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Regulatory Analysis and Development  
Policy and Program Development  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
Station 3A-03.8  
US Department of Agriculture  
4700 River Road, Unit 118  
Riverdale MD 20737-1238

**SUBJECT: Request for Public Comment:**  
**Draft List of Taxa that Are or Contain Plant Pests**  
**Docket ID APHIS-2024-0046**  
**Submission of Comments**

To Whom It May Concern:

Thank you for the opportunity to comment on the subject **Request for Public Comment** concerning USDA-APHIS-BRS's **Draft List of Taxa that Are or Contain Plant Pests** (hereinafter **Draft List**). The Biological Products Industry Alliance (BPIA) submits herewith these comments.

By way of introduction, BPIA promotes the responsible development of safe and effective biological products, including biopesticides, biofertilizers, and biostimulants. These beneficial tools are used in various settings, including commercial agriculture, forestry, golf courses, home gardens, horticulture, and ornamentals. BPIA also supports public health through education, outreach, and advocacy activities at the state, federal, and international levels. BPIA's membership includes large and small producers of biological products used extensively by US farmers, including organic growers, and producers of pesticide inert ingredients.

## DISCUSSION

BPIA is grateful for the opportunity to provide input on this **Draft List**. BPIA is committed to leveraging scientific understanding to underscore the importance of biological products in agriculture, their usefulness, and their environmental advantages. Embracing biological products can substantially decrease greenhouse gas emissions, contributing to sustainability through bio-based solutions.<sup>1</sup>

## COMMENTS ON THE DRAFT LIST AND ITS UTILITY

BPIA appreciates BRS's efforts and partnership with the American Phytopathology Society (APS) to develop this **Draft List**. After thorough review, BPIA offers the following comments and suggestions related to the scope and regulatory purpose of the **Draft List**.

### 1. PURPOSE OF THE DRAFT LIST

BPIA is interested in understanding the intent and impact of this **Draft List** on BRS decision-making, with the objective that this effort will provide guidance and increased regulatory certainty. BPIA urges BRS to share the literature sources used by all organizations consulted in the preparation of this **Draft List**. As BRS has noted, this **Draft List** will evolve and change over time based on innovation and sensitivity improvements in the techniques to identify microorganisms; currently accepted scientific evidence; and studies of developers, researchers, and the Agency.

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<sup>1</sup> See references listed in Enclosure 1.

In an announcement email describing the new **Interactive Tool for Genetically Modified Microorganisms<sup>2</sup>** (“**GM Tool**”) released by USDA, EPA, and FDA on October 2, 2024, APHIS states the following:

*“Due to continuous progress in the understanding of plant disease, a complete list of all plant pests is unavailable. In general, USDA/APHIS regulates organisms by species, rather than by subspecies, strain, or other sub-grouping, when determining plant pest status of an organism. If you are unsure whether your genetically modified microorganism is a plant pest, please consult the Plants and Microbes branch of the USDA/APHIS/BRS at [biotechmicrobes@usda.gov](mailto:biotechmicrobes@usda.gov) and provide information on the microorganism as well as the genetic modification.”<sup>3</sup>*

Given this statement, BPIA seeks to understand how the **Draft List** will be used, applied and maintained.

Having a basic list at the species level may result in overly simplistic evaluations based on the **Draft List** alone, without any consideration of the details of the product to be used and how it is intended to be utilized. The majority of taxa on the **Draft List** are native to the United States, some in overwhelming abundance. Developers seeking to use such organisms must provide data and/or literature substantiating the presence or prevalence of the organism of interest in the release area. This extensive level of detail is required to support both common organisms, such as *Bacillus subtilis*, as well as for organisms that are less commonly known or used. BPIA requests that BRS consider a mechanism as part of this **Draft List** to consider exemption of a particular species or strain from BRS oversight if the species or strain can be demonstrated to have little or no new or additional pathogenic effect on plants.

