



# **Industrial Hemp Agricultural Research Pilot Program Program Guidance**

## **Statutory Authority**

The recently enacted 2018 Farm Bill changed the requirements for growing industrial hemp in the United States. Foremost among those changes, the 2018 Farm Bill removes industrial hemp from the federal list of controlled substances and defines hemp as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”<sup>1</sup>

The 2018 Farm Bill authorizes the U.S. Department of Agriculture (USDA) to establish a national licensing system for hemp and to adopt federal regulations for industrial hemp licensing. The Farm Bill also provides states the option to obtain primary regulatory authority for industrial hemp in that state, pursuant to a USDA-approved plan.<sup>2</sup>

The only lawful pathway to grow industrial hemp in New York State is through participation in New York’s Industrial Hemp Agricultural Research Pilot Program (the Program), authorized under the provisions of the 2014 Farm Bill and administered by the Department of Agriculture and Markets (the Department). Anyone planning to grow industrial hemp or process industrial hemp for any purpose in New York State must obtain an authorization as a Research Partner before they can undertake their project.

## **Industrial Hemp Agricultural Research Pilot Program**

Under current New York State law, industrial hemp and products derived from such hemp are agricultural products that may be grown, produced and possessed in the state

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<sup>1</sup> New York’s Controlled Substances Act does not exclude industrial hemp from the state law definition of *Cannabis sativa* L. However, participants in the Agricultural Research Pilot Program that operate within the scope of their Research Partner Agreement may engage in their research work involving industrial hemp notwithstanding the scheduling of certain parts of the *Cannabis sativa* L. plant as a controlled substance under state law. (See Section 506 of Agriculture and Markets Law)

<sup>2</sup> As of April 2019, the USDA has not yet issued guidance for its new hemp-licensing program.

only as part of the Program. No other growing or processing of industrial hemp in New York State is permitted (Agriculture and Markets Law, Section 506).

Institutions of higher education and research partners approved by the Department may undertake research projects to study the growth and cultivation, sale, distribution, transportation and processing of such hemp and products derived from such hemp. This program requires that those growing or cultivating industrial hemp must be registered with the Department.

The Program has three authorization types: (1) growing industrial hemp; (2) processing for non-CBD purposes (food, fiber, industrial material and/or other non-cannabinoid uses); and (3) processing for CBD purposes.<sup>3</sup> For each of these authorizations, the Department requires, among other things, the description of the proposed research, the identification of the location(s) of the growing or processing operations, and the identification and disclosure of information concerning the individuals involved in the research project. If the project is approved, the Research Partner must sign a Research Partner Agreement which sets forth the approved scope of work and the terms and conditions of the authorization to engage in the specified research.

## **Applications**

Those seeking to participate in the Program must submit an application. If the application is approved, the applicant must execute a Research Partner Agreement, which, among other things, describes the authorized scope of work, establishes the standards for the work, and sets forth the respective duties and obligations of the parties.

An application to grow or process industrial hemp shall be made upon a form prescribed by the Commissioner and shall include an application fee of \$500. No waivers of the application fee will be granted.

The application is for a three-year authorization to participate in the Program. It is anticipated that with the implementation of the USDA's hemp licensing program authorized by the 2018 Farm Bill, the Department will terminate the Research Partner Agreements and transition the Research Partners to the licensing/approval structure authorized by the USDA.

Each application and renewal application shall provide the information deemed necessary by the commissioner, including but not limited to:

- A description and map of each location where industrial hemp will be cultivated or possessed, by physical address and by GPS co-ordinates, visually depicting

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<sup>3</sup> The Department no longer issues authorizations for farmers as "affiliated growers" of a Research Partner. Every farmer growing hemp must have its own grower Research Partner Agreement.

the buildings, structures, and improvements on the premises and identifying their use, and describing the relevant activities conducted at the location.

