Proposed Registration Decision for the New Active Ingredient *Bacillus licheniformis* strain 414-01

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1. Summary

This document announces that the U.S. Environmental Protection Agency (EPA) completed its initial evaluation of the proposed new microbial pesticide active ingredient *Bacillus licheniformis* strain 414-01 (hereafter *B. licheniformis* 414-01) and concluded that it meets the regulatory standard under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is seeking public comment on its proposed decision.

Bacillus licheniformis strain 414-01 is derived from the naturally occurring *Bacillus licheniformis*, a soil bacterium found throughout the United States. The enzymes produced by *Bacillus licheniformis* contribute naturally to nutrient cycling in the soil and have also been found to have many beneficial industrial uses (e.g., animal feed, for aquaculture as a detergent additive to help break down organic stains, and sewer treatment cultures). In pesticide products, *B. licheniformis* 414-01 is proposed for seed and soil treatment on corn, cotton, potato, sorghum, soybean, sugar beet, and wheat applied via soil drench, in furrow, and chemigation via drip and applied to the foliage and ground for peanut crops.

Exposure to *B. licheniformis* 414-01 occurs naturally because of its ubiquity. When used as microbial active ingredient, *B. licheniformis* 414-01 is not expected to result in significant exposures in water, in or on food, or in residential areas due to the specific use patterns and application methods employed. According to the results of the acute toxicological studies conducted using the microbial active ingredient by itself or in combination with other (inert) ingredients, *B. licheniformis* 414-01 is not infective, pathogenic, or toxic, and shows a pattern of clearance from the organs of test animals. Although there is potential for occupational exposure, the use of a combination of personal protective equipment (PPE) and baseline work clothes by handlers and applicators is required on the end-use products' (EPs) labels, thereby minimizing exposure. Further, as mentioned above, no toxicological endpoints at the limit dose and no adverse effects of concern related to this microbial active ingredient have been identified in the supporting data.

Exposure to nontarget organisms of *B. licheniformis* 414-01 is possible via runoff and/or drainage water, as well as consumption of plant root parts, seeds, or soil during or after routine applications. Because of the application methods via seed treatment and soil-directed application and lack of toxicity/pathogenicity observed in the laboratory testing, exposure to *B. licheniformis* 414-01 is expected to be low from the proposed uses. While risk is predicted to be low for all nontarget organisms from foliar applications due to lack of toxicity, spatial analysis was conducted with the EPA's Use Data Layer (UDL) Overlap tool to confirm lack of exposure of listed species from the uses of *B. licheniformis* 414-01 on peanuts via foliar application due to the possibility of exposure for invertebrates (particularly soft-bodies invertebrates) on treated field given the mode of action on nematodes. While nontarget organisms could be exposed during foliar spray operations, based on lack of toxicity/pathogenicity observed in the honeybee testing and the unlikelihood of listed invertebrates being on or near the treated field, no effects are expected for nontarget terrestrial invertebrates. Furthermore, effects to