BPIA suggests that this current iteration of the **Draft List** be reviewed taking prevalence into consideration. Several groups within USDA already collect detailed information on occurrence and prevalence of microbial species in the US. If an applicant provides data to demonstrate prevalence and abundance of an organism in the environment (particularly in the state/area in which transport/release is intended), that organism likely poses no additional plant pest risk as proposed. Its prevalence should be considered in a similar manner to the current PPQ permit process and subject to exemption from BRS oversight. For wild-type strains, developers must have evidence through scientific-literature or soil analysis of an organism’s presence in a state or region to receive approval to release it in the environment under PPQ’s permitting regulations in **7 CFR Part 330**. If an organism is already present in the environment, such indigenous existence should be a consideration as to whether its proposed use would pose any increased plant pest threat to the environment and should also be an important mitigating factor as to that organism’s inclusion on such a **Draft List**.

Additionally, BPIA asks BRS to consider that the **Draft List** could be used inaptly and without context by other regulatory bodies at the federal, state, and international level. Although this information is not intended for non-USDA purposes, this information may yet be consulted for uses for which it is not well-suited. As an example, individual states and tribes often look to federal guidance documents, including lists like this one, when reviewing agricultural-use products, as those non-federal authorities are often the primary registration and enforcement lead agency for agricultural biological products. To the extent possible, it is important to be clear as to the scope of the policy and to avoid confusing and contradictory information for products that are already approved and registered, such as biopesticides that have EPA approval but also require concurrent state registration or renewal. Several organisms on the **Draft List** are duly-registered biopesticide products, yet their use and continued state registrations could be called into question even though they have been thoroughly reviewed and pose no plant pest risk when used for their labeled and intended uses.

There are other regulated and approved uses of microbial organisms outside of agriculture—human, animal, and food ingredients—to be considered as well. Providing further information around the scope, intended audience, and use cases will be helpful to avoid misinterpretation and misapplication of this **Draft List** by others.

Maintenance of this **Draft List** and any other similar tools (such as the **GM Tool**) will require the development of clearly defined processes specifying how changes in identification or naming will be addressed and on what schedule.

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<sup>2</sup> Posted at [https://zingtree.com/live/126497995/embed?tree\\_id=126497995000&z=embed#1](https://zingtree.com/live/126497995/embed?tree_id=126497995000&z=embed#1).

<sup>3</sup> **APHIS Stakeholder Registry** ([aphis@subscribers.usda.gov](mailto:aphis@subscribers.usda.gov)) email entitled “**EPA, FDA, and USDA Release Tool to Help Biotechnology Developers Navigate Regulatory Landscape**” dated 2024-10-02.

It is imperative that these processes be transparent and publicly available, with any changes reflected in a timely manner. These types of changes will have a huge impact on the regulated industry. There are differences within species and strains of microorganisms that require elaboration and context. Condensing this information into a single list of potential pathogenicity at the species level may be far too general, implying that all species and strains are pathogenic when in fact they likely are not. While there are certainly some organisms that generally do pose a plant pest risk, it is implausible that across the extensive list of bacteria, viruses, and fungi that each individual isolate or strain of every one of those listed species is a plant pest as defined in **7 CFR Part 340**. Indeed, many of them are beneficial in the suppression and control of true plant pests as evidenced by the inclusion of organisms that are already approved for use in EPA-registered products as well as APHIS-allowed products. There are also positive effects exhibited by many nutrient solubilizing/fixing organisms, which could result in a net-reduction in amounts of fertilizers applied.

## 2. LISTED ORGANISMS

As currently presented, this **Draft List** could be interpreted to mean that any organism on the list is a plant pest until proven otherwise. Without a clear definition or threshold to meet, the onus to prove an organism is not a plant pest is subject to constant change. For instance, *Bacillus megaterium*<sup>4</sup> and *Bacillus pumilus*<sup>5</sup> are abundant in nature globally and currently available in commercial products for sale and use in the US. Moreover, in recent years, *Bacillus megaterium* has been evaluated numerous times with “No Permit Required” letters issued. Another example is the case of *Clavibacter* species, where BRS has classified *Clavibacter michiganensis*<sup>6</sup> and *nebraskensis*<sup>7,8</sup> as **HIGH**, but both organisms are ubiquitous and commonly found across the US. These are just a few examples of where the **Draft List** may be confusing to developers and researchers.