- A detailed research plan and summary of the issues and matters that the applicant intends to study in conjunction with growing, cultivating, or processing industrial hemp.
- A marketing plan.
- A seed/propagule acquisition plan.
- Statement of relevant experience of the individual responsible for the research project.
- \$500 application fee.

## **Disqualifying Factors**

*An authorization to conduct research in this Department pilot program is not a right. The decision to grant such an authorization is in the sole discretion of the Department based upon, among other things, its needs or interests, the evaluation of the proposed project, and the qualifications and experience of the applicant.*

Disqualifying factors may include but are not limited to:

- An incorrect or incomplete application
- Poor research design
- Lack of experience or qualification to undertake the proposed project
- Recent drug-related felony or misdemeanor convictions of researchers
- Proposing to use a growing or processing location already registered by an existing Research Partner
- Inability of the Department to adequately supervise or regulate the proposed project
- The proposed undertaking of medical research
- The proposed use of processed CBD as a food additive or the processing of food in such a way to concentrate CBD content.

## **Overview of the Application Review Process**

Once an applicant submits a completed application to the Department with a \$500 application fee, the next steps are as follows:.

1. The Department reviews the application and notifies the applicant of the decision.
2. The Department will send approved applicants a Research Partner Agreement to be signed and notarized by the applicant.
3. The applicant will return the signed and notarized Research Partner Agreement to the Department.
4. Upon receipt, the Department will issue and mail to the Research Partner (formerly the applicant) an official Industrial Hemp Research Partner Authorization and the fully executed Research Partner Agreement.

***An applicant is not authorized to grow or process industrial hemp until it has received the official Industrial Hemp Research Partner Authorization document from the Department.***

## **Amendments to Applications**

Research Partners can submit requests to amend their original application by submitting a Grower Amendment Form. Amendments may include, among other things, adding additional acreage, change of location of grow sites, and changes to the scope of work contained in the research plan set forth in the initial application. All requests to amend are subject to review and approval by the Department. Amendments to an existing Research Partner's scope of work are not subject to the \$500 application fee.

Compliance with prior years' program reporting requirements, if applicable, is a condition to the granting of an amendment.

## **Renewal of Applications**

It is the responsibility of the Research Partner to submit an application renewal in a timely fashion to ensure that its current authorization to participate in the Program does not lapse. An application renewal should be submitted at least 60 days prior to the expiration date printed on the authorization document. Research Partners interested in renewing must submit the appropriate application document and should check the box labeled Renewal.

## **Acquisition of Seeds and Plants**

- **Purchasing Seed:** Seed procurement is the responsibility of the Research Partner. Research Partners who plan to obtain seed through an international import should check with the seed supplier to determine what documentation is required for such a transaction.
- **Selling Seed:** Viable industrial hemp seed shall not be sold to any individual or entity not authorized as a Research Partner.
- **Purchasing Hemp Plants:** Industrial hemp plants may be procured only by Research Partners and they may be purchased only from an authorized New York State Research Partner or from a license holder from another state that has a pilot program. All interstate shipments of hemp plants must be from a plant grower licensed in the state of origin or be accompanied by a phytosanitary certificate.
- **Compliance with seed laws:** Be aware of [plant variety protection \(PVP\) laws](#) and regulations and be certain that the seed procured is in compliance with PVP and all other applicable New York State seed laws and regulations. More information on New York's seed laws may be found at <http://www.agriculture.ny.gov/PI/commodities/ARTICLE9.pdf>.

## Inspections

The Research Partner shall inspect the registered locations as often as necessary to ensure compliance with the requirements of the Program.

The registered locations of a Research Partner are subject to inspection by the Commissioner and by his or her authorized agents, employees, or officers, pursuant to Agriculture and Markets Law section 20, as often and to the extent necessary to ensure compliance with the respective Research Partner Agreement and State and Federal laws relating to the possession, sale, or cultivation of industrial hemp. The Commissioner may authorize agents, employees, or officers of the New York State Department of Health and law enforcement to accompany him or her during an inspection of the registered locations of a Research Partner.

