pose an unreasonable risk (US-EPA 2012). A MOE greater than 1 supports the conclusion of minimal risk to tested species.

The range of expression levels of Cry1B.868 and Cry1Da_7 proteins in MON 95379 maize tissue, over the course the MON 95379 maize life cycle, are provided in Table 4-6. These values served as the basis for high-end estimates of exposure levels of Cry1B.868 and Cry1Da_7 proteins to target pests and non-target species. Given that the highest expression levels for both Cry1B.868 and Cry1Da_7 protein were measured in V2-V4 stage leaves (OSL1) of MON 95379 maize, the expected environmental concentrations tested in the activity spectrum assessment were based upon 20.9 micrograms (µg) Cry1Da_7/gram (g) fresh weight (fw) and 111.4 µg Cry1B.868/g fw leaf tissue (MON 2023). Levels of Cry1Da_7 protein could not be quantified in pollen and therefore the assay limit of quantitation (LOQ) of 0.125 µg Cry1Da_7/g dry weight (dw) pollen was used as a worst-case estimate of exposure to Cry1Da_7 protein via pollen.

Direct exposure of nontarget species to Cry1B.868 and Cry1Da_7 proteins may occur through feeding on MON 95379 maize plant parts, including grain and pollen. Secondary exposure may occur from preying on herbivores that have fed on MON 95379 maize leaf tissue. However, the concentration of Cry proteins in herbivore prey is lower than what is expressed in plant tissues (Obrist et al. 2006). Therefore, direct exposure to terrestrial herbivore nontarget species through the consumption of leaf tissue (the expression of both proteins is higher in leaf tissue than other plant parts) is sufficient to account for indirect exposure from preying on herbivores that have fed on MON 95379 maize leaf tissue.

Table 4-6 Fresh Weight 95th Percentile Expression of Cry1Da_7 and Cry1B.868 Proteins in Maize Tissues Collected from MON 95379 Produced in United States Field Trials in 2018

Tissue Type[a]	Development Stage[b]	Cry1Da_7 (µg/g fw)[c]	Cry1B.868 (µg/g fw)[c]
OSL1	V2-V4	20.9	111.4
pollen	R1	<LOQd	61.9
forage	R5	11.1	48.8
grain	R6	0.5	41.2

[a]OSL = over season leaf
[b]The crop development stage at which each tissue was collected. In cases where multiple development stages were analyzed, the growth stage with the maximum observed value was used for calculating EECs.
[c]Protein levels are expressed as the 95th percentile of the mean expression expressed in microgram (µg) of protein per gram (g) of tissue on a fresh weight basis (fw).
[d]LOQ = limit of quantitation. The LOQ for Cry1Da_7 in pollen was 0.125 µg/g dry weight.
Source: (MON 2020)

4.3.3.1.1 Mammals and Birds

Commercial cornfields, which are intensively cultivated and have frequent disturbances, provide less suitable habitat for wildlife than undisturbed lands (AFT 2020). As such, the types and numbers of animal species found in and near cornfields will be less diverse. Cornfields can, however, provide food and cover for wildlife, such as for birds, as well as large and small mammals.

The types and numbers of birds that inhabit cornfields vary regionally and seasonally. Following harvest, it is common to find large flocks of migratory bird species foraging in cornfields, such as Canada geese

(*Branta canadensis*), snow geese (*Chen caerulescens*), sandhill cranes (*Grus canadensis*), and various other species (USGS 2012; AFT 2020).

A variety of large mammals forage on corn at various stages of plant growth. Most are ground-foraging omnivores that feed on the corn grain remaining in the fields following harvest (Palmer et al. 1992; Vercauteren and Hygnostrom 1993; Krapu et al. 2004). Large- to medium-sized mammals that are common foragers of cornfields include those in Table 4-7 (Fleharty and Navo 1983; ODNR 2001). The most notable of these is the white-tailed deer that inhabit woodlots adjacent to cornfields and frequent corn fields for both food and cover, especially in mid-summer. Agricultural crops, particularly corn and soybean, comprise a major portion of deer diets in Midwestern agricultural regions; deer are considered responsible for more corn damage than any other wildlife species (MacGowan et al. 2006). Cornfields are vulnerable to deer damage from emergence through harvest, although damage to corn at the tasseling stage most directly impacts yield (Stewart et al. 2007). Losses to crop yield from feeding by raccoons have also been documented (Beasley and Rhodes Jr. 2008). Mature corn has been shown to constitute up to 65% of raccoon's diet in some areas prior to harvest (MacGowan et al. 2006). As with larger mammals, small mammals may use cornfields for shelter and forage (USDA-NRCS 1999; Sterner et al. 2003).

Several studies on the toxicity and safety of *Bt* insecticides have shown them to be safe for mammals at several thousand-fold doses higher than those expected to be found in the environment or biotechnology driven plants (McClintock et al. 1995; Rubio-Infante and Moreno-Fierros 2015). Studies on the toxicity of Cry proteins in crops transformed using genetic engineering, including Cry1 proteins, find no toxic effect in mammals (Schnepf et al. 1998; OECD 2007).

Table 4-7: Animals Commonly Found in Corn Fields

Birds		**Mammals**	
Common Name	**Scientific Name**	**Common Name**	**Scientific Name**
Red-winged blackbird	*Agelaius phoeniceus*	Large Mammals	
Grackle	*Quiscalus quiscula*	White-tailed deer	*Odocoileus virginianus*
Horned lark	*Eremophila alpestris*	Raccoon	*Procyon lotor*
Brown-headed cowbird	*Molothrus ater*	Wild boar	*Sus scrofa*
Vesper sparrow	*Pooecetes gramineus*	Woodchuck	*Marmota monax*
Ring-necked pheasant	*Phasianus colchicus*	Small Mammals	
Wild turkey	*Meleagris gallopavo*	Deer mouse	*Peromyscus maniculatus*
American crow	*Corvus brachyrhynchos*	House mouse	*Mus musculus*
Blackbird	*Turdus merula*	Meadow vole	*Microtus pennsylvanicus*
Various quail species	*Coturnix* spp.	Ground squirrel	*Spermophilus tridecemlineatus*

4.3.3.1.2 Potential Effects on Mammals and Birds

MON 95379 maize cropping systems are not expected to affect vertebrate animal communities adjacent to or within fields any differently from that of current corn cropping systems. The nutrient composition of grain and forage derived from MON 95379 maize was determined to be comparable to other corn varieties (MON, 2020).

The Cry1B.868 and Cry1Da_7 proteins expressed in MON 95379 maize tissues have been shown to primarily affect lepidopteran (butterfly and moth) species (MON 2020). The receptors in the midgut of target insects, in this case lepidopteran species, are not present in mammals, indicating the two Cry proteins will have a negligible effect on mammals. Bayer's acute oral toxicity studies indicate Cry1B.868 and Cry1Da_7 proteins are not toxic to mammals, with an acute oral LD_{50} (median lethal dose at which 50% of the population are estimated to die) in mice (*Mus musculus*) greater than 5,000 milligrams (mg)/kilogram (kg) body weight (bw) (MON 2020). The MOE calculated using Cry1B.868 and Cry1Da_7 protein levels expressed in leaf and grain tissue exceed 1, indicating negligible risk to small mammals. No other adverse effects were observed such as changes in body weight, food consumption or gross pathology. Therefore, the No Observable Adverse Effect Level (NOAEL) for Cry1B.868 and Cry1Da_7 proteins is 5,000 mg/kg bw (highest concentration tested) (MON 2020). Similarly, birds are not sensitive to the two Cry proteins. In bobwhite quail (*Colinus virginianus*), the acute oral LD_{50} for Cry1B.868 protein and Cry1Da_7 protein was greater than 3,500 mg/kg and 1,000 mg/kg, respectively, the highest dose tested (MON 2020). At 3,500 mg/kg Cry1B.868 protein, there was an observed mean body weight change in males; no other sublethal effects or gross necropsy were observed. The NOAEL for the Cry1Da_7 protein was 1,000 mg/kg bw (highest concentration tested). The MOE for Cry1B.868 and Cry1Da_7 in granivore and herbivore wild bird species indicate that dietary exposure poses negligible risk to birds.

Allergen bioinformatics indicate that Cry1B.868 and Cry1Da_7 proteins do not share amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins which could have adverse effects on animal health (MON 2020). Studies further found that gastrointestinal digestion is sufficient to degrade intact Cry1B.868 and Cry1Da_7 proteins and any fragments resulting from digestion, making it highly unlikely the proteins would be absorbed in the small intestine to have an impact on mammalian health (MON 2020).

Based on the lack of receptors in mammal and avian digestive systems, lack of acute toxicity and allergenicity, and the MOEs, the two Cry proteins expressed in MON 95379 maize will have no effect on mammals or birds.

4.3.3.2 Aquatic Species

The exposure of water resources to the Cry proteins from *Bt* corn through erosion of soil with adsorbed protein, surface water runoff of soluble protein, and aerial deposits of pollen and crop dust containing protein is extremely small (US-EPA 2008; Carstens et al. 2012). However, exposure through the movement of maize debris (leaves, husks, cobs, and stems) into water resources is possible (Tank et al. 2010).

Tank et al. (2010) surveyed 217 stream sites in Indiana 6 months after maize harvest and found 86% of stream sites contained maize leaves, cobs, husks, and/or stalks. They found 67% of the sites had maize leaves, an important distinction because cobs and stalks decompose more slowly than leaves and may not be from the prior harvest season. Based on maize leaf degradation rate in water, the authors suggest the leaves recently entered the water and not immediately after harvest. The streams sampled were within 500 meters (m) from maize fields with the majority (94%) within 200 m from maize fields. Of the stream sites sampled with maize leaf debris, 19% had detectible Cry1Ab protein (mean concentration was 95 +/- 73 nanograms (ng)/g dry mass and highest concentration measured was 409 ng/g of dry mass) (Tank et al.

2010). In another study, the concentration of Cry1Ab protein in stream and tile drain water was low, ranging from 3 ng/Liter (L) up to 60 ng/L (Griffiths et al. 2017).

Jenson et al. (2010) looked at the effects of Cry1Ab and Cry1Ab+Cry3Bb1 proteins in corn leaf debris collected from streams 2 weeks after harvest on crane fly larvae (*Tipula* (*Nippotipula*) cf. *abdominalis* [Diptera: Tipulidae]), two caddisflies (*Lepidostoma* spp. and *Pycnopsyche scabripennis* [Insecta: Trichoptera]), and an aquatic isopod (*Caecidotia communis* [Malacostraca: Isopoda]). There were no significant differences in growth parameters for the caddisfly species except for a greater final dry mass for *P. scabripennis* larvae fed the stacked near isoline (contained Cry1Ab+Cry3Bb1 proteins) compared to the Cry1Ab near-isoline and the non-*Bt* control. They observed reduced growth in the crane fly larvae and isopod fed the Cry1Ab near-isoline leaf tissue compared with larvae fed the control and stacked near-isoline treatments. There were no significant differences in survival in the crane fly larvae but there was a lower percent survival for isopod fed the Cry1Ab near-isoline. Jenson et al. (2010) exposed the European corn borer, which is sensitive to the Cry1Ab protein, to the corn leaves and found no significant differences in growth parameter, indicating a lack of Cry protein activity after 2 weeks. Jensen et al. (2010) concluded the sublethal effects in the aquatic nontarget species were likely not caused by exposure to the Cry proteins given the lack of effects to the European corn borer, lack of toxicity to purified Cry1Ab protein in prior studies, and no observed effects between the stacked near-isoline compared with the non-*Bt* isoline (Jensen et al. 2010).

A toxicity study on embryos of the aquatic vertebrate zebrafish (*Danio rerio*) found no adverse effects when exposed to Cry1C or Cry2A (*Bt* proteins expressed in rice and other plants for the control of lepidopteran pests) at 0.1, 1, or 10 mg/L over 130 hour post fertilization (hpf) (embryos 2 hpf were used for in the tests) (Gao et al. 2018).

4.3.3.2.1 Potential Effects on Aquatic Species

Exposure of aquatic organisms, particularly aquatic invertebrates, to toxic levels of Cry proteins is negligible based on dissipation and degradation studies and exposure models with worst-case assumptions (Jensen et al. 2010; Carstens et al. 2012). *Bt*-derived proteins from maize tissue rapidly dissipate or adsorb to organic matter and sediment in aquatic environments (Prihoda and Coats 2008; Jensen et al. 2010; Griffiths et al. 2017), as summarized in (MON 2020). In one study, 97% of unbound Cry1Ab protein in stream water microbially degraded within 72 hours at 21.5 C; however, degradation under field conditions may be slower at colder temperatures (Griffiths et al. 2017). Assuming Cry1Ab concentrations found in streams (e.g., Tank et al 2010, Griffith et al. 2017) represent the concentration of other Cry proteins from corn that may end up in streams, these concentrations are below the activity spectrum concentrations for Cry1B.868 and Cry1Da_7 proteins towards lepidopteran species, which are sensitive to these two Cry proteins.

Based on the rapid dissipation of Cry proteins from maize tissue, the very low estimated environmental concentrations (EECs) for aquatic organisms, and the specificity of the Cry1B.868 and Cry1Da_7 proteins to lepidopteran invertebrates, APHIS finds a determination of nonregulated status of MON 95379 maize, and subsequent commercial production of this corn variety, will have no effect on aquatic species.

4.3.3.3 Soil Biota

Soil health, of which soil biota are a primary component, determines the efficacy by which crops can provide food, fiber, fuel, and industrial products, how soils regulate services protecting water and air quality, and soil erosional capacity. Soil biota consist of microorganisms (bacteria, fungi, archaea and algae), soil animals (protozoa, nematodes, mites, springtails, spiders, insects, and earthworms), and plants (e.g., algae) living all or part of their lives in or on the soil, or pedosphere (Fortuna 2012). Soil biota play a key role in the formation and turnover of soil organic matter (including mineralization), biodegradation of anthropogenic substances (e.g., pesticides), nutrient cycling, suppression of plant diseases, promotion of plant growth, soil structure formation, and most biochemical soil processes (Gupta et al. 2007; Parikh and James 2012). Plant roots, including those of corn, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere (root zone). Millions of species of soil organisms exist but only a fraction of them have been cultured and identified (Fortuna 2012).

Some microorganisms can cause plant diseases, which can result in substantial economic losses through yield reduction and cost of control strategies. Soil borne corn crop diseases include fungal corn rusts, corn leaf blights, ear smuts, ear and kernel rot fungi, and maize mosaic viruses (Strunk and Byamukama 2019).

Relative to crop production, the main factors affecting soil biota populations and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, pesticide and fertilizer application, and irrigation) (Kowalchuk et al. 2003; Garbeva et al. 2004; Gupta et al. 2007). Climate, particularly the water and heat content of soil, is a principal determinant of soil biological activity.

4.3.3.3.1 Potential Effects on Soil Biota

Potential changes to the soil microbial community because of cultivating biotechnology-derived crops has been of much research interest since their introduction in the late 1990s (e.g., (Bertola et al.; Motavalli et al. 2004). Potential impacts considered include changes to the structure and function of microbial and insect communities near the roots of biotechnology-derived plants due to altered root exudation, transfer of novel proteins into the soil, or a change in microbial populations due to changes in agronomic practices used to produce transgenic crops (e.g., pesticide use). Current agronomic practices associated with currently available biotechnology-derived and non- biotechnology-derived corn would not alter the way soil microorganisms are affected in U.S. corn cropping systems. Most studies to date have found no significant effect of *Bt* crop traits on soil community structures (Qaim et al. 2008; Velasco et al. 2013; Hannula et al. 2014; Li et al. 2015; Rahman et al. 2015; Yaqoob et al. 2016).