Such an approach may deter innovation and instead require that any and all species-level organisms or fragments therefrom are plant pests that cannot be used or subjected to restrictive permitting. This lack of flexibility appears to run counter to the mandate of **EO 14081**. Such a position will be very limiting to future innovations in agriculture over time.

BPIA also notes that many of the species of microorganisms on the proposed **Draft List** are regulated by PPQ in their wild-type form but are broadly granted permits for transport and release, be they of domestic or foreign origin. This is based in part on perceived pathogenicity, but also due to prevalence and homology to a domestic version, to prevent any negative impact on the environment. BRS may wish to consider a similar streamlined review and approval of genetically-modified versions of these organisms.

## 3. CLASSIFICATION SCHEME

The comments below address issues with the purpose of the classification scheme presented. BPIA finds that it is imperative that the literature references from which the *pathogenicity* levels have been determined need to be shared so that the interested and affected stakeholders can comment astutely on the classifications and provide information to refute those classifications, where appropriate.

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<sup>4</sup> Used for a variety of uses including plant growth promotion and phosphate solubilization in agriculture, and as an industrial protein production host.

<sup>5</sup> Used as a biopesticide and biostimulant.

<sup>6</sup> CABI Digital Library, CABI Compendium, Publication 15338: Datasheet on *Clavibacter michiganensis* (bacterial canker of tomato): <https://doi.org/10.1079/cabicompendium.15338>. Retrieved 2024-09-30.

<sup>7</sup> Osdaghi E, Robertson AE, Jackson-Ziems TA, Abachi H, Li X, Harveson RM. (2023) “*Clavibacter nebraskensis* causing Goss's wilt of maize: Five decades of detaining the enemy in the New World.” *Mol Plant Pathol* 24(7):675–692; <https://doi.org/10.1111/mpp.13268>. Retrieved 2024-09-30.

<sup>8</sup> CABI Digital Library, CABI Compendium, Publication 15339: Datasheet on *Clavibacter nebraskensis* (Goss's bacterial wilt and leaf blight): <https://doi.org/10.1079/cabicompendium.15339>. Retrieved 2024-09-30.

*a. Evidence Levels for Pathogenicity*

In the **Draft List**, the Agency proposes classifications of different species as **LOW**, **MEDIUM**, **HIGH**, or **NOT YET DETERMINED** evidence for pathogenicity. BPIA has several questions regarding the classifications. Those questions include:

1. How will this classification be used by BRS?
2. How does BRS define the term “*pathogenicity*” as used in the development of this list? Some of the organisms listed, including some fungi, are entomopathogenic, acting on insect pests that feed on certain plants, but that activity is not plant-pathogenic.
3. What criteria are necessary to classify a genus or species as pathogenic? Please describe the criteria and thresholds that are used to make this determination (*e.g.*, is one study or reference sufficient, or are multiple references indicating clear evidence of plant pathogenicity required)? Do the data need to be field-generated or will BRS rely on lab-only data, which may not represent real-world exposure and effects? Do the source data need to be published in a peer-reviewed journal?
4. How was microbe identification conducted? Did BRS/APS rely on partial sequence fragments or was full sequencing conducted? How will BRS ensure that nomenclature is continually updated as these genus and species names are revised over time?
5. Is there a mechanism or pathway to appeal the pathogenicity classification of an organism? If so, please describe.

BPIA suggests removing the classification scheme to simplify the list and to reduce confusion.

Further, there is no additional information provided for the species listed as **NOT YET DETERMINED**. BPIA urges BRS to remove this classification as it provides no useful data to stakeholders or regulators and its inclusion is likely to lead to confusion.

BPIA appreciates BRS engaging with the regulated community and other stakeholders and looks forward to further opportunities to review any proposed updates prior to implementation.

*b. Specific Comments by Organism Type*

BPIA has reviewed the organism type categories as described in the **Draft List**. As stated previously, BPIA wishes to understand what criteria and scientific methods BRS used to determine the pathogenicity each organism. Please describe the methods and criteria used by BRS to make such determinations for each organism type. Further, BPIA has listed specific comments for each type below.

**i. Bacteria (listed as “Prokaryotes”)**

The document discusses three organism types—bacteria, viruses, and fungi—yet the table following lists “prokaryotes, viruses, and fungi.” As prokaryotes is a broader term than bacteria, which also includes within it the domain, Archaea, BPIA suggests the term listed in the table should be revised to read “**Bacteria**” for consistency.