## Sampling

1. A Harvest Report Form (available at <https://www.agriculture.ny.gov/PI/hemp-harvest-report-form.pdf>) must be submitted to the Department at least 20 days prior to the expected harvest date.
2. Once the Department has received the form, a Horticultural Inspector will contact the grower to set up a date, time, and location for inspection.
3. The Horticulture Inspector will arrive on site to take a pre-harvest sample, ideally within 14 days of harvest.
4. The Horticulture Inspector will verify that the locations and descriptions of the industrial hemp fields are consistent with what was reported on the original application and on any addendum to the original application.  
The Horticulture Inspector will collect samples in labeled paper bags and will send the composite sample to the Department for testing.

## Testing for THC Levels

1. A Research Partner shall prepare, maintain, and make available to the Commissioner, upon request, a record that sets forth an accurate inventory of industrial hemp plants and seeds and shall reasonably ensure that the industrial hemp seed and/or plants that are possessed or grown or cultivated meet the definition of industrial hemp.
2. In addition to regulatory testing conducted by the Department, Research Partners are encouraged to submit industrial hemp samples to a third-party laboratory for THC testing of their crop to ensure compliance. The Department does not maintain a list of approved testing labs.
3. The Research Partner shall immediately make available to the Department such records relating to sampled specimens with a concentration above 0.3 percent of

delta-9 tetrahydrocannabinol on a dry basis, in a form and at a location satisfactory to the Commissioner.<sup>4</sup>

## **Destruction of Noncompliant Material**

A Research Partner shall promptly dispose of all industrial hemp in its possession reasonably believed, based upon the results of regulatory or other sampling, to have a concentration of more than 0.3 percent of delta-9 tetrahydrocannabinol on a dry weight basis.

## **Required Testing of CBD Products**

Research Partners making any CBD product intended for human or animal consumption or absorption into the body must ensure their CBD products meet the standards set by the New York State Medical Marijuana program (10 NYCRR Part 1004.14) with respect to cannabinoid profile, solvents, pesticides, heavy metals, bacteria and molds. Research Partners must use an independent laboratory accredited by either the ISO/IEC 17025:2005,2017 standard or the NYS Department of Health Wadsworth Laboratory Environmental Laboratory Approval Program (ELAP).

## **Process Audits of CBD Processing Facilities**

In accordance with the Department's CBD Processor Research Partner Agreement, any facility manufacturing CBD products intended for human or animal consumption or absorption into the body shall be audited prior to sale or distribution of product to verify compliance with the relevant federal standard (as bulleted below). Such audits must be conducted by a qualified, independent third party. The results of such a third-party audit shall be submitted to the Department prior to sale or distribution of the product. The third-party audit must provide evidence that the CBD processor is complying with the following requirements:

- A CBD product developed and/or produced under a Research Partner Agreement, to the extent it is or will be a component of a dietary supplement,<sup>5</sup> shall satisfy the requirements of the Research Partner Agreement if manufactured, tested and labeled in accordance with this agreement and FDA law and regulations concerning dietary supplements, including, without limitation, 21 CFR 111.403(L) and 21 CFR 101.

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<sup>4</sup> In line with Department testing procedures, the sum of both delta-9 tetrahydrocannabinol and THCA is used to define the percent of delta-9 tetrahydrocannabinol on a dry-weight basis. In prior years, the Department based its compliance determinations on THC content only. However, the Department has adopted the 2018 Farm Bill requirement to test the sum of THC and THCA.

<sup>5</sup> A *Dietary Supplement* is any product a product intended to supplement the diet, containing a vitamin, mineral, herb, botanical, amino acid, and/or dietary substance used to supplement a person's diet by increasing the total dietary intake and as further specified in § 201(ff) of the Food Drug and Cosmetic Act

- A CBD or other cannabinoid product developed and/or produced under a Research Partner Agreement, to the extent it introduces cannabinoids into or onto the human body or the body of an animal through topical application or other method for purposes other than as a dietary supplement, the Research Partner shall satisfy the requirements of the Research Partner Agreement if the product is manufactured and labeled in accordance with 21 CFR 111 and 21 CFR 201 and complies with the provisions set forth in the Research Partner Agreement.