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While Bt occurs naturally in soil, growing biotechnology-derived Bt corn increases the amount of Cry endotoxins present in agroecosystems (Blackwood and Buyer 2004). Most proteins, however, do not persist or accumulate in soils because they are inherently degradable in soils that have normal microbial populations (Icoz and Stotzky 2008). Cry protein concentrations in the rhizosphere vary during the growth of the plant and can be affected by microbial activity, which depends in part on soil temperature and humidity (Baumgarte and Tebbe 2005).

The risks Cry1B.868 and Cry1Da_7 proteins may present to soil biota is a function of the potential hazard they may present and exposure. The transport and fate of Cry1B.868 and Cry1Da_7 proteins in the environment determines the potential routes and duration of exposure. Cry1B.868 and Cry1Da_7 protein will be produced continually in MON 95379 maize, in all tissues (MON 2023). The primary route of direct exposure to the Cry1B.868 and Cry1Da_7 protein for soil-dwelling invertebrates, such earthworms and Collembola, would be from root tissue (MON 2023). Soil biota could also be exposed to Cry1B.868 and Cry1Da_7 proteins via decaying plant material left on the field, or plant material plowed into the soil.

Soil dissipation studies indicate Cry1B.868 protein is unlikely to persist or accumulate in agricultural soils, with a predicted dissipation half-life value (DT_{50}) of 19, 9, and 8 days in sandy loam, silt loam, and clay loam soils, respectively (MON 2020). Cry1Da_7 protein has a longer predicted dissipation half-life than Cry1B.868, with a DT_{50} value of 40 and 36 days in silt loam and clay loam soils, respectively. A DT_{50} value for Cry1Da_7 protein was not determined for sandy loam, with 66% of the protein remaining in the soil on day 213 (MON 2023).

Studies on other Cry1 proteins found that they do not persist or accumulate in the environment, including in soils after long-term *Bt*-maize cropping, likely due to biotic and abiotic stressors in the environment that could promote protein degradation (Dubelman et al. 2005; Gruber et al. 2012). With the exception of Cry protections, MON 95379 maize is phenotypically and agronomically equivalent to traditional commercial maize. As noted above, Cry proteins do not accumulate or persist in soils (Icoz and Stotzky 2008), as they are continually being degraded by natural processes.

In laboratory studies, Bayer found no lethal or sublethal effects in the earthworm (*Eisenia andrei*) and collembola (*Folsomia candida*) at 3,500 µg/g for Cry1B.868 and 500 µg/g Cry1Da_7, in soil and diet, respectively (MON 2023). They also found no acute toxicity in the other non-lepidopteran invertebrates they tested (MON 2023). Based on these studies, Bayer concluded Cry1B.868 and Cry1Da_7 proteins will have no effect on soil-dwelling invertebrates. Considering all of these factors, it is unlikely the Cry1B.868 and Cry1Da_7 proteins would present a hazard to soil biota (MON 2020; USDA-APHIS 2020c). Based on these studies, APHIS concludes that Cry1B.868 and Cry1Da_7 protein will not accumulate to cause impacts on soils or soil organisms because the persistence in soils is unlikely, the proteins are specific for lepidopterans, and the production is limited to no more than, 100 acres per growing season across Nebraska, Hawaii, and Iowa.

4.3.3.4 Invertebrates

The invertebrate community in cornfields represents a diverse assemblage of feeding strategies (Stevenson et al. 2002). Although certain invertebrates in corn fields are considered pests, such as the European corn borer (*Ostrinia nubilalis*) and corn rootworm (*Diabrotica* spp.), the majority are beneficial, performing valuable functions; they pollinate plants, contribute to the decay and processing of organic matter, reduce weed seed populations through predation, cycle soil nutrients, and prey on other insects and mites that are considered to be plant pests (Landis et al. 2005). Some of these beneficial species include the convergent lady beetle (*Hippodamia convergens*), carabid beetles, the caterpillar parasitoids (e.g., *Macrocentrus cingulum*), and the predatory mite (*Phytoseiulus persimilis*) (Landis et al. 2005; Shelton 2011). Earthworms, termites, ants, beetles, and millipedes contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz et al. 2008).

Invertebrate kernel and leaf feeders are primarily members of four insect orders: Lepidoptera (larval butterflies and moths), Coleoptera (beetles), Hymenoptera (larval wasps) and Orthoptera (grasshoppers). Invertebrate root feeders are primarily among the order Coleoptera. The most ecologically relevant route of exposure for soil-dwelling organisms, such as earthworms and collembola, is considered primarily to be from root tissue or root exudates, with some addition of post-harvest decaying plant tissue that enters the soil (Bachman et al. 2016).

The most agronomically relevant invertebrates in corn production fields are those arthropods that feed on corn and adversely affect yield. These include lepidopteran species that feed on the corn ear or stalk and coleopteran species that feed on other corn vegetative structures. Two of the most important insect pests of corn in the United States include the European corn borer and WCR.

4.3.3.4.1 Potential Effects on Invertebrates

Due to the species specificity of the insecticidal traits, and to some extent a likely reduction in use of synthetic chemical insecticides, MON 95379 maize seed production would be expected to present fewer hazards to non-target insect populations, as compared to broad spectrum chemical insecticides. As discussed in Section 4.3.1.2.2 –Agronomic Inputs, over the top insecticide use in corn production has significantly declined during the last 20 years due in part to the adoption of IR corn varieties. The use rate of insecticides applied to corn fell from an average of around 0.08 kg/acre in 1998 to about 0.02 kg/acre in 2011, a 75% decrease (USDA-ERS 2014). Currently, adopters of biotechnology driven IR corn used around 11.2% (0.005 kg/acre) less insecticide than nonadopters. Reductions in insecticide use with IR corn, while marginal, is of environmental benefit to both terrestrial and aquatic biota. In this respect, production of IR crops, to include MON 95379 maize, has the potential to be more environmentally benign, as compared to conventional synthetic chemical-based pest management approaches.

Given the low acreage proposed for MON 95379 maize (100 total acres per year), it is unlikely that there will be a significant risk to most non-target insect populations in the United States. This conclusion is further supported by the biology of the non-target insects, which are generally not known to feed on maize tissue as their feeding and reproductive ecology is typically tightly associated with a preferred host plant. The use of MON 95379 maize on a limited basis (as described by Bayer in their submissions) would represent a small fraction of total corn acres in three states and should not significantly impact most non-target communities.

At the highest dose tested in the toxic activity spectrum evaluations, Cry1B.868 and Cry1Da_7 protein toxicity was limited to lepidopteran species (Table 4-8) (MON 2020). Because of this specificity, the evaluation of effects on invertebrates first covers effect to non-lepidopteran species followed by effects to lepidopteran species.

Table 4-8: Activity Spectrum Results from Feeding Assays with Cry1B.868 and Cry1Da_7 Proteins in Invertebrate Pests of Corn. All Species are Herbivore Representative Function and the Value Measured EC_{50}/LC_{50} (µg/mL diet)

Order	Family	Genus Species	Cry1B.868		Cry1D_7	
			Value	Activity	Value	Activity

Lepidoptera	Noctuidae	*Spodoptera frugiperda*	0.15	Yes[b]	0.096	Yes[b]
Lepidoptera	Noctuidae	*Helicoverpa zea*	120	Yes[b]	0.042	Yes[b]
Lepidoptera	Crambidae	*Ostrinia nubilalis*	9.8	Yes[b]	11	Yes[b]
Lepidoptera	Nymphalidae	*Danaus plexippus*	0.077	Yes[c]	0.016	Yes[c]
Coleoptera	Chrysomelidae	*Diabrotica virgifera virgifera*	>301[a]	No[d]	>58[a]	No[d]
Coleoptera	Chrysomelidae	*Diabrotica undecimpunctata howardi*	>837[a]	No[d]	>65[a]	No[d]
Coleoptera	Chrysomelidae	*Leptinotarsa decemlineata*	>1708[a]	No[d]	>106[a]	No[d]
Coleoptera	Coccinellidae	*Epilachna varivestis*	>837[a]	No[d]	>65[a]	No[d]
Hemiptera	Miridae	*Lygus hesperus*	>700[a]	No[e]	>50[a]	No[e]
Hemiptera	Pentatomidae	*Euschistus heros*	>700[a]	No[f]	>50[a]	No[f]

[a] The most conservative (i.e. lowest) concentration observed at the highest treatment level is reported based on diet stability analysis conducted at multiple times during exposure. The measured concentrations were above the 95th percentile values of Cry1B.868 protein expression (µg/g fw) in MON 95379 leaf tissue.
[b] EC_{50} value was estimated in a 7-day exposure to Cry1B.868 protein treated diets for 5 concentrations.
[c] LC_{50} value was estimated in a 7-day exposure to Cry1B.868 protein treated diets for 7 concentrations.
[d] Activity was measured for survival in a 7-day feeding exposure to Cry1B.868 protein.
[e] Activity was measured for survival in a 6-day feeding exposure to Cry1B.868 protein.
[f] Activity was measured for survival in a 5-day feeding exposure to Cry1B.868 protein.
Source: (MON 2020).

4.3.3.4.2 Non-Lepidopteran Invertebrates

To assess the potential effects of MON 95379 maize on non-lepidopteran invertebrate species, Bayer conducted toxicity studies of Cry1B.868 and Cry1D_7 on select surrogate species (MON 2020). Surrogate species were continuously fed the Cry protein (length of the studies varied, but dietary exposure was approximately between 14 and 28 days) (Table 4.6). The results of these studies show that the Cry1B.868 and Cry1D_7 proteins are practically nontoxic to insects in the orders Coleoptera, Hemiptera, Hymenoptera, Neuroptera, and Collembola. In a study on ladybird beetle, there was one observed sub-lethal effect (10% reduction in mean mass) at the 3,500 Cry1B.868 protein µg/g diet. Sub-lethal effects were not observed in other non-lepidopteran species. The MOEs for the surrogate species in these insect orders ranged from greater than 7 and 8,000, indicating minimal risk to these species.

In the toxicity studies, the insects were fed diets limited to Cry1B.868 and Cry1Da_7 proteins; however, in the field forage is more diverse and insects would have access to a range of wild and crop plants. Similarly, predator and parasitoid insects would have access to a range of insects that do not feed strictly on plants that produce the Cry1B.868 and Cry1Da_7 proteins. The access to other food sources reduces exposure levels. In addition, the protein concentrations in the laboratory diets exceeded the protein concentrations found in MON 95379 maize, including leaves and pollen (MON 2020).

Bioassays on other non-lepidopteran insect pests of corn found no activity for Cry1B.868 and Cry1Da_7 proteins (MON 2020). These species include *Diabrotica virgifera virgifera* (Coleoptera: Chrysomelidae), *D. undecimpunctata howardi*, *Leptinotarsa decemlineata* (Coleoptera: Chrysomelidae), *Epilachna varivestis* (Coleoptera Coccinellidae), *Lygus hesperus* (Hemiptera: Miridae), and *Euschistus heros* (Hemiptera: Pentatomidae) (Table 4-9) (MON 2020).

Table 4-9: Toxicity of Cry1B.868 and Cry1Da_7 to predator, parasitoid, and pollinator arthropods and earthworm			
Species	**Order**	**Notes**	**Test**[1]
Coleomegilla maculata, ladybird beetle, larvae	Coleoptera	Predator	Cry1B.868: LC_{50} >3,500 µg/g diet NOAEC 700 µg/g diet (at 3,500 µg/g diet, there was a 10% reduction in mean mass)
			Cry1Da_7: LC_{50} > 150 µg/g diet NOAEC 150 µg/g diet (highest concentration tested)
Poecilus cupreus, carabid beetle, larvae	Coleoptera	Ground dwelling	Cry1B.868: LC_{50} >3,500 µg/g diet NOAEC 3,500 µg/g diet
			Cry1Da_7: LC_{50} > 400 µg/g diet NOAEC 400 µg/g diet (highest concentration tested)
Geocoris punctipes, big-eyed bug, nymphs	Hemiptera	Predator	Cry1B.868: LC_{50} > 3,500 µg/g diet NOAEC 3,500 µg/g diet
			Cry1Da_7: LC_{50} > 500 µg/g diet NOAEC: 500 µg/g diet (highest concentration tested)
Pediobius foveolatus, parasitoid wasp (adult)	Hymenoptera	Parasitoid	Cry1B.868: LC_{50} > 3,500 µg/g diet
			Cry1Da_7: LC_{50} > 500 µg/g diet (highest concentration tested)
Chrysoperia carnea, green lacewing (adult)	Neuroptera	Predator	Cry1B.868: LC_{50} > 3,500 µg/g diet (statistically significant reduced survival at both 700 and 3,500 µg/g diet concentrations, but did not cause 50% mortality)
			Cry1Da_7: LC_{50} > 500 µg/g diet (highest concentration tested)
C. rufilabris, green lacewing (larvae)	Neuroptera	Predator	Cry1B.868: LC_{50} >3,500 µg/g diet NOAEC 3,500 µg/g diet (highest concentration tested)
			Cry1Da_7: LC_{50} > 500 µg/g diet NOAEC 500 µg/g diet (highest concentration tested)
C. rufilabris, green lacewing (adult)	Neuroptera	Predator	Cry1B.868: LC_{50} > 700 µg/g diet (highest concentration tested)
Folsomia candida, springtail	Collembola	Soil dwelling	Cry1B.868: LC_{50} > 3,500 µg/g diet NOAEC 3,500 µg/g diet (highest concentration tested)
			Cry1Da_7: LC_{50} > 500 µg/g diet (highest concentration tested) NOAEC 500 µg/g diet (highest concentration tested)
Apis mellifera, honey bee (adult)	Hymenoptera	Pollinator	Cry1B.868: LC_{50} > 900 µg/g diet NOAEC 900 µg/g diet (highest concentration tested)
			Cry1Da_7: LC_{50} > 500 µg/g diet (highest concentration tested) NOAEC 500 µg/g diet (highest concentration tested)
A. mellifera, honey bee (larvae)	Hymenoptera	Pollinator	Cry1B.868: LC_{50} > 900 µg/g diet NOAEC 900 µg/g diet (highest concentration tested)

Table 4-9: Toxicity of Cry1B.868 and Cry1Da_7 to predator, parasitoid, and pollinator arthropods and earthworm			
Species	**Order**	**Notes**	**Test[1]**
			Cry1Da_7: LC_{50} > 500 µg/g diet (highest concentration tested) NOAEC 500 µg/g diet (highest concentration tested)
Eisenia andrei, earthworm		Soil dwelling	Cry1B.868: LC_{50} > 3,500 µg/g soil dry weight NOAEC 3,500 µg/g soil dry weight (highest concentration tested)
			Cry1Da_7: LC_{50} > 500 µg/g diet (highest concentration tested) NOAEC 500 µg/g diet (highest concentration tested)

As discussed earlier, soil organisms may be exposed to the Cry1B.868 and Cry1Da_7 proteins by incorporation of above ground plant tissues (stover) into soil after harvest, and to a much lesser extent, by pollen deposited on the soil, or by root exudation. The most relevant route of exposure for MON 95379 maize to soil invertebrates is via tillage of late season maize tissue into the top 6 inches of soil. Based on expression levels in forage tissue, soil concentrations for Cry1B.868 and Cry1Da_7 protein were calculated to be 0.35 µg/g soil and 0.08 µg/g soil respectively (**Table 4-10**). With cultivation of MON 95379 maize in the United States likely limited to a maximum of 100 acres per growing season, this further supports a conclusion of minimal exposure of Cry1B.868 and Cry1Da_7 to soil organism populations.

Table 4-10: Predicted Environmental Concentrations (PECs) and Dissipation Kinetics of Cry1B.868 and Cry1Da_7 in Soil			
Parameter	**Soil Type**	**Cry1B.868**	**Cry1Da_7**
PEC (µg protein/g soil)	n.a.[a]	0.35	0.08
DT50 (d)[a]	Sandy Loam	19	>213[b]
DT90 (d)	Sandy Loam	49	>213[b]
DT50 (d)	Silt Loam	9	40
DT90 (d)	Silt Loam	24	>213[b]
DT50 (d)	Clay Loam	8	36
DT90 (d)	Clay Loam	28	>213[b]

[a]n.a. = not applicable; DT_x = X% dissipation time
[b]The dissipation parameter could not be determined as it fell outside of the exposure period of the study. The Cry1Da_7 protein concentrations remaining at the end of the study expressed as percentage of maximum protein concentrations detected were 66%, 25%, and 22% in Sandy Loam, Silt Loam, and Clay Loam soils respectively.

Given the narrow specificity of the two Cry proteins in MON 95379 maize, Cry1B.868 and Cry1D_7 proteins are not expected to affect species outside the insect order Lepidoptera. Its receptor-mediated mechanism of action and absence of activity in bioassays with multiple species outside of the order Lepidoptera support this conclusion. Based on the data reviewed, APHIS does not expect Cry1B.868 and

Cry1Da_7 protein to be harmful to non-lepidopteran invertebrate populations at the expected tissue expression levels in MON 95379 maize.

4.3.3.4.3 Lepidopteran Invertebrates

Bayer conducted laboratory studies to establish the toxicity of Cry1B.868 and Cry1Da_7 proteins from MON 95379 maize to lepidopteran species. The results show that Cry1B.868 and Cry1Da_7 proteins are active against the lepidopteran pest species, such as fall armyworm (*Spodoptera frugiperda* (Noctuidae)), corn earworm (*Helicoverpa zea* (Noctuidae)), and European corn borer (*Ostrinia nubilalis* (Crambidae)) ((MON 2020), Table 4-11). The two proteins are active against the monarch butterfly (Nymphalidae), a non-pest of corn.

Table 4-11: Activity spectrum results for Cry1B.868 and Cry1Da_7 proteins in lepidopteran species.

Invertebrate	Cry1B.868 EC_{50} or LC_{50} µg/ml diet[1]	Cry1Da_7 EC_{50} or LC_{50} µg/ml diet[1]
Spodoptera frugiperda, fall armyworm	0.15	0.096
Helicoverpa zea, corn earworm	120	0.042
Ostrinia nubilalis, European corn borer	9.8	11
Danaus plexippus, monarch butterfly	0.077	0.016

[1]EC_{50} value was estimated in a 7-day exposure to protein treated diet ³ 5 concentrations; LC_{50} value was estimated in a 7-day exposure to protein treated diet for 7 concentrations
Reference: (MON 2020).

The monarch butterfly does not feed on maize but may ingest maize pollen that falls on its larval host plant milkweed. Previous work with maize pollen and deposition on milkweed has demonstrated that density of pollen deposition decreases exponentially with increasing distance from the field edge (Pleasants et al. 2001). At 4 to 5 meters (m) from the edge of a maize field, the maize pollen density on milkweed leaves was expected to be less than 25 grains per centimeter^2 (cm^2) 95% of the time; a density less than 10% of the 95th percentile measured at the field edge (MON 2020). Based on these results, at 10 m from the field edge, the expected density of deposition would be less than 2 grains per cm^2 indicating there is essentially no exposure to pollen beyond 10 m and the only significant exposure to non-target Lepidoptera could occur in areas at the field edge.

There are several laboratory and field studies on the effects of *Bt* corn pollen and the degree to which monarch larvae would be exposed to toxic amounts of Cry protein in pollen that lands on its larval host plant (Wraight CL 2000; Angharad M.R. Gatehouse et al. 2002; Carpenter et al. 2002). In a laboratory study, Gatehouse (2002) found that *Bt*-expressing crops did not pose a significant effect on monarch butterfly. Similarly, other researchers estimate the risk of *Bt* corn in the USA to monarch populations was insignificant (Hellmich et al. 2001; Oberhauser et al. 2001; Pleasants et al. 2001; Stanley-Horn et al. 2001). After reviewing the data, EPA concluded that *Bt* corn was not a significant factor in field death of monarch larvae, particularly relative to factors such as the widespread use of pesticides and destruction of the butterfly's winter habitats (US-EPA 1995a, 2000; Mark et al. 2001).

Several factors affect maize pollen deposition. The potential exposure from off-crop pollen deposition was limited to the downwind side of the field (MON 2020). Standard agricultural practices for weed management would minimize the growth of monarchs or other non-pest host plants within the boundaries of the maize field. Also, density of pollen deposition decreases exponentially with increasing distance from the field. In addition, wind and rain events during or following pollen shed can reduce 54%-86% of pollen densities on non-target lepidopteran host plants near the field (Pleasants et al., 2001). Because of minimal off-crop exposure of MON 95379 maize to non-target lepidopteran species, the exposure to enough MON 95379 maize pollen to cause lethal impacts to most non-target lepidopteran species would be minimal.

Recent studies, however, have revealed a much higher toxicity of *Bt* pollen and anthers than found in previous studies (Anderson et al. 2004; Dively et al. 2004; Jesse and Obrycki 2004). Although Gatehouse (2002) and other previous studies suggested that the risk to monarchs remains insignificant, a close analysis of the issues may allow alternative assessments related to different transformation events. In addition, uncertainties related to the conditions of observations, inadequacies of models, and concentration of Cry protein in each Bt crop have not been examined (Andow and Claudia 2006).

The Cry1B.868 protein is expressed in MON 95379 maize pollen at levels higher than the corn events evaluated in the scientific literature. Based on the expression level of Cry1B.868 protein in MON 95379 maize pollen, APHIS finds monarch butterfly larvae feeding on milkweed located within corn fields would be exposed to enough protein to receive a toxic dose. Monarch butterfly larvae located along the borders of corn fields would also likely be exposed to enough MON 95379 maize pollen to ingest toxic levels of the Cry1B.868 protein. As reviewed earlier, monarch butterfly populations located further away from corn fields would likely not be impacted due to the reduced levels of pollen found further away from the fields edge.

The EPA completed an environmental risk assessment for Cry`Da_7 and Cry1B.868 proteins in corn (US-EPA 2024). While Cry1Da_7 and Cry1B.868 are active against lepidopteran species, the EPA analysis determined that negligible to no exposure is expected for the three federally listed threatened and endangered ('listed') lepidopteran species that are present in or near the states proposed for the Section 3 seed increase registration. This conclusion is based on the limited acreage designated for seed increase, which in turn will limit the potential exposure. Therefore, since EPA has determined there is a reasonable expectation of no discernible effects to occur to any non-lepidopteran non-target organisms exposed to both Cry1Da_7 and Cry1B.868, and EPA has determined negligible to no exposure is expected for listed lepidopteran species in the proposed locations, effects to listed species and their designated critical habitats are not expected and EPA is making a "No Effect" determination under the Endangered Species Act (ESA). The Services have concluded that the approach used by EPA should produce effects determinations that appropriately identify actions that are not likely to adversely affect listed species, and that are consistent with those that otherwise would be made by the Services (FR 2004. 69 (150) 47732-47762; 50 CFR Part 402 Joint Counterpart Endangered Species Act Section 7 Consultation Regulations). APHIS has reviewed and adopted the no effects determination by EPA and in this way is compliant with ESA.

4.3.3.5 Plant Communities

Plant diversity in surrounding areas is an important component of a sustainable agricultural system (Scherr and McNeely 2008; CBD 2019). Hedgerows, woodlands, fields, and other surrounding habitat serve as important reservoirs for beneficial insects, as well as plant pests. Corn fields and field edges are also habitat for weeds that adversely impact corn production directly through interference and resource competition (discussed below) and can also harbor both beneficial or damaging insects and plant microbes. Most weeds, however, provide valuable ecosystem services. By providing habitat, pollen and nectar resources, and serving as hosts, plants adjacent to corn fields can support a suite of beneficial arthropod species that serve as pollinators of insect-pollinated crops, and biological control agents, insects that prey on corn plant pests, such as lady beetles, spiders, and parasitic wasps (Scherr and McNeely 2008; Nichols and Altieri 2012). Surrounding plant communities can also help regulate run-off, reduce soil erosion, and improve water quality (Reichenberger et al. 2007; Egan et al. 2014). Hence, effective management of surrounding plant communities can provide benefits to corn crop production via control of insect pests and agricultural run-off (Altieri and Letourneau 1982), and support pollinator services to other plants that benefit from insect pollination (Nichols and Altieri 2012).

Members of plant communities in and around cornfields that adversely affect corn cultivation are generally characterized as weeds, and these plants are controlled to maximize crop yield and quality (Section 4.3.1.2.2.3). Most relevant to environmental review of transgenic cropping systems are those sexually compatible plant communities with which the transgenic crop plant can interbreed, discussed following in Section 4.3.3.4.

4.3.3.5.1 Potential Effects on Plant Communities

Because the agronomic practices and inputs that will be used for MON 95379 maize production would be no different, the potential impacts on vegetation proximate to MON 95379 maize fields would be the same as that for other corn varieties. Most relevant to the environmental review of biotechnology-derived cropping systems are sexually compatible plant communities with which the biotech crop plant can interbreed, discussed in the following section.

4.3.3.6 Gene Flow and Weediness of Corn

Gene flow as a mechanism for the unintended movement of plant transgenes to non-biotech crops, other biotechnology-derived crops, and wild or feral plants has been a topic of interest and research since the advent of transgenic crops in the 1990s. Factors such as the particular type of transgenic plant being grown, adjacent cropping systems, occurrence of wild relative species with which the transgenic plant may crossbreed, and transgenic trait all require consideration when evaluating the potential environmental impacts that could result from gene flow (Warwick et al. 2009; Ellstrand 2014). Gene flow among transgenic crops and conventional and organic cropping systems is of particular interest to farmers, food or feed processors, and international, federal, and state regulators, as such gene flow can adversely affect crop management, net returns on crops and their products, and domestic and international trade. Gene flow from transgenic plants to wild relative species is a topic of interest among ecologists and environmentalists, as well as federal and state regulators, due to concerns that a transgene may confer weediness traits to, or alter the fitness of, wild relative species.

Of particular interest to APHIS is the possible occurrence of gene flow from a transgenic plant to sexually compatible wild relative species that could lead to introgression of the trait gene into a wild population, and development of a phenotype that could adversely affect agricultural interests and/or the environment.

4.3.3.6.1 Factors Governing Gene Flow among Crop Plants and Wild Relative Species

The rate and success of pollen mediated flow is dependent on numerous factors such as the presence, abundance, and distance of sexually compatible plant species; overlap of flowering times among populations; method of pollination; biology and amount of pollen produced; and weather conditions, including temperature, wind, and humidity.

The salient environmental concern is whether the flow of a transgenic trait gene to a wild relative will have adverse ecological consequences. For a significant environmental impact to occur, gene flow would have to lead to the production of a fertile hybrid plant that produces viable offspring, and the resulting transgenic-wild plant hybrid having some type of competitive advantage that can lead, ultimately, to introgression of the transgene into a wild plant population. The transgene in a wild relative or other crop plant may very well prove detrimental to the hybrid, or have no effect (Ellstrand et al. 2007; Ellstrand 2014; Goldstein 2014). The ecological consequences of a transgene in a wild species depends on the type of trait, the stability of the gene in the genome, the fitness conferred to the hybrid through expression of the trait gene, and ecological factors in the area of the hybrid (Felber et al. 2007; Ellstrand 2014).

It is generally assumed that traits that impart increased fitness will persist in populations and those that impart negative effects on plant fitness will not. If a resulting transgenic-wild type hybrid had a competitive advantage over wild populations, it could persist in the environment and potentially disrupt the local ecology. Where the transgenic trait does not provide fitness, and is not deleterious to survival of the hybrid, the transgene may persist in wild populations with no effects on the local ecology. This could be the case for several introduced traits.

In respect to the occurrence of a transgenic-wild type hybrid, gene flow from a transgenic crop plant to wild or weedy relative species does not necessarily constitute an environmental harm in and of itself, nor does it inherently imply environmental damage (Ellstrand 2014). The salient issue is what the resultant ecological consequences of such gene flow to a wild population may be (Ellstrand 2014). Current understanding suggests that the presence of a transgenic trait outside the area of cultivation will likely have little or no adverse consequences unless:

(1) the trait confers novel or enhanced fitness or weediness to the wild relative hybrid, resulting in the evolution of increased weediness or invasiveness in wild type hybrids, or

(2) the trait confers to transgenic-wild relative hybrid progeny reduced fitness, resulting in a selective disadvantage in wild relative populations (Kwit et al. 2011; Ellstrand 2014).

Hence, in evaluating potential environmental impacts it is not the risk of gene flow itself that is the chief concern, but rather the environmental consequences that could occur as the result of such an event; whether the transgene will persist in a wild population, and whether hybrid or introgressed populations will have adverse ecological consequences.

4.3.3.6.2 Gene Flow among Corn (*Zea mays* L.) and Wild Relative Species

Corn (*Zea mays* L. subsp. *mays*) is one of the oldest domesticated plants in the world, the origins of which date back to around 5,000 – 3,600 years ago in southern Mexico (de Wet et al. 1978; Eubanks 1995). How corn evolved is still a matter of investigation, although most investigators agree that what we know as cultivated corn most likely descended from an annual species of "teosinte" (*Zea mays* ssp. *parviglumis*), a closely related wild grass endemic to Mexico (Piperno and Flannery 2001). Teosinte is the common name applied to several distinct wild *Zea* species closely related to corn (*Zea mays* L. ssp. *mays*). Cultivated corn (*Zea mays* L. subsp. *mays*) is sexually compatible with teosinte (*Zea* spp.), with a few exceptions. The closest relative of *Zea* in the United States is the genus *Tripsacum*, with which corn does not readily hybridize (OECD 2003).

Teosinte

Wild teosinte relatives of corn comprise a group of annual and perennial species that commonly occur within the tropical and subtropical areas of Mexico, Guatemala, Costa Rica, Honduras, El Salvador, and Nicaragua (Sánchez González et al. 2018). The natural geographic distribution of teosinte extends from the Western Sierra Madre of the State of Chihuahua, Mexico to the Pacific coast of Nicaragua and Costa Rica, including the western part of Mesoamerica. The Mexican annuals *Zea mays* ssp. *parviglumis* and *Zea mays* ssp. *mexicana* show a wide distribution in Mexico, while *Zea diploperennis*, *Zea luxurians*, *Zea perennis*, *Zea mays* ssp. *huehuetenangensis*, *Zea vespertilio* and *Zea nicaraguensis* have more restricted and distinct ranges, representing less than 20% of the total occurrences from published sources for the period 1842-2016 (Sánchez González et al. 2018).

Except for *Z. perennis*, *Zea mays* and teosinte cross readily, and their hybrids are fully fertile (de Wet and Harlan 1972). Hybridization and introgression between *Z. mays* and the subspecies *Z. mays* subsp. *mexicana* occurs in Mexico, and has probably been taking place since the advent of corn domestication wherever these two taxa are sympatric (de Wet et al. 1978; Ellstrand et al. 2007). Hybrids appear to maintain their unity of type in the wild (de Wet and Harlan 1972). In general, humans select in the direction of corn (*Zea mays*), and nature strongly favors teosinte over their hybrid, which is less well adapted for natural seed dispersal (de Wet and Harlan 1972). The rate at which domesticated corn crop genes may enter teosinte populations will be limited by genetic barriers, phenological differences, and the relative fitness of the hybrids (Ellstrand et al. 2007).

Teosinte do not appear to be present in the United States other than in botanical gardens or at research stations. The USDA Plants Database lists *Zea mexicana* (Syn. *Z. mays* ssp. *mexicana*) as present in Florida, Alabama, and Maryland, having been introduced from Mexico (USDA-NRCS 2019a). It has, apparently, occasionally been cultivated in the Southern United States for forage (Hitchcock 1951). The documentation cited for occurrence in Florida only shows distribution of native or naturalized populations in Miami-Dade, Orange, and Levy Counties (Wunderlin et al. 2019). While citations were provided in the Plants database for distribution in Maryland and Alabama, current Maryland plants databases have no listed *Zea* species, other than *Z. mays* (UMD 2005; MPA 2019), nor are any *Zea* species or subspecies other than *Z. mays* (corn) listed in Alabama (Kral et al. 2019).

Zea perennis (Syn. *Euchlaena perennis* Hitchc.) is listed as occurring in Texas and South Carolina. It is described as having been cultivated at academic research stations in Texas, and established on James Island, South Carolina (Hitchcock 1951). It is not known if the James Island population has persisted. There are no *Zea* species found in the comprehensive online South Carolina Plant Atlas (USC 2019); which catalogues over 3000 species.

Teosinte identified as *Zea mays* ssp. *parviglumis* is listed as having occurred in Miami-Dade County, Florida (Wunderlin et al. 2019), an area that is now largely urban. *Zea diploperennis* and *Zea luxurians* are also listed in the USDA Plants database, but there is no information about the presence of any wild populations in the United States.

Experts familiar with the teosinte collections in the United States, some of whom were involved with revision of the Manual of Grasses for North America (Roché et al. 2007), are not aware of any naturalized or native populations of teosinte currently growing in the United States (USDA-APHIS 2013).

Tripsacum

Three species of Tripsacum have been identified in the United States: Eastern gamagrass, Mexican gamagrass, and Florida gamagrass. Eastern gamagrass is the only Tripsacum species of widespread occurrence USDA-NRCS, 1996 #629}(USDA-NRCS 2002; OECD 2003). As previously reviewed, teosinte (Zea spp.) do not appear to be present in the United States other than in botanical gardens or at research stations. Thus, there is no plausible opportunity for interbreeding.

Although not closely related cytologically (e.g., differing numbers of chromosomes), gene exchange can take place between *Z. mays* and *Tripsacum* (de Wet et al. 1978). Certain species of *Tripsacum* can and have been crossed with *Zea mays* or at least some accessions of each species can cross under experimental lab conditions, but only with difficulty. The resulting hybrids are male sterile and usually female sterile (de Wet et al. 1978; Leblanc et al. 1996; Lee et al. 2017; Iqbal et al. 2019). Hybrids between *T. dactyloides* and *Z. mays,* however*,* have been found to be male sterile, but usually female fertile (de Wet and Harlan 1972). Attempts at artificially induced introgression from *Tripsacum* species into *Z. mays* failed to produce either teosinte-like offspring or the combination of characteristics assumed to indicate introgression during the evolution of several South American races of corn (Mangelsdorf and Reeves 1959; de Wet and Harlan 1972). The probability of natural introgression from *Tripsacum* in the direction of *Z. mays* seems to be low (de Wet et al. 1978).

Hybrid combinations with *Z. mays* (as pollen donor) and *T. dactyloides* are known to give rise to recovered *Z. mays* within three or more further backcrosses with *Z. mays*. It is, however, not too likely that this process commonly occurs in nature (de Wet et al. 1978). With each successive backcross, the offspring become more *Z. mays* like, and less capable of surviving in competition without the help of humans. Hybrids have been observed to not only produce low yields, but are also partially female sterile (de Wet et al. 1978).

In summary, gene exchange is possible between *Zea* and *Tripsacum*, and several South American races of corn, where teosinte is absent, exhibit past evidence of hybridization (de Wet et al. 1978). Natural introgression between *Zea* and *Tripsacum*, however, appears unlikely (de Wet et al. 1978). Hybrids between *Z. mays* and *Tripsacum*, as well as their derivatives when backcrossed with *Z. mays*, are poorly adapted for survival in competition with both their wild and cultivated parents (de Wet et al. 1978). Although hybridization of *Tripsacum* and *Z. mays* has been accomplished in the laboratory using special techniques under highly controlled conditions (Wozniak 2002; Lee et al. 2017), pollen-directed gene flow from corn (*Zea mays*) to wild *Tripsacum* species is considered an unlikely event (Wozniak 2002; Lee et al. 2017). APHIS is unaware of any reported cases of hybridization among naturally occurring *Tripsacum* and *Z. mays* in the United States.

4.3.3.6.3 Corn as a Weed or Volunteer

In the United States, there are no *Zea* species listed on the Federal Noxious Weed List (7 CFR part 360) (USDA-NRCS 2019a). Corn (*Zea mays*), as a highly domesticated crop plant with limited seed dispersal and dormancy, does not readily form persistent feral populations; does not present as a weed outside of areas of cultivation (USDA-NRCS 2019a; USDA-APHIS 2024).

Corn can and periodically does occur as a volunteer plant in subsequent crops planted in the same field. Corn seed can remain in fields because of harvester inefficiency, dispersal by birds and other foraging wildlife, or from fallen ears. When seeds survive to the next growing season, volunteer plants may develop within subsequent crops rotated with corn, such as soybean, dry beans, sugar beets, as well as subsequent corn crops.

Volunteer corn is more of agronomic/economic than environmental concern; the presence of volunteers can result in minor to significant yield impacts on subsequent crops planted in the same field, interfere with harvest, and cause unacceptable levels of contamination in harvested soybean (Stahl et al. 2013), depending on the density of the volunteer corn (Stahl et al. 2013; Jhala et al. 2020). In controlled agronomic studies, volunteer corn densities ranging from 800 to 13,000 plants per acre resulted in yield losses of 0 to 54% in soybean and 0 to 13% in corn (Stahl et al. 2013). Similarly, soybean yield reductions have been found to range from 10% to 41% where early-emerging volunteer corn densities ranged from 0.5 to 16 plants m^2, although no soybean yield loss occurred with a late-emerging cohort of volunteer corn (Marquardt et al. 2012a). Thus, the potential impact of volunteer corn on the yield of subsequent crops can be substantial. Volunteer corn can also encourage dispersal and survival of WCR and gray leaf spot disease limiting the benefits of a corn-soybean rotation (Jhala and Rees 2018). Successful control of volunteer corn is accomplished with the use of various combinations of cultivation practices and use of herbicides with differing modes of action (Jeschke and Doerge 2010; Stahl et al. 2013).

4.3.3.6.4 Probability and Potential Effects on Gene Flow

MON 95379 maize, if grown for commercial purposes, would be cultivated as current corn varieties and present the same potential risk for gene flow, specifically the propensity for and frequency of gene flow, as current corn varieties. Accordingly, MON 95379 maize cropping systems would not be expected to present more or less risk for gene flow to wild relative species, or other corn crops, as do current corn varieties.

While it is possible that *Tripsacum* species may occur in areas where MON 95379 maize is cultivated, gene introgression from MON 95379 maize into *Tripsacum* populations under natural conditions is considered highly unlikely, for two reasons. First, in contrast with corn and teosinte, which may hybridize under certain conditions, as discussed previously, the potential for hybridization and successful introgression of *Z. mays* genes into *Tripsacum* is rare (de Wet and Harlan 1972; de Wet et al. 1978; Eubanks 1995). Special techniques are required to hybridize *Z. mays* and *Tripsacum*; hybrids of *Tripsacum* species with *Zea* species do not commonly occur outside of a laboratory. Offspring are often sterile or have reduced fertility, and are unable to withstand even mild winter conditions (de Wet and Harlan 1972; de Wet et al. 1978; Eubanks 1995).

Second, while corn pollen can travel as far as 1⁄2 mile (800 m) in 2 minutes in a wind of 15 miles per hour (27 km/h) (Nielsen 2016), most pollen is deposited within a short distance of the corn plant. Numerous studies show the majority (84-92%) of pollen grains travel less than 16 feet (5 meters) (Pleasants et al. 2001). At a distance of 200 feet (60 m) from the corn plant, the pollen concentration averages only about 1%, compared with pollen samples collected about 3 feet (0.9 m) from the pollen source (Burris 2002; Brittan 2006). The number of outcrosses is reduced to one-half at a distance of 12 feet (3.6 m) from the pollen source, and at a distance of 40 to 50 feet (12 to 15 m), the number of outcrosses is reduced by 99%. Thomison (2004) showed cross-pollination between cornfields could be limited to 1% or less by a separation distance of 660 feet (200 m), and to 0.5% or less by a separation distance of 984 feet (300 m).

However, cross-pollination frequencies could not be reduced to 0.1% consistently, even with isolation distances of 1,640 feet (500 m).

Based on all of these factors, it is unlikely hybridization of MON 95379 maize and *Tripsacum* species would occur. In the event such hybrids developed, it is unlikely that the Cry protein traits extant in MON 95379 maize would present any risk to communities of *Tripsacum* species or their ecological role in the communities of other plants.

Volunteer MON 95379 maize

MON 95379 maize is no more likely to occur as a volunteer in subsequent seasons after its planting than conventional corn for two reasons. First, MON 95379 activities in the United States will be limited to breeding and seed increase activities (MON 2020). These breeding and seed production activities will take place at research and breeding facilities following typical recommended practices employed to achieve high quality seed and control volunteer maize. Therefore, the intended use of MON 95379 maize in the U.S. is not expected to impact crop rotation practices or volunteer management practices in maize.

Second, factors contributing the occurrence of volunteer corn include pre-harvest seed loss, stalk and root lodging characteristics, and ear-drop. All of these can contribute to the occurrence of volunteer corn (considered a weed in subsequent crops). Pre-season, in-season and post-harvest agronomic practices, including insect, disease or weed control management, crop rotation or volunteer management, will not differ for MON 95379 seed production when compared to the current maize practices implemented by nursery sites.

In the United States, corn (*Zea mays*) nor *Tripsacum* is listed as a weed, neither are on the Federal Noxious Weed List (7 CFR part 360) (USDA-NRCS 2019b). Corn, domesticated *Zea mays*, has been cultivated throughout the United States without any evidence it forms persistent feral populations. Elsewhere, corn is grown without any report of it being a serious weed or that it forms persistent feral populations (Gould 1968; OECD 2003) because corn possesses few of the characteristics of those plants that are notably successful as weeds. Volunteer corn lacks vigor and competitiveness because the volunteer plant is two generations removed from the hybrid planted (Davis, 2009). These plants do not result in feral populations in following years because maize is incapable of sustained reproduction outside of domestic cultivation (Gould 1968).

Corn periodically does occur as a volunteer plant in subsequent crops planted in the same field (Marquardt et al. 2012b). Corn seed can remain in fields as a result of harvester inefficiency, dispersal by birds and other foraging wildlife, or from fallen ears. When seeds survive to the next growing season, volunteer plants may develop within subsequent crops rotated with corn, such as soybean, dry beans, sugar beets, as well as subsequent corn crops. Volunteer corn can be present as single plants or as clumps formed when an ear drops to the ground and is partially buried. When seeds survive to the next growing season, volunteer plants may develop within subsequent crops rotated with corn, or outside of the cropped area.

Various post-emergence herbicides are available to control volunteer corn in each of the major corn rotational crops. However, because of the variety of resistance traits available in both corn and soybeans, choosing an effective herbicide that won’t harm the crop requires careful planning. For example, in soybeans, the list includes glyphosate, glufosinate, the FOP ACCase inhibitors (quizalofop, fluazifop-p-butyl, fluazifop + fenoxaprop), and the cyclohexanedione ACCase inhibitors (clethodim, sethoxydim; "DIM" herbicides) (Boehm 2019; Jhala et al. 2019). Imazamox (Raptor®) is an ALS inhibitor and another option for post-emergence control of volunteer corn (at 2-8 inches) in soybean, alfalfa, dry beans, peas, lima bean, snap bean, clover, and edamame. For volunteer control of corn in wheat crops, including MON 95379 maize, additional post-emergence herbicide options are available such as Powerflex® (pyroxsulam), GoldSky® (florasulam+ pyroxsulam + fluroxypyr), and Perfectmatch® (clopyralid+ fluroxypyr+ pyroxsulam) (Ikley 2020).

These data suggest that MON 95379 maize is no more likely to become weedy than conventional varieties of the crop. There are no weediness characteristics (e.g., increased hardiness, rapid growth, stress tolerance, pest/disease resistance) associated with MON 95379 maize. MON 95379 maize volunteers can be managed using a variety of currently available cultural methods, as well as herbicides.

4.3.3.7 Biological Communities

As a highly managed landscape, biological communities in and around large-scale cropping systems is limited. The homogeneity of the plants in a crop (monoculture), and frequent disturbance of land through planting, harvesting, cover cropping, tillage, pesticide application, scouting, and related production activities limit the diversity of plants and animals in and around crop fields (Altieri 1999; Landis et al. 2005; Sharpe 2010; Towery and Werblow 2010). While biological communities will be inherently limited, growers, as well as federal and state agencies/programs, recognize the need for environmental stewardship and maintenance of varied cropland communities essential to sustainable farming (SARE 2012).

Various taxa contribute to essential ecological functions upon which agriculture depends, such as pollinators, soil biota, and predators of crop pests (CBD 2019). One invaluable function of biological communities is the support of diverse populations of beneficial insects on farms. In one study of corn farms across the Northern Great Plains, (Lundgren and Fergen 2014) found that farms with fewer insect communities had more plant pests, and that more cornfields with more varied insect communities had fewer plant pests. The results from their study show that designing cropping systems for varied insect taxa by varying vegetation on farms, lengthening crop rotations, using cover crops in rotations, intercropping, managing field margins, and using minimal-till agriculture can facilitate control of plant pests, requires fewer insecticide inputs, and can save farmers time and money.

Relative to HR/IR crops, by facilitating conservation tillage, decreasing insecticide use, and helping sustain maximum yield—which alleviates pressure to convert additional land into agricultural use—HR/IR crops can contribute to reducing the impacts of agriculture on biological communities (Carpenter 2011; Raman 2017). A U.S. National Research Council assessment of the relationship between biotech crop adoption and farm sustainability in the United States concluded that, generally, HR and IR crops have had fewer adverse effects on the environment than non-biotech crops produced conventionally (NRC 2010b). During the 1996 – 2016 timeframe the adoption of HR and IR technology has reduced pesticide spraying in the United States by 361 million kg (796 million pounds), and also facilitated reductions in fossil fuel use and tillage, resulting in a reduced greenhouse gas and NAAQS emissions from cropping areas (Brookes and Barfoot 2017). In the United States, reductions in fossil fuel use are estimated to be 94.5 million gallons for biotech corn and soybean crops during the same timeframe (Brookes and Barfoot 2018c).

Studies in sweet corn, which is routinely treated with foliar insecticides during production, have documented that the conservation of natural enemies of plant pests with *Bt* based crops can facilitate biological control in cropping systems. Musser and Shelton (2003) found that *Bt* sweet corn (lepidopteran resistant) was less toxic to the major predators in the cropping system (ladybeetles *C. maculata* and *H. axyridis* and the minute pirate bug, *Orius insidiosus*), than the commonly used pyrethroid insecticide lambda cyhalothrin, and insecticides spinosad and indoxacarb. This study demonstrated that *Bt* sweet corn provided control of lepidopteran pests, and did not negatively affect the predation rates of egg masses of the European corn borer (a significant plant pest), as did lambda cyhalothrin and indoxacarb (Musser and Shelton 2003; Romeis et al. 2019). A follow-up study proposed a model that integrates biological and chemical control with transgenic IR crops for suppressing not only the target pests, but secondary pests such as aphids that affect marketability (Musser et al. 2006).

HR and IR crops have also made important contributions to increasing global production levels. As of 2018, these biotech traits have facilitated—since the introduction of the technology in the mid-1990s—addition of 278 million metric tons and 498 million metric tons to the global production of soybeans and corn, respectively (Brookes and Barfoot 2018b). The average yield impact across the total area planted to HR and IR corn during the 1996 – 2018 timeframe has been +16.5% (Brookes and Barfoot 2018b). To maintain global production levels at 2018 levels, without biotech crops, would have required farmers to plant an additional 4.9 million acres (12.3 million hectares) of soybeans, 3.3 million acres (8.1 million hectares) of corn, 1.25 million acres (3.1 million hectares) of cotton, and 0.2 million acres (0.7 million hectares) of canola, an area equivalent to the combined agricultural area of the Philippines and Vietnam (Brookes and Barfoot 2018b).

4.3.3.7.1 Potential Effects on Biological Communities

Commercial production of MON 95379 maize would not be expected to affect biological communities in and around MON 95379 maize crops any differently than conventional corn cropping systems. As discussed in the sections addressing soil biota and wildlife, the Cry1B.868 and Cry1Da_7 proteins are unlikely to present any risks to plant, animal, fungal, or bacterial communities. The same or functionally similar enzymes are ubiquitous among plants and microorganisms and commonly consumed by wildlife. The agronomic practices and inputs used for MON 95379 maize would be the same as those used for other corn varieties, biotechnology-derived and non-biotech alike. Consequently, there are no unique risks to biological communities beyond that already posed by conventional corn cropping systems that would likely derive from cultivation of MON 95379 maize.

In general, insecticidal biotech crops such as MON 95379 maize, for the most part, have the potential to be more environmentally benign than chemical insecticide-based pest management approaches (Gatehouse et al. 2011; Romeis et al. 2019). While biological communties will be inherently limited in commercial corn crops due to frequent disturbance, tillage, mechanized planting, planting of a monoculture crop, and application of pesticides, as reviewed above, biotech HR/IR crops have generally reduced the environmental impacts of crop production, relative to conventional broad-spectrum chemical approaches to pest management (NRC 2010b; NAS 2016a; Raman 2017; Brookes and Barfoot 2018c; Romeis et al. 2019). Growers, and federal and state agencies, recognize the need for maintenance of some degree of cropland biological communities. A variety of federally supported programs, such as the USDA funded Sustainable Agriculture Research and Education Program (SARE), and partnership programs among the EPA and the agricultural community support agricultural practices that are intended to protect the environment, conserve natural resources, and promote cropland biological communities (i.e., (USDA-NIFA 2017; US-EPA 2019c)). The USDA Natural Resources Conservation Service, through its Conservation Stewardship Program, Landscape Initiatives, Environmental Quality Incentives Program, Landscape Planning, and other services provides technical and financial support to growers to assist in managing the complex interaction of cropping systems and the natural environment (USDA-NRCS 2019c). Tools are also developed by industry. For example, *Field to Market: The Alliance for Sustainable Agriculture* supports various programs that helps farmers and the food supply chain benchmark sustainability performance including management that promotes biological communties (Field-to-Market 2019).

4.3.3.7.2 Potential Effects on Threatened and Endangered Species (TES)

FWS Consultation History

The EPA completed an ecological risk assessment (ERA) for Cry`Da_7 and Cry1B.868 proteins in corn (US-EPA. 2024). While Cry1Da_7 and Cry1B.868 are active against lepidopteran species, the EPA analysis determined that negligible to no exposure is expected for the three federally listed threatened and endangered ('listed') lepidopteran species that are present in or near the states proposed for the Section 3 seed increase registration. This conclusion is based on the limited acreage for this seed increase, which will limit the potential for exposure. Therefore, since EPA has determined there is a reasonable expectation of no discernible effects to occur to any non-lepidopteran non-target organisms exposed to both Cry1Da_7 and Cry1B.868, and EPA has determined negligible to no exposure is expected for listed lepidopteran species in the proposed locations, effects to listed species and their designated critical habitats are not expected and EPA is making a "No Effect" determination under the Endangered Species Act (ESA). The Services have concluded that the approach used by EPA should produce effects determinations that appropriately identify actions that are not likely to adversely effect listed species, and that are consistent with those that otherwise would be made by the Services (FR 2004. 69 (150) 47732-47762. 50 CFR Part 402 Joint Counterpart Endangered Species Act Section 7 Consultation Regulations. APHIS has reviewed and adopts the no effect determination made by EPA and in this way satisfies compliance with ESA section 7 consultation.

Human Health

Human health considerations related to biotechnology-derived crops, specifically, are those related to (1) the safety and nutritional value of foods derived from biotech crops, and (2) the potential health effects of pesticides that may be used in association with biotech crops. As for food safety, consumer health concerns are in regard to the potential toxicity or allergenicity of the introduced genes/mRNA//proteins, the potential for altered levels of existing allergens in modified plants, or the expression of new antigenic proteins (substances capable of stimulating an immune response). Some consumers may be concerned about the potential consumption of pesticide residues on/in foods derived from biotechnology-derived crops. Occupational exposure to pesticides is also considered.

The safety and nutritional assessment of biotechnology-derived crop plants includes characterization of the physicochemical and functional properties of the introduced genetic material and gene products, determination of the safety of the gene products (e.g., proteins, enzymes), and compositional assessment of the biotech crop plant. Compositional assessments compare the biotech crop plant with non-transgenic, conventional varieties of that crop, and evaluate characteristics such as protein, fat, carbohydrates, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, and vitamins. The introduced Cry1B.868 and Cry1Da_7 proteins are reviewed below.

4.3.3.8 Food Safety

In addition to direct consumption (e.g., grits, corn on the cob), humans consume corn products such as corn meal, corn oil, and corn syrup. Various food items are comprised of corn products, such as cereals, tortillas, and snack foods. Most dent corn is used for animal feed and fuel ethanol production. Some dent corn varieties with specific starch properties are used for food purposes—generally referred to as food grade corn. These are typically contracted and sold to wet-millers and dry-millers for processing into tortilla chips, corn syrup, and other corn products (USDA-ERS 2019c).

As summarized in Section 1.3–Coordinated Framework for the Regulation of Biotechnology, the FDA regulates the safety of plant-derived foods pursuant to the FFDCA and FSMA. The FDA created a voluntary premarket food safety consultation process in the 1990's. This consultation process enables developers to engage with the FDA on the safety and legality of foods derived from their new plant varieties and helps to ensure that any safety or regulatory issues associated with a food from a new plant variety are resolved prior to commercial distribution (US-FDA 1992, 2006). Bayer completed a New Protein Consultation about the safety, nutrition, and regulatory compliance of human food from MON 95379 corn with the FDA (NPC 0000179) on November 7, 2022 (US-FDA 2022). FDA concludes with "no further questions" determination that the potential inadvertent presence in the food supply of Cry1B.868 and Cry1D_7 proteins would not raise safety concerns (US-FDA 2022).

In addition to the FDA consultation, foods produced from biotechnology-derived plants undergo a safety evaluation among international agencies before entering foreign markets, such as reviews by the European Food Safety Agency (EFSA 2020) and the Australia and New Zealand Food Standards Agency (ANZFS 2020). The Codex Alimentarius, established by the World Health Organization and Food and Agriculture Organization of the United Nations, is a set of international standards, principles, and guidelines for the safety assessment of foods derived from modern biotechnology. These standards help countries coordinate and harmonize review and regulation of foods derived from biotechnology-derived plants to ensure public safety and facilitate international trade (WHO-FAO 2009). Currently, the Codex Alimentarius Commission is comprised of over 180 member countries, including the United States. Most governments incorporate Codex principles and guidelines in their review of foods derived from biotechnology-derived crop plants.

The food and feed safety reviews of biotechnology-derived crops introduced into the United States and international markets to date have generally concluded that there are no significant nutritional differences between conventional and biotechnology-derived plant products, beyond those intended (e.g., (NAS 2016b; Delaney et al. 2017; US-FDA 2019; ANZFS 2020).

4.3.3.8.1 Safety of the Herbicide Resistance and Insect Resistance Traits

Domestic Bt corn acreage grew from approximately 8% in 1997 to 19% in 2000, and to 82% in 2020 (USDA-ERS 2021). Since the turn of the 21st century, there have been large increases in the percentage of acreage planted with seeds that were "stacked" with both HT and Bt traits. In 2000, approximately 1 percent of corn was produced using stacked seeds. As of 2018, approximately 80% of the domestic corn and cotton planted were genetically engineered, stacked seeds (USDA-ARS 2020)

The US-EPA has established separate tolerance exemptions for various Cry proteins (e.g., Cry1Ab, Cry1Ac, Cry1A.105, Cry1F, Cry2Ab2 and Cry3A, Cry3Bb1, Cry34/35, Cry51Aa2) expressed in crops produced through genetic engineering (U.S. EPA, 1995a; b; 1996a; 2004a; b; c; 2005b; a; 2006a; b; 2018). The USDA has deregulated Cry protein-containing crops produced through genetic engineering. Similarly, many global regulatory agencies have reviewed and affirmed the safety of numerous Cry proteins (US-EPA 1995a, b, 1996, 2004c, a, b, 2005b, a, 2006b, a; ILSA 2010, 2011, 2013a, c, b, 2014; Koch et al. 2015b; US-EPA 2018). Due to a lack of adverse toxic and allergenic effects of a wide array of *Bt* spray formulations, crops derived from biotechnology and Cry proteins in food or feed, there is a global consensus of reasonable certainty of no harm when Cry proteins are consumed by mammals and other terrestrial vertebrates.

There are no human health or ecological risks associated with exposure to Cry proteins, which have a long history of safe use in commercially produced crops developed through genetic engineering. The FDA has previously consulted on the use of Cry proteins for various crops produced through genetic engineering. None of these modified crop varieties have been identified as presenting any risk to human or animal health. Previous evaluations of Cry have shown that it does not share amino acid sequence similarity to known toxins, nor does it possess characteristics associated with food allergens (Herouet et al. 2005; ILSA 2011; ILSI-CERA 2011).

Safety of Cry1B.868 and Cry1Da_7 proteins

There are no health hazards that have been associated with consumption of nucleic acids, such as dsRNA, in foods. The mediators of RNAi, such as dsRNA, small interfering RNAs (siRNA), and microRNAs (miRNA), occur in all commonly consumed plant and animal based foods, (e.g., (Ivashuta et al. 2009; Jensen et al. 2013; Frizzi et al. 2014)). It follows there is a history of safe consumption of dsRNA in the human diet. This includes plant dsRNAs with nucleic acid sequences complementary to human genes/transcripts (Jensen et al. 2013; Frizzi et al. 2014; Dever et al. 2015)). The FDA concluded that nucleic acids introduced into crop plants, in and of themselves, do not raise safety concerns (US-FDA 1992).

Cry1B.868 and Cry1Da_7 proteins Safety Evaluations

The potential toxicity of the *Cry1B.868 and Cry1Da_7* proteins was assessed by comparison of its nucleic acid sequence to the sequences in the Bayer toxin database[10]. Evaluation of the *Cry1B.868 and Cry1Da_7 proteins* sequence and protein sequences in the Monsanto toxin database was conducted with BLASTP. BLAST is an algorithm and program for comparing biological sequence information, such as the amino

[10] The Monsanto toxin database is comprised of sequences found in UniProtKB/Swiss-Prot (https://www.uniprot.org/).

acid sequences of proteins, or the nucleotides of DNA and/or RNA sequences. No alignments were returned between the *Cry1B.868 and Cry1Da_7 proteins* sequence and protein sequences in the Monsanto toxin database that suggested an association between the *Cry1B.868 and Cry1Da_7 proteins* and potential toxicity (MON 2020).

Bayer conducted a 14-day acute oral toxicity study in mice using *Cry1B.868 and Cry1Da_7 proteins*. Study design was based on OECD, Section 4 (Part 423): Acute Oral Toxicity – Acute Toxic Class Method, Guideline for the Testing of Chemicals. The Cry1B.868 and Cry1D_7 proteins produced no evidence of adverse effects following administration of 2000 mg/kg body weight/day. There were no instances of clinical abnormalities, changes in body weight, or mortality observed in any of the animal studies. The concentration of *Cry1B.868 and Cry1Da_7 proteins* in MON 95379 maize is 0.51 to 4.8 ng/mg tissue dry weight (dw) in grain and 0.054 to 39 ng/mg tissue dw in leaf (depending on growth stage). These are levels far below that which humans or other animals may obtain a 2000 mg/kg body weight/day intake via diet.

Bioinformatic assessment of the *Cry1B.868 and Cry1Da_7 proteins* sequence for potential allergenicity was conducted according to Codex Alimentarius Commission guidelines (CODEX 2003). Two separate searches for the *Cry1B.868 and Cry1Da_7 proteins* sequence was performed using the Comprehensive Protein Allergen Resource (COMPARE) 2019 database available at http://comparedatabase.org. This peer-reviewed database is comprised of 2,081 sequences. Results of the search of the Cry1B.868 and Cry1D_7 proteins' sequences using the COMPARE database of known and putative allergen sequences found no alignments that were a length of 80 or greater, with a sequence identity of ≥ 35%. (Pioneer 2019). No contiguous 8-residue matches between the *Cry1B.868 and Cry1Da_7 proteins* sequence and the allergen sequences were identified. Taken together, the comparisons of the Cry1B.868 and Cry1D_7 protein sequences to the allergen sequences found no association between the *Cry1B.868 and Cry1Da_7 proteins* and potential allergenicity.

4.3.3.9 Pesticides, Tolerance Limits for Foods, and Exemption from the Requirement for a Tolerance

The EPA regulates the sale, distribution, and use of pesticides under FIFRA (Section 1.3–Coordinated Framework). The EPA also regulates certain biotechnology-derived microorganisms used as biofertilizers, bioremediation agents, and for the production of various industrial compounds including biofuels under the Toxic Substance Control Act (TSCA). Before a pesticide may legally be used in the United States, the EPA must evaluate the pesticide to ensure that it will not result in an unreasonable risk to human health or the environment. Pesticides that complete this evaluation are issued a "registration" that permits their sale and use according to requirements set by the EPA.

Before a pesticide can be used on a food crop, the EPA, pursuant to the FFDCA and Food Quality Protection Act of 1996 (FQPA), also establishes tolerance limits, which is the amount of pesticide residue allowed to remain in or on each treated food commodity (21 U.S. Code § 346a - Tolerances and exemptions for pesticide chemical residues). Pesticide tolerance limits established by the EPA are to ensure the safety of foods and feed for human and animal consumption (US-EPA 2019a). If pesticide residues are found above the tolerance limit, the commodity will be subject to seizure by the government.

Section 408(c)(2)(A)(i) of the FFDCA allows the EPA to establish an exemption from the requirement for a tolerance if the EPA determines that the exemption is “safe.” Safe is defined as meaning that there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide residue." To make a safety finding, the EPA considers, among other things; the potential toxicity of the 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. Any pesticides used with MON 95379 maize would need to comply with EPA requirements (Section 1.3–Coordinated Framework for the Regulation of Biotechnology).

Both the FDA and USDA monitor foods for pesticide residues to enforce tolerance limits and ensure protection of human health. The USDA Pesticide Data Program (PDP) collects data on pesticides residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities commonly consumed by infants and children (USDA-AMS 2019a). The Monitoring Programs Division administers PDP activities, including the sampling, testing, and reporting of pesticide residues on agricultural commodities in the U.S. food supply. The program is implemented through cooperation with state agriculture departments and other federal agencies. The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the FQPA. PDP data:

- enable the EPA to assess dietary exposure;
- facilitate the global marketing of U.S. agricultural products; and
- provide guidance for the FDA and other governmental agencies to make informed decisions.

Bayer has submitted a registration application to the EPA Biopesticides and Pollution Prevention Division (BPPD) under FIFRA Section 3(c)(7)(C) as MON 95379 maize produces the insecticidal active ingredients, Cry1B.868 and Cry1Da_7 proteins and is a Plant-Incorporated Protectant (PIP) (US-EPA 2024). This application will include a petition for exemption from the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) for the Cry1B.868 and Cry1D_7 proteins. The EPA also sets limits for potential drinking water contaminants that need to be regulated to protect public health (40 CFR part 141). These contaminant limits are required by the Safe Drinking Water Act (SDWA). The EPA works with States, Tribes, and many other partners to implement SDWA standards.

4.3.3.10 Worker Safety

Agriculture is one of the most hazardous industries in the United States. Worker hazards include those associated with pesticide application, and the operation of farm machinery. Agricultural operations are covered by several Occupational Safety and Health standards including Agriculture (29 CFR 1928), General Industry (29 CFR 1910), and the General Duty Clause. Further protections are provided through the National Institute of Occupational Safety and Health (NIOSH).

To address the potential hazards associated with exposure to pesticides during field application and handling, the EPA issued the Worker Protection Standard (WPS) (40 CFR Part 170) in 1992. The WPS contains requirements for pesticide safety training, notification of pesticide applications, personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. The Occupational Safety and Health Administration (OSHA) also requires employers to protect their employees from hazards associated with pesticides.

On November 2, 2015, EPA revised the WPS to decrease pesticide exposure incidents among agricultural workers, handlers, and their families (80 FR 211, November 2, 2015, p. 67495). The revised WPS requirements went into effect during 2017–2018. On November 1, 2019, the EPA proposed narrow updates to the WPS regulation to improve the agency's Application Exclusion Zone provisions (US-EPA 2020f).

4.3.3.11 Potential Effects on Human Health

There are no risks to public health or worker safety that would derive from approval of the petition for MON 95379 maize. It is unlikely that MON 95379 maize, a dent corn variety (e.g., *Zea mays* var. *indentata*), would be directly consumed by humans. Direct consumption of corn is generally limited to sweet corn (*Zea mays* var. *saccharata* var. *rugosa*), popcorn (*Zea mays* var. *everta*), and flint corn (*Zea mays* var. *indurata*) (e.g., polenta). Dent corn is produced primarily for animal feed and industrial uses such as fuel ethanol production, although some specialty dent corn varieties with specific starch properties may be used for grits, and processed into food products such as tortilla chips, corn oil, etc.

As reviewed above, the Cry1B.868 and Cry1Da_7 proteins present no health hazard in the event MON 95379 maize is inadvertently ingested. In terms of nutritional properties MON 95379 maize grain is compositionally the same as other dent corn varieties (MON 2020). Bayer completed a New Protein Consultation about the safety, nutrition, and regulatory compliance of human food from MON 95379 corn with the FDA (NPC 0000179) on November 7, 2022 (US-FDA 2022). FDA concludes with "no further questions" determination that the potential inadvertent presence in the food supply of Cry1B.868 and Cry1D_7 proteins would not raise safety concerns (US-FDA 2022). The National Bioengineered Food Disclosure Law (NBFDL), passed by Congress in July of 2016, directed USDA to establish a national mandatory standard for disclosing foods that are or may be bioengineered. The implementation date of the Standard was January 1, 2020, except for small food manufacturers, whose implementation date is January 1, 2021. The mandatory compliance date is January 1, 2022. Regulated entities may voluntarily comply with the Standard until December 31, 2021. The Standard requires food manufacturers, importers, and certain retailers to ensure bioengineered foods are appropriately disclosed. Any food products derived from MON 95379 maize would require labeling subject to NBFDL standards, and consumers would choose to consume such foods based on preference.

The EPA WPS regulations provide protections to agricultural workers, pesticide handlers, and other persons via training, pesticide safety and hazard communication requirements, personal protective equipment requirements, and provision of supplies for routine washing and emergency decontamination. Agricultural workers and handlers, owners/managers of agricultural establishments, commercial (for-hire) pesticide handling establishments, and crop production consultants are provided guidance for compliance with WPS regulations (US-EPA 2016).

4.3.4 Livestock Health and Welfare

The term livestock is defined in different ways, although for the purposes of this EA livestock means all domesticated animals reared in an agricultural setting to produce commodities such as meat (e.g., pork, poultry, fish), eggs, milk, leather, and wool. Horses, which provide labor, are also considered livestock in the United States.

Dent corn, the variety of MON 95379 maize subject of this EA, accounts for around 95% of animal feed grain production in the United States, a primary feed source for beef and dairy cattle, poultry, and hogs. Animal feed derived from dent corn comes not only from the grain, but also from silage (the above-ground portions of the corn plant), stalk residues in fields that might be grazed, and residuals derived from corn refining and milling, such as corn gluten feed, corn gluten meal, corn germ meal, corn steep liquor, and amino acids.

4.3.4.1 Potential Effects on Livestock Health and Welfare

As outlined in Section 3.2, "Preferred Alternative," this Environmental Assessment (EA) focuses solely on the analysis of small-scale, confined breeding, testing, and seed increase nurseries. These nurseries will be limited to no more than 100 acres per growing season across Nebraska, Hawaii, and Iowa (Bayer, 2022) and are not intended for livestock use in the U.S. If used for animal feed, MON 95379 maize/progeny would be expected to be of benefit to animal health and welfare. As discussed for human health, there are no risks to food animal health and welfare that are associated with the Cry1B.868 and Cry1Da_7 proteins traits present in MON 95379 maize. The nutrient composition of grain and forage samples derived from MON 95379 maize and a near-isogenic control corn was evaluated. The compositional analyses of grain included crude protein, crude fat, crude fiber, ash, carbohydrates, fatty acids, total amino acids, key anti-nutrients, and key secondary metabolites. Compositional analyses of forage included crude protein, crude fat, crude fiber, ash, carbohydrates, calcium, and phosphorus. No statistical differences were observed in any of the analytes measured in MON 95379 maize and as compared to other dent corn varieties. Based on these analyses, the grain and forage of MON 95379 maize are comparable to conventional corn with respect to nutrient composition (MON 2020). Bayer consulted with the FDA as to the safety of feed derived from MON 95379 maize, and FDA concludes with “no further questions” determination about the safety, nutrition, and regulatory compliance of human food from MON 95379 corn (US-FDA 2022).Based on the FDA’s consultation, laboratory data and scientific literature provided by Bayer (US-FDA 2022), and safety data available on other Bt products, APHIS has concluded that MON 95379 maize would have no anticipated significant impacts on the Livestock Health and Welfare.

4.3.5 Socioeconomics

4.3.5.1 Domestic and International Markets

4.3.5.1.1 U.S. Corn Commodities

The major U.S. feed grains are corn, sorghum, barley, and oats, with corn being the dominant one, representing over 95% of total feed grain production and use (USDA-ERS 2023b). The U.S. is the world's largest producer, consumer, and exporter of corn, with around 90 million acres planted annually, primarily in the Heartland region. In 2024, the United States produced 4.99 billion bushels of corn for grain. This production is a 22% increase from the previous June 1, 2023 report (USDA-NASS 2024a).

Most corn is used domestically for livestock feed and ethanol production, while also being processed into products like starch, sweeteners, corn oil, and alcohols. Corn exports are growing, accounting for about 15% of the country's total use (USDA-ERS 2023b; USDA-NASS 2024a). The primary dent corn commodities are animal feed and fuel ethanol, which account for around 40% – 48%, and 30% – 35% of use, respectively. The remainder is processed for food and industrial products. During processing, corn is either wet or dry milled depending on the desired end products:

- Wet millers process corn into high fructose corn syrup (HFCS), glucose and dextrose, starch, corn oil, beverage alcohol, industrial alcohol, and fuel ethanol.

- Dry millers process corn into flakes for cereal, corn flour, corn grits, corn meal, and brewers grits for beer production.

Both the dry-milling and wet-milling methods of corn processing generate economically valuable co-products, the most prominent of which are distillers' dried grains with solubles (DDGS), which can be used as a feed ingredient for livestock (USDA-ERS 2019a). In the United States, feed for both dairy and beef cattle has been the primary use of DDGS, but increasingly larger quantities of DDGS are making their way into the feed rations of hogs and poultry (USDA-ERS 2019a).

Dent/field corn accounts for around 90% to 95% of total U.S feed grain production and use on an annual basis (DIS 2017). The other three major feed grains are sorghum, barley, and oats. Across the United States, more than 9.6 billion food-producing animals are raised annually. These include broilers, turkeys, egg-laying hens (layers), hogs, dairy cows, cattle on feed, horses, fish (aquaculture), and sheep, all of which are raised on corn-based feeds (DIS 2017). Around 120 to 140 million tons of corn grain per year are used in feeds for these animals (DIS 2017).

4.3.5.1.2 Ethanol

The Renewable Fuel Standard (RFS) is a federal program that requires transportation fuel sold in the United States to contain a minimum volume of renewable fuels. It originated with the Energy Policy Act of 2005 and was expanded by the Energy Independence and Security Act of 2007. Congress created the RFS program to reduce greenhouse gas emissions and expand the nation's renewable fuels sector while reducing reliance on imported oil. The EPA implements the program in consultation with the USDA and the Department of Energy (US-EPA 2020e).

The RFS requires renewable fuel to be blended into transportation fuel in increasing amounts each year, escalating to 36 billion gallons by 2022. The four renewable fuel categories under the RFS are: biomass-based diesel, cellulosic biofuel, advanced biofuel, and total renewable (conventional) fuel, the latter of which typically refers to ethanol derived from corn starch. The RFS began mandating the use of corn ethanol in U.S. fuels in 2006.

U.S. corn processing capabilities allow for production of fuel ethanol and DDGS on a level currently unmatched by any other country. The ethanol industry was comprised of approximately 205 plants in 27 states with a production capacity of 17.1 billion gallons as of 2019. The United States produced 15.8 billion gallons of corn ethanol in 2019, this comprised 54% of global corn ethanol production (RFA 2019). The industry created $23.3 billion in household income and contributed $43 billion to the national Gross Domestic Product (RFA 2020).

4.3.5.1.3 IR crops

IR crops have proven effective in control of insect pests, and economically beneficial, thus the extent of their adoption in the United States (USDA-ERS 2015). From 1996–2018, IR corn targeting corn boring pests provided a 7% increase in yield, and increased farm income of $81/ha ($32.8/acre). (Brookes 2022)

Another economic benefit derived from IR corn varieties is the area wide suppression of insect pest populations. In areas where cultivation of Bt corn and Bt cotton is high there has been observed a reduction in insecticide use and associated costs in adjacent cropping systems cultivating non-Bt varieties—a result of the area-wide suppression of insect pest populations (NAS 2016a). Due to the use of IR maize, the cumulative global economic benefit between 1996 and 2020 has been $67.8 billion, with $3.7 billion of that earned just in 2020 (Brookes 2022). In general, current peer review literature and other reports indicate that cultivation of Bt crops can potentially provide tangential benefits to adjacent farms by tempering the prevalence of certain insect pest populations, reducing the need for insecticide use in Bt and nearby cropping systems (NAS 2016a; Brookes 2022).

4.3.5.2 International Trade

The United States is the world's largest corn producer providing over a third of the total supply of corn in the world market. Field (dent) corn is the largest component of global coarse grain trade—other grains include sorghum, barley, oats, rye, millet, and mixed grains—generally accounting for about two-thirds of the volume over the past decade (USDA-ERS 2019a). Field corn grain exports represent a principal source of demand for U.S. producers and make the largest net contribution to U.S. agricultural trade for all agricultural commodities—reflective of the importance of field corn exports to the U.S. economy. The United States currently exports between 10% and 20% of its annual production (USDA-ERS 2019a). In 2019, around 14.3% of production (13.7 billion bushels) was exported to more than 73 different countries (USGC 2020a), at an estimated value of around $7.6 billion (USDA-FAS 2020). The United States produces more ethanol and DDGS than consumers and industry can use, providing an ample export supply. As a result, the United States dominates trade in these two corn-based commodities. In 2018/2019, 1.55 billion gallons of U.S. ethanol—548 million bushels in corn equivalent—were exported to 69 countries (USGC 2020b). U.S. corn processed into fuel ethanol and DDGS generates around $4 to $5 billion in trade annually (USDA-FAS 2019).

U.S. corn exports are expected to remain steady over the next decade, largely due to demand for feed grains in support of meat production, and fuel ethanol (Westcott and Hansen 2015).

4.3.5.2.1 Identity Preservation

As food, feed, fuel, and industrial crop commodities and production systems have diversified to meet market demands, the need for segregation and identity preservation of agricultural commodities has increased. Farmers who grow corn that is used for different purposes in the same general area need to communicate and plan with their neighboring growers to ensure their crop commodity identities are preserved and price premiums can be realized (e.g., specialty starch corn, waxy corn, high lysine corn, blue corn). Identity preservation (IP) refers to a system of production, handling, and marketing practices that maintains the integrity and purity of various agricultural commodities (Sundstrom et al. 2002). IP typically involves independent, third-party verification of the identification, segregation, and traceability of a product's unique, value-added characteristic (USDA-AMS 2019b). Verification is provided at every stage, including seed, production, processing, and distribution. Seed certification programs such as that used by the Association of Official Seed Certifying Agencies (AOSCA) play a major role in maintaining seed purity standards at levels established by the industry for national and international trade (Sundstrom et al. 2002). Similarly, commodity traders, marketing organizations, and food processors have established purity and quality standards for specific end-product uses.

IP is important to international trade. The low-level presence (LLP) or adventitious presence (AP) of biotechnology-derived crop trait material in internationally traded conventional, organic, or other biotech crop commodities can disrupt trade and incur economic losses. LLP refers to the unintended presence, at low levels, of biotech crop material that is authorized for commercial use or sale in one or more countries, but not yet authorized in an importing country. AP refers to instances when trace amounts of biotech crop material that has not been approved for commercial use by any country is found in the commercial crop or food supply.

Asynchronous approvals—some countries may lag approval for import of new biotech corn varieties—and zero tolerance policies can result in the diversion of trade by some exporters, and rejection or market withdrawals by importers of corn. Consequently, incidents of LLP or AP can lead to income loss for exporters and consequently for producers, and consumers in importing countries can potentially face higher domestic prices when an import is deterred or directed to another trading partner (Atici 2014). The challenges associated with maintaining product identity in international trade can also increase costs, as well as the premiums paid, for certain biotechnology-derived crops.

In general, LLP/AP or compromise of corn commodity identity can cause disruptions in international trade when biotech crop trait material is inadvertently incorporated into food or feed shipments. As such, countries producing biotechnology-derived crops are required to take those measures necessary in the production, harvesting, transportation, storage, and post-harvest processing of biotech crops to avoid the potential for LLP/AP in conventional or organic crop commodities.

4.3.5.3 Potential Socioeconomic Impacts

4.3.5.3.1 Domestic Economic Environment

MON 95379 maize is produced for South America farmers and there are no socioeconomic impacts on the domestic environment expected. Other than small scale seed production in three states, there is no new varieties of corn and specialty commodities are expected to be developed and marketed domestically. Thus, the economic impacts associated with the introduction of MON 95379 maize into commerce would be considered potentially beneficial for farmers in South America.

As with synthetic chemical pesticides, insects are capable of developing resistance to Cry toxins, including those targeting lepidopteran pests. As adoption of Cry based IR corn increased over the last 20 years, without fully implemented insect resistance management (IRM) planning, the selection pressure on insects resistant to Cry toxins, or evolving resistance, became greater (Cullen et al. 2013). The first field evolved lepidopteran resistance to commercial Bt formulations was observed in a *Plutella xylostella* population in 1986 (Tabashnik et al. 1990). In 2002, Tabashnik et al. (2013) reported *Helicoverpa zea* as the first species reported to have evolved field resistance to Bt crops (cotton). Since then, several reports of field-evolved resistance to Bt crops have been published in recent reviews (Tabashnik et al. 1990; Tabashnik et al. 2013; B. Peterson 2017). Insect resistance to transgenic Cry traits can pose a threat to the long-term viability of the trait (US-EPA 2020g). New modes of action in PIPs targeting corn rootworm would be beneficial in maintaining sustainable corn rootworm management strategies in U.S. crops (Gassmann et al. 2016; Niu et al. 2017). MON 95379 maize would diversify the currently available Cry protein-based MOA for lepidopteran pest control through the combination of an RNAi mediated MOA and new Cry1B.868 and Cry1D_7 protein MOA. Because MON 9379 maize would provide farmers with an additional control option for management of lepidopteran pests —diversify PIP MOAs would be expected to provide economic benefits to growers and corn markets by protecting corn grain yields and helping sustain the efficacy of Cry1 based corn varieties.

Another potential economic benefit derived from IR corn varieties is the area wide suppression of insect pest populations. In some areas where cultivation of *Bt* corn and *Bt* cotton is high, there has been observed an associated reduction in insecticide use, and decrease in insect related crop injury in adjacent cropping systems cultivating non-*Bt* crops (Dively et al. 2018). In general, current peer review literature and other reports indicate that cultivation of *Bt* crops can potentially provide tangential benefits to adjacent farms by tempering the prevalence of certain insect pest populations, reducing the need for insecticide use in nearby cropping systems, and the associated costs (Dively et al. 2018; Frisvold 2019).

4.3.5.3.2 Beneficial Insect Populations

Biological control of plant pests provided by populations of predator and parasitoid species is an invaluable ecosystem service. It is an underlying pillar of IPM, and likely provides one of the highest returns on investment in IPM, yet its economic value has rarely been estimated (Naranjo et al. 2015). One seminal estimate valuing biological control, as an ecosystem service, arrived at a value of around $400 billion per year worldwide (Costanza et al. 1997). Studies providing sufficient data to estimate the value for arthropod natural enemies alone are rare and generally have valuated the avoided costs of insecticides, which, for an array of cropping systems have ranged from $0/acre to $918/acre ($2,202/ha).

Conservation biological control involves changes to the crop environment, such as the landscape in which the crop is embedded, to favor the abundance and pest-suppression activity of native or introduced natural enemies.[11] This involves minimizing factors that can harm natural enemies and/or providing them additional food and shelter (Naranjo et al. 2015). Cropland estimates for conservation biological control have suggested a value of around $14/acre ($33/ha) to $45/acre. (Pimentel et al. 1997; Naranjo et al. 2015). Losey and Vaughan (2006) estimated a value of $4.5 billion annually for the natural biological control of crop pests in the United States (Losey and Vaughan 2006), but this estimate may be very conservative (Landis et al. 2009).

In addition to functioning as biological controls for crop pests through predation and parasitism, beneficial insects provide pollination for more than two-thirds of the world´s cultivated plant species (Costanza et al. 1997). In the United States, the value of the pollination services has been estimated to be between $5 and $14 billion per year (Southwick and Southwick Jr 1992; Morse and Calderone 2000), from which a large proportion is attributed to insect pollinators (Losey and Vaughan 2006; González et al. 2016).

Insecticides are one of the more important and widely used tactics in IPM, but they can also become barriers to effective biological control. IR crops incorporating PIPs targeting specific species of insects,

[11] There are several approaches to biological control: natural, classical, augmentative, and conservation. Natural means the control of insect pests by predators and parasitoids as an ecosystem service. Classical means the intentional introduction of an exotic biological control agent for permanent establishment and long-term pest management. Augmentative means the release of additional numbers of a natural enemy when too few are present to control a pest effectively. Conservation means the intentional management of a landscape to support beneficial species.

and which are less reliant on chemical insecticides, generally have fewer impacts on arthropod biodiversity in and around crop fields, relative to broad-spectrum insecticide based cropping systems (Gatehouse et al. 2011; Romeis et al. 2019).

In general, PIP based insecticidal crops such as MON 95379 maize, for the most part, have the potential to be more environmentally benign than chemical insecticide-based pest management approaches (Gatehouse et al. 2011). While biodiversity will be inherently limited in commercial corn crops due to frequent disturbance, tillage, mechanized planting, planting of a monoculture crop, and application of fertilizers and pesticides, IR crops have generally reduced the environmental impacts of crop production (NRC 2010b; Carpenter 2011; NAS 2016a; Romeis et al. 2019).

4.3.5.3.3 Trade Economic Environment

MON 95379 maize is not intended for commercialization in the United States. Instead, Bayer's activities related to MON 95379 maize are strictly limited to small-scale seed increase nurseries.

Since Bayer will seek regulatory approvals for MON 95379 maize in South America to comply with global biotechnology regulations, there will be no commercial-scale production or marketing of MON 95379 maize in the U.S. The seed increase activities related to MON 95379 maize will continue to follow international standards and agreements, but commercialization is not planned or intended.

Bayer is a member of Excellence Through Stewardship® (ETS). Bayer products are commercialized in accordance with Bayer policies regarding stewardship of those products and with ETS policy. This stewardship program in part helps growers and marketers understand and meet their grain and grain byproduct marketing responsibilities and export approvals (MON 2020).

4.3.6 Compliance with Federal and State Laws and Regulations, Executive Orders, Policies, and Treaties

4.3.6.1 Federal Laws and Regulations

The laws most relevant to APHIS determinations of regulatory status are the National Environmental Policy Act of 1969 (NEPA), the Clean Water Act of 1972 (CWA), the Safe Drinking Water Act of 1974 (SDWA), the Clean Air Act of 1970 (CAA), the Endangered Species Act of 1973 (ESA), and the National Historic Preservation Act of 1966 (NHPA). Compliance with the requirements of the ESA has been addressed in section 4.3.3.7.2. Compliance with the requirements of NEPA, CWA, SDWA, CAA, and NHPA, are specifically addressed in the following subsections.

4.3.6.1.1 National Environmental Policy Act (NEPA)

NEPA (42 United States Code (U.S.C) 4321, *et seq*.) is designed to ensure transparency and communication of the possible environmental effects of federal actions prior to implementation. The Act and implementing regulations require federal agencies to document, in advance and in detail, the potential effects of their actions on the human environment, to ensure that there is a full understanding of the possible environmental outcomes of federal actions by both the decision-makers and the public. This EA documents the potential environmental outcomes of the alternatives considered, approval or denial of Bayer’s petition, consistent with the requirements of NEPA.

4.3.6.1.2 Clean Air Act, Clean Water Act, and Safe Drinking Water Act

The CAA, CWA, and SDWA authorize the EPA to regulate air and water quality in the United States. Because MON 95379 maize is agronomically equivalent to currently cultivated corn varieties, the potential sources of impacts on water resources and air quality are the same under both the No Action and Preferred Alternatives. MON 95379 maize production would entail the use of pesticides and fertilizers, and to some extent tillage, which will contribute to potential cumulative impacts on air quality, and potentially water quality. The sources and degree of potential impacts would be no different than that which occurs with current corn production. As discussed in Chapter 4, the transgenes and gene products extant in MON 95379 maize present no known risks to water or air quality. Considering these factors, approval of the petition would not lead to circumstances that resulted in non-compliance with the requirements of the CWA, CAA, and SDWA.

4.3.6.1.3 National Historic Preservation Act

The NHPA of 1966 and its implementing regulations (36 CFR part 800) requires federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate. Approval of the petition is not a decision that would directly or indirectly result in alteration of the character or use of historic properties protected under the NHPA, nor would it result in any loss or destruction of cultural or historical resources. MON 95379 maize would be cultivated on lands allocated or zoned for agricultural uses. As discussed in this EA, there are no weediness characteristics associated with MON 95379 maize that could impact historic properties.

4.3.6.2 Executive Orders Related to Domestic Issues

On January 20, 2025, President Trump issued Executive Order (EO) 14154 entitled “Unleashing American Energy,” and EO 14148 entitled “Initial Recissions of Harmful Executive Orders and Actions.” These EOs revoked multiple EOs related to, among other topics, climate change, environmental justice, and racial equity including, but not limited to, EOs 13985 and 14096. On January 21, 2025, President Trump issued EO 14173 entitled “Ending Illegal Discrimination and Restoring Merit-Based Opportunity,” which also revoked several EOs, including, but not limited to, EO 12898 related to environmental justice. On February 19, 2025, CEQ issued a Memorandum for Heads of Federal Departments and Agencies related to implementation of NEPA. In this memorandum, CEQ stated that EOs 14096 and 12898 related to environmental justice had been revoked and “[t]herefore, NEPA documents should not include an environmental justice analysis, to the extent that this approach is consistent with other applicable law.” Memorandum available at https://ceq.doe.gov/docs/ceq-regulations-and-guidance/CEQ-Memo-Implementation-of-NEPA-02.19.2025.pdf. As a result of President Trump revoking EOs 13985, 14096, and 12898 and CEQ’s February 2025 guidance, this draft EA does not include references to the revoked EOs or analyses.

The following executive orders (EO) require consideration of the potential impacts of federal actions on human health, cultural resources, wildlife, and the environment.

- **EO 13045 – Protection of Children from Environmental Health Risks and Safety Risks**

Children may suffer disproportionately from environmental health and safety risks due to their developmental stage, higher metabolic rates, and behavior patterns, as compared to adults. This EO requires each federal agency to identify, assess, and address the potential environmental health and safety risks that may disproportionately affect children.

The No Action and Preferred Alternatives were analyzed with respect to EO 13045. Neither alternative evaluated in this EA is expected to have disproportionate adverse impacts on children. As reviewed in the EA, it is highly improbable that the trait genes and gene products in MON 95379 corn present any risks to human health, nor to animal health and welfare.

- **EO 13175 – Consultation and Coordination with Indian Tribal Governments**

  Executive departments and agencies are charged with engaging in consultation and collaboration with tribal governments; strengthening the government-to-government relationship between the United States and Indian tribes; and reducing the imposition of unfunded mandates upon Indian tribes. The EO emphasizes and pledges that federal agencies will communicate and collaborate with tribal officials when proposed federal actions have potential tribal implications.

Tribal entities are recognized as independent governments and agricultural activities on tribal lands would only be conducted if approved by the tribe. Tribes would have control over any potential conflict with cultural resources on tribal properties. Approval or denial of the petition is not expected to have any effect on Indian tribal self-governance or sovereignty, tribal treaties, or other rights.

Consistent with EO 13175, APHIS generally sends petitions for consideration and approval by tribal entities. However, in this case, the product will be cultivated on a small scale, covering no more than 100 acres across three states. Due to its limited scope, it is unlikely to affect any tribal entities, and a request for tribal review was not submitted.

The No Action and Preferred Alternatives were analyzed with respect to EO 13045 and EO 13175. Neither alternative is expected to have a disproportionate adverse impact on children nor is any alternative expected to have potential Tribal implications.

- **EO 13751 – Safeguarding the Nation from the Impacts of Invasive Species**

  Invasive species are a significant issue in the United States, causing both adverse economic and environmental impacts. This EO directs actions to continue coordinated federal prevention and control efforts related to invasive species. This order maintains the National Invasive Species Council (Council) and the Invasive Species Advisory Committee; expands the membership of the Council; clarifies the operations of the Council; incorporates considerations of human and environmental health, climate change, technological innovation, and other emerging priorities into federal efforts to address invasive species; and strengthens coordinated, cost-efficient federal action.

One concern with the cultivation of certain transgenic crops is their potential dispersal or spread into non-agricultural areas. Field corn (*Zea mays*) is a crop plant that was domesticated, bred for thousands of years, for large-scale food production. Domestication of *Zea mays* has rendered this cultivar less capable of survival in the wild, it is largely dependent on humans for persistence in the environment and not typically found outside areas of cultivation (OECD 2003).

APHIS evaluated the potential weediness and invasiveness of MON 95379 maize and concluded that it is unlikely that MON 95379 maize will become weedy or invasive in areas where it is grown (USDA-APHIS 2020d). As discussed in Section 4.3.3.4–Gene Flow and Weediness of Corn, the potential for a weedy or invasive species of corn to develop because of outcrossing of MON 95379 maize with other sexually compatible species of corn, or wild *Tripsacum* species, is negligible. As APHIS concluded in its PPRA, the introduced trait genes in MON 95379 maize are not expected to alter characteristics associated with reproductive biology—change the ability of the plant to interbreed with other plant species (USDA-APHIS 2020d).

- **EO 13186 – Responsibilities of Federal Agencies to Protect Migratory Birds**

  The United States has recognized the critical importance of migratory birds as a shared resource by ratifying international, bilateral conventions for the conservation of migratory birds. These conventions impose substantive obligations on the United States for the conservation of migratory birds and their habitats. Through the Migratory Bird Treaty Act (Act) the United States has implemented these conventions with respect to the United States. This Executive Order directs executive departments and agencies to take certain actions to further implement the Act.

Migratory birds may transit corn fields and forage on corn, namely residual corn kernels left in the field post-harvest (Sherfy et al. 2011). For example, during migration, about 90% of the sandhill crane diet consists of corn, when corn is available (NGP 2020). As reviewed in this EA, it is unlikely the trait genes and their protein products present any risks to the health of migratory birds. MON 95379 maize is compositionally and nutritionally equivalent to non-modified corn comparators. Studies on the toxicity of the Cry1B.868 and Cry1D_7 proteins in MON 95379 maize find that birds are not sensitive to the two Cry proteins. There may be reduced availability of lepidopteran pest larvae in MON 95379 maize fields, however other insect species would be available, and the forage range of insect-eating birds is expected to be greater than the fields planted with MON 95379 maize. Rather, MON 95379 maize would likely provide a food source for some species of migratory birds.

4.3.6.3 State and Local Requirements

The PPA contains a preemption clause (7 U.S.C. § 7756) that prohibits state regulation of any, "plant, biological control organism, plant pest, noxious weed, or plant product" to protect against plant pests or noxious weeds if the Secretary (USDA) has issued regulations to prevent the dissemination of biological control organisms, plant pests, or noxious weeds within the United States. The PPA preemption clause does however allow states to impose additional prohibitions or restrictions based on special needs supported by sound scientific data or risk assessment. Consequently, while the PPA limits states' issuance of laws and regulations governing regulated organisms and bars conflicting state regulation, it does allow state oversight when there is a special need for additional prohibitions or restrictions.

States use a variety of mechanisms to regulate the movement or release of biotech crops within their jurisdiction. For example, South Dakota simply authorizes holders of a federal permit issued under 7 CFR part 340 to use within the state (SD Stat § 38-12A-31 (2015)). Minnesota issues state permits for release of genetically engineered organisms only after federal applications or permits are on file (MN Stat §

18F.07 (2015)). Nebraska may rely on APHIS or other experts before they issue their permit (NE Code § 2-10,113 (2015)). These illustrative examples show the range of state approaches to regulating the movement and release of biotech crops within state boundaries.

Neither of the alternatives considered would affect APHIS partnerships with states in the oversight of biotech crops, specifically in the regulation of environmental releases. Under both alternatives, APHIS would continue working with states. The range of state legislation addressing agricultural biotechnology, namely in the way of permitting, crop protection, seed regulation, and economic development, would be unaffected by denial or approval of the petition.

4.3.7 Conclusions: Potential Impacts on the Human Environment

As discussed in the Scope of Analysis for this EA (Section 4.1), in considering whether the effects of the proposed action could be significant, APHIS analyzed the affected environment and degree of the potential effects identified. As part of this analysis APHIS considered those requirements outlined in sections 102(2)(C)(ii),(iv), and (v) of NEPA which are addressed below. APHIS has not identified any significant impacts on the human environment that would derive from approval or denial of the petition.

4.3.7.1 Adverse environmental effects that cannot be avoided should the proposal be implemented.

Commercial scale crop production—whether a conventional, organic, or biotechnology-derived cropping system—always has some degree of environmental impact (Robertson and Swinton 2005; NRC-IM 2015; Ritchie 2017). The potential introduction of pesticides and fertilizers (organic or synthetic) to surface water or groundwater, soil erosion, fossil fuel use and emission of air pollutants, and effects on wildlife habitat and biodiversity are issues that all farmers, not just those growing biotech crops, work with in providing food, feed, fiber, fuel, and industrial products sufficient to meet societal needs. The degree of environmental impacts can be minor or noticeably adverse depending on a variety of factors that include the type and quantity of chemical/fertilizer inputs utilized; tillage practices; prevalence and diversity of insect pests and weeds; the efficacy of nutrient, insect pest, and weed management programs; geography and proximity of surface waters and groundwater to crops; local biota; weather; and cover cropping and crop rotation practices. With around 360,000 corn farms utilizing around 90 million acres of the land in the United States (USDA-NASS 2019c), the scale of potential impacts, namely in an aggregate sense, requires integration of crop production with sustainability and conservation practices—for biotech, non-biotech, and organic crops. While implementing such practices can often result in significant mitigation of environmental impacts, not all impacts can be fully attenuated, and some degree environmental trade-offs in crop production are inevitable (Robertson and Swinton 2005; NRC-IM 2015).

On approval of the petition, Bayer will not seek a commercial registration for MON 95379 from the EPA since it will not be commercialized in North America. Hence, upon approval of the petition, impacts of MON 95379 maize on land use and wildlife habitats would be negligible. Under the proposed terms of an EPA seed increase registration application, MON 95379 will be cultivated for small-scale breeding, testing, and seed increase nurseries with a maximum total of 100 acres per growing. The agronomic practices and inputs that would be used in the cultivation of MON 95379 maize, and any contribution of these practices and inputs to impacts on soils, water quality, or air quality, as well as biological resources, would be similar to that of other corn crops currently cultivated.

Since the production of MON 95379 maize is for South America, there are no federal, state, and private sector collaborative initiatives or support needed to alleviate the collective impacts of crop production on the physical environment (MON 2020).

4.3.7.2 The relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity.

Long-term agricultural productivity depends on the sustainable use of natural resources, namely topsoils, groundwater, populations of beneficial insects such as pollinators and plant pest predators, and the plants that support beneficial insects. MON 95379 maize is agronomically equivalent to other dent corn cultivars and utilizes the same types, and same/similar quantities of resources (e.g., groundwater, agronomic inputs), as all other conventional and biotech dent corn varieties. The annual production of MON 95379 maize would face the same challenges in sustaining air and water quality, and top-soils and soil quality as other corn crops. Any groundwater use is expected to be similar to that of other dent corn varieties—there is no indication this variety utilizes more or less water during development.

4.3.7.3 Irreversible or irretrievable commitments of resources that would be involved in the proposal should it be implemented.

An irreversible or irretrievable commitment of resources refers to impacts on or losses of resources that cannot be recovered or reversed. Irreversible commitments of resources involve those where the resources cannot be restored or returned to their original condition. Irreversible commitments entail the loss of future options and applies to the use of resources such as nonrenewable fossil fuels, and resources that are renewable only over long-time spans. Irretrievable is a term that refers to those resources that, once used or consumed, would cause the resource to be unavailable for use by others and future generations (e.g., land use).

Corn production involves the irreversible consumption of nonrenewable petroleum-based products (e.g., fuels necessary to operate equipment, cleaning agents, pesticide additives/adjuvants). Crude oil cannot be replaced once utilized for energy or other purposes. Some crop production systems may utilize renewable wind or solar energy sources. Topsoil is also considered nonrenewable; its erosional capacity can be affected by the types of tillage and irrigation systems employed on cropland. Over the long-term continued crop production on the same site can contribute to wind and sheet rill erosion. Materials such as aluminum, steel, wood, and plastics would be consumed as part of the process of crop production. Most of these materials are non-renewable and could be irreversibly utilized if not recycled (plastics, metals). Crop production inherently entails the irretrievable removal of natural habitat and associated wildlife from the landscape.

Renewable and nonrenewable resources utilized for MON 95379 maize production would differ little from that of other dent corn varieties. Any irreversible or irretrievable commitments of resources in MON 95379 maize production would be the same as or very similar to that of other dent corn cropping systems. Because MON 95379 corn is agronomically similar to currently cultivated corn varieties, small-scale seed increase production would not impact lands. Subtle variations in fossil fuel and energy use would occur relative to the frequency and duration of pesticide and fertilizer applications with this crop, and harvesting and facilities efficiencies, relative to other dent corn crops.

4.3.7.4 Whether the action would violate or conflict with federal or state laws or local requirements governing protection of the environment.

As reviewed in Section 4.3.8, approval of the petition would not lead to circumstances that resulted in non-compliance with any federal, state, or local laws and regulations providing protection for environmental and human health.

4.3.7.5 Possible conflicts between the proposed action and the objectives of federal, regional, state, tribal, and local land use plans, policies, and controls for the area concerned.

There are no conflicts with approval of the petition, and subsequent commercial production of MON 95379 maize, with federal, state, tribal, or local land use plans or policies.

4.3.7.5.1 Federal Lands

There are four major federal land management agencies that administer 606.5 million acres (as of September 30, 2018). These are the Bureau of Land Management (BLM), Fish and Wildlife Service (FWS), National Park Service (NPS) in the Department of the Interior (DOI), and the Forest Service (FS) in the USDA. A fifth agency, the Department of Defense (DoD), administers 8.8 million acres in the United States (as of September 30, 2017). Together, the five agencies manage about 615.3 million acres, or 27% of the U.S. land base (CRS 2020). Many other agencies administer the remaining federal acreage. The lands administered by the four major agencies are managed primarily for purposes related to preservation, recreation, and development of natural resources (CRS 2020).

APHIS approval of the petition would have no effect on lands governed by federal land management agencies. Any cultivation of MON 95379 maize on federal lands would require approval by a federal land management agency.

4.3.7.5.2 Tribal Nations, State and Local Land Use Plans and Policies

Approval nor denial of the petition is not expected to have any effect on Tribal Nations self-governance or sovereignty, tribal treaties, or other rights. The No Action and Preferred Alternatives were analyzed with respect to EO 13045 and EO 13175. Neither alternative is expected to have a disproportionate adverse impact on children nor is any alternative expected to have potential Tribal implications.

4.3.7.6 Energy requirements and conservation potential of various alternatives and mitigation measures.

There will be no commercial-scale production or marketing of MON 95379 corn, therefore the energy requirements involved with the full life cycle of MON 95379 maize production and marketing would differ little from that of other commercial corn crops. USDA-NRCS provides guidance on energy management in crop production via practices such as integrated pest management, precision agriculture, irrigation water and nutrient management, and crop residue management (USDA-NRCS 2020a). Energy conservation estimation tools are also provided to help growers estimate costs and saving associated with irrigation, nitrogen use, and tillage.

4.3.7.7 Natural or depletable resource requirements and conservation potential of various alternatives and mitigation measures.

There are no depletable resource requirements unique to the production and marketing of MON 95379 maize. Use of natural resources (e.g., irrigation water, soils, fertilizers) would be no different than that of other corn varieties. Natural resource conservation opportunities, whether USDA funded or otherwise implemented by growers or/and state agencies would not differ from that of other conventional and biotechnology-derived commercial corn crops. Available mitigation measures to curtail potential environmental impacts, such as those summarized below in 4.3.8.9, would likewise not differ.

4.3.7.8 Urban quality, historic and cultural resources, and the design of the built environment, including the reuse and conservation potential of various alternatives and mitigation measures.

As discussed in 4.3.7– Compliance with Federal and State Laws and Regulations, Executive Orders, Policies, and Treaties, cultivation of this corn variety would not be expected to directly or indirectly result in alteration of the character or use of historic properties protected under the NHPA, nor result in any loss or destruction of cultural or historical resources. The design of the built environment in relation to crop production activities would be resolved at the state local and state levels of governance (e.g., city, county, and/or state authorities governing land use).

4.3.7.9 Means to mitigate adverse environmental impacts.

There are several federal, state, and private sector collaborative initiatives to help farmers alleviate the collective impacts of crop production on the physical environment, as well as biological resources. Some of the USDA and partner programs supporting agricultural sustainability and natural resources conservation are summarized below. Practices will vary from region to region and farm to farm, however, some common sets of practices have emerged, including integrated insect pest and weed management, soil conservation tactics, water resources conservation and protection, cropland biodiversity, and nutrient management. Each contributes in some way to environmental stewardship, long-term farm sustainability, and improved quality of life. For a more detailed description of USDA sustainability and conservation initiatives, see the USDA websites provided in the references below.

The EPA Mississippi River/Gulf of Mexico Hypoxia Task Force (US-EPA 2017b) and USDA Natural Resources Conservation Service (NRCS) National Water Quality Initiative (NWQI) (USDA-NRCS 2017) aim to reduce NPS contaminants in agricultural run-off, and run-off itself. The purpose of the NWQI, in collaboration with the EPA and state water quality agencies, is to reduce nonpoint sources of nutrients, sediment, and pathogens related to agriculture in high-priority watersheds in each state.

The USDA funded Sustainable Agriculture Research and Education Program (SARE) supports sustainable agricultural practices that are intended to protect the environment, conserve natural resources, and promote cropland biodiversity (USDA-NIFA 2017).

The USDA-NRCS's Natural Resources Conservation Programs help people reduce soil erosion, enhance water supplies, improve water quality, increase wildlife habitat, and reduce damages caused by floods and other natural disasters (USDA-NRCS 2019c).

The USDA-NRCS Environmental Quality Incentives Program (EQIP) provides financial and technical assistance to agricultural producers to address natural resource concerns and deliver environmental benefits such as improved water and air quality, conserved ground and surface water, increased soil health and reduced soil erosion and sedimentation, improved or created wildlife habitat, and mitigation against increasing weather volatility (USDA-NRCS 2020b).

The USDA–NRCS Regional Conservation Partnership Program (RCPP) specifically promotes coordination of NRCS conservation activities with partners that offer value-added contributions to expand USDA's collective ability to address on-farm, watershed, and regional natural resource concerns (USDA-NRCS 2020d). The 2018 Farm Bill made a number of substantial changes to RCPP: RCPP is now a standalone program with its own funding of $300 million annually.

The USDA National Institute of Food and Agriculture (NIFA) promotes sustainable agriculture through national program leadership and funding for research and extension. It offers competitive grants programs and a professional development program, and it collaborates with other federal agencies through the USDA Sustainable Development Council (USDA-NIFA 2017).

The USDA Conservation Reserve Program (CRP) is a voluntary land retirement program that provides financial compensation to landowners to remove highly erodible and environmentally sensitive land from agricultural production and install resource-conserving practices or preserve wildlife habitat. CRP is the largest federally administered private-land retirement program, with annual outlays approaching $2 billion per fiscal year. CRP enrollment is capped each year, and under the 2014 farm bill, enrollment was limited to no more than 24 million acres during fiscal years 2017 and 2018. The 2018 farm bill expanded CRP acreage to a maximum of 27 million acres by 2023. Nearly 24 million acres are enrolled in CRP as of 2019 (NSAC 2020).

4.3.7.10 Economic and technical considerations, including the economic benefits of the proposed action.

Economic considerations have been evaluated in Section 4.3.6–Socioeconomics. The economic impacts associated with the introduction of MON 95379 corn into commerce would be potentially beneficial, to both farmers and corn commodities markets.

4.3.7.11 The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.

Unlike previously registered Bt events, Cry1Da_7 and Cry1B.868 both have high toxicity to monarch butterflies, and Cry1B.868 has relatively high protein expression levels in the pollen. Since Bayer will not pursue commercial registration for MON 95379 in North America, it will have no impact on endangered or threatened species, nor on habitats designated as critical under the Endangered Species Act of 1973. This conclusion is based on the limited acreage for seed production, which minimizes the potential for exposure. If Bayer later chooses to commercialize MON 95379 maize in the U.S., they would need to apply to the EPA for an Environmental Risk Assessment.

4.3.7.12 The degree to which the proposed action affects public health or safety.

As reviewed in Section 4.3.4–Human Health, approval of the petition and subsequent availability of MON 95379 maize to commercial markets would not present any risks to public health or worker safety.

4.3.7.13 Whether the affected environment includes reasonably foreseeable environmental trends and planned actions in the affected areas.

Approval of the petition would provide for the commercial production of MON 95379 maize, subject to any FDA consultation, and EPA and state requirements. APHIS maintains a publicly available list of petitions and determinations of nonregulated status on its website (USDA-APHIS 2019). Genetically engineered insect and herbicide resistant varieties of corn were first deregulated in 1995 (USDA-APHIS 2020b), with adoption rates increasing rapidly in the years that followed. As of November, 2020, APHIS has issued determinations of nonregulated status in response to 38 petitions for biotech corn varieties, all but one of these are insect and/or herbicide resistant. Currently, over 90% of U.S. corn, upland cotton, and soybeans are produced using transgenic varieties. Annual production of corn comprises around 90 million acres.

Farmers generally adopt a biotech crop based on the benefits they can derive from it, such as effective insect pest or/and weed control, increased crop yields per acre, increased farm net returns, and time savings (Fernandez-Cornejo et al. 2014b; Brookes and Barfoot 2018a). Potential net benefits are a function of the particular crop farmed and geographic location; pest and weed pressures; agronomic input and market commodity prices; and efficacy of existing on-farm crop production systems.

Advances in agricultural biotechnology are expected to continue, and refine the precision with which crop varieties will be developed, leading to a greater diversity of commercial crop varieties (NAS 2016a). While it is difficult to predict the scope of improved crop varieties that will emerge in the coming years, traits likely to be introduced and adopted by growers include improved tolerance to abiotic stresses such as drought and temperature extremes; increased efficiency in plant physiological processes such as photosynthesis and nitrogen use; resistance to fungal, bacterial, and viral diseases; and new types of herbicide resistance (NAS 2016a).

All biotechnology-derived crops in commercial production in the United States have undergone review—and will continue to undergo review—under the Coordinated Framework (summarized in Section 1.3). For those biotechnology-derived plants that APHIS has determined are not subject to 7 CFR part 340, APHIS evaluated the plant and incorporated trait for potential plant pest risks, and potential environmental impacts via NEPA analyses (USDA-APHIS 2019). In general, to date, biotechnology-derived crops have been found to have no more or fewer adverse effects on the environment than non-biotech crops produced conventionally (NRC 2010b; NAS 2016a; Brookes and Barfoot 2017). Future requests for deregulation and introduction of biotechnology-derived crops would continue to be subject to APHIS review for plant pest risk, NEPA analyses as appropriate, and EPA and FDA requirements under the Coordinated Framework.

APPENIDX 1: LIST OF PREPARERS

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Name, Title, Project Function	**Education and Experience**
Elizabeth Nelson *Chief, Environmental Risk Analysis Services* Reviewer	▪ Ph.D., Public Health, Capella University ▪ MBA, University of Maryland University College ▪ M.S., Health Care Administration, University of Maryland University College ▪ B.S., Biology, Bowie State University ▪ 18years of professional experience in environmental compliance, policy, and management, including preparation of NEPA documentation
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Adam Tulu EA Team Lead	▪ Ph.D., Environmental Biochemistry, University of Maryland ▪ B.S., Environmental Science, University of Maryland ▪ B.S., Computer Science, Hilcoe School of Computer Science, Ethiopia ▪ Certified on NEPA analysis from Utah State University ▪ 10 years of professional experience in biochemistry and molecular biology ▪ 9 years of professional experience in NEPA analyses and environmental risk assessment of genetically engineered organisms
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