Similarly, there are many bacterial species that are already present in registered products (such as biopesticides,<sup>9</sup> biostimulants, and biopharmaceuticals) that do not pose plant risks, including *Agrobacterium*, *Azospirillum*, *Azotobacter*, *Bacillus*, *Burkholderia*, *Paenibacillus*, *Pantoea*, *Priestia*, *Pseudomonas*, *Streptomyces*, and *Xanthomonas* spp. In addition, the wild types of many species of these genera of microorganisms are permitted for release. This incongruity could be interpreted as different regulatory decisions, which further complicates the use of the **Draft List**.

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<sup>9</sup> See <https://www.epa.gov/ingredients-used-pesticide-products/biopesticide-active-ingredients> for a listing of current and historic biopesticides approved by USEPA, including microbial products containing genera listed on the proposed **Draft List**.

## ii. Viruses

Akin to the discussion on bacteria above, there are viruses that are already present in products that do not pose plant risks, including Pepino mosaic virus, and Zucchini yellow mosaic virus. Unfortunately, there are limited sources of information on viral species and their potential to pose risks as plant pests. Ensuring that the sources used in this assessment of potential plant pest pathogenicity of viruses are reliable and scientifically defensible is of utmost importance.

## iii. Fungi

Based on the [Draft List](#), nearly all fungi are listed as **HIGH** evidence of pathogenicity. Microbes, including fungi, are found naturally in the environment and plants are constantly exposed to them, most without any ill effect. Many fungi species are already in use as biopesticides, biostimulants, and for other purposes, and we are concerned that the **HIGH** classification is confusing .

It is important to note that expressing pathogenicity against plant pests does not equate to the organism itself being a plant pest. To wit, there are numerous EPA-registered fungal agents registered as biopesticides, including *Alternaria*, *Ampelomyces*, *Aspergillus*, *Chondrostereum*, *Chlonostachys*, *Choletotrichum*, *Coniothyrium*, *Gliocladium*, *Isaria*, *Myrothecium*, *Paecilomyces*, *Phytophthora*, *Puccinia*, *Pythium*, *Trichoderma*, *Ulocladium*, and *Verticillium* spp. without causing plant pest pathogenicity or risk.

Moreover, over 300 species of fungi are by APHIS' own regulatory determinations "nonregulated." Therefore, BPIA suggests that the list of fungi be more carefully examined to provide more specificity on a species level rather than the many instances of broad categorization by genus alone.

BPIA also notices the list of fungi includes multiple genera belonging to the Kingdom Chromista, such as *Phytophthora*, *Plasmopara*, and *Peronospora*. As these are not fungi, perhaps a new classification for "**Chromista**" should be added to the discussion of plant pests and a separate table should be added to a revised [Draft List](#) for these genera.

## CONCLUSIONS

In summary, BPIA believes the current [Draft List](#) could benefit by revisions focusing on true plant pest potential, providing evidence on how the decision was made, and removing the classification scheme. Should BRS choose to keep the evidence of plant pest pathogenicity potential classification levels, BPIA would ask that USDA clarify exactly how the proposed classification scheme will be used to make regulatory decisions. BPIA requests transparency in the sources and decision-making process and criteria for these classifications. Further, BPIA wishes to stress the importance of stakeholder engagement in any updates to the [Draft List](#) to prevent adverse impacts on the industry and support sustainable agricultural practices. BPIA urges BRS to leverage the *Coordinated Framework*<sup>10</sup> and scientific literature in the further development and refinement of such a list

BPIA appreciates the opportunity to comment on this [Draft List](#) and looks forward to a continuing partnership partner with USDA-APHIS-BRS to develop standards and criteria to enable future innovation.

Should you have any questions about this response, please feel free to contact me.

Sincerely,

**BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE**



Keith J. Jones  
Executive Director

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<sup>10</sup> EXECUTIVE ORDER 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," issued 2022-09-12.

ENCLOSURE 1: BIOLOGICAL PRODUCTS POTENTIAL GREENHOUSE GAS REDUCTION  
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