To be considered qualified by the Department, a third-party auditor must be accredited by the American National Standards Institute, the ANSI National American Board, or the International Standards Organization (ISO) in the field of dietary supplement manufacturing.<sup>6</sup>

Applicants should be aware that the U.S. Food and Drug Administration has taken the position that CBD products are *not* dietary supplements. Applicants should understand the different regulatory approaches of the FDA and the State, and they should seek competent professional guidance with respect to the risk of engaging in the processing of CBD and the manufacture of CBD products under all applicable law. All Research Partners must make their own independent determination with respect to the legal obligations and requirements under federal and state law with respect to any product it produces.

## **Annual Reports**

All Research Partners are required to file an annual report summarizing the results of their research pilot project and presenting any data collected in the course of that research. Annual reports are due on the anniversary of the project start date. Failure to file annual reports in a timely manner is grounds for revocation of permit.

## **Other Considerations**

- Losses sustained due to violation(s) of state or federal law, weather or any other condition during the course of the research are the responsibility of the Research Partner. Applicants who are unable to bear the potential loss of assets and production costs of participating in the Industrial Hemp Agricultural Research Pilot Program should not apply to become Research Partners.
- No pesticides are registered nationally or at the state level for industrial hemp. Research Partners are warned that any pesticide applications made to industrial hemp crops are unregistered uses and are subject to enforcement action from New York State Department of Environmental Conservation.

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<sup>6</sup> Examples of accredited third-party auditors in the field of dietary supplement manufacturing include the U.S. Pharmacopeial Convention, the Underwriters Laboratories Registrar, and NSF International.

- The Department reserves the right to make determinations regarding the appropriateness of proposed growing and/or processing locations. Applicants must have an ownership or lease interest in the growing/processing location.
- Shared processing facilities are not allowed.
- Growing of industrial hemp in residential settings or as an ornamental is not allowed.

## Glossary of Terms

**Authorization:** the final document issued upon approval of an Industrial Hemp Research Pilot Program application and the execution of the Research Partner Agreement, which allows the Research Partner to participate in the Program.

**CBD (Cannabidiol):** an extracted chemical component of the *Cannabis sativa* plant that is commonly used in wellness products.

**Fiber, Grain or other Industrial Use:** industrial hemp grown, processed and/or used for other than CBD-related purposes.

**Growing of Industrial Hemp:** the planting and cultivation of *Cannabis sativa* with a THC content of not more than 0.3 percent, up to and including the harvesting and drying of the crop. Growing of industrial hemp does not include any processing steps beyond harvesting and drying.

**Harvest Report:** the document filed within 20 days of the anticipated date of harvesting an industrial hemp crop. Filing the Harvest Report starts the process of scheduling a time for a NYS Horticulture Inspector to visit the grow site to take samples of the industrial hemp plants that will then be sent to the Department for THC testing. The Harvest Report form can be found at <https://www.agriculture.ny.gov/PI/hemp-harvest-report-form.pdf>

**Research Partner:** a person or entity that has been authorized by the Department to grow and/or process industrial hemp as part of the NYS Industrial Hemp Agricultural Research Pilot Program.

**Research Partner Agreement:** the agreement that sets forth the terms and conditions for the research pilot, including, among other things, the scope of work, permitted activities, and obligations of a Research Partner in the Department's Program. Sample Research Partner Agreements are available for review on the Department's website at <https://www.agriculture.ny.gov/PI/PIHome.html>

**Scope of Work:** the information provided in the application or approved amendments to participate in the Industrial Hemp Agricultural Research Pilot Program as a Research Partner.

**For assistance with questions regarding the NYS Industrial Hemp Research Pilot Program, please call (877) 249-6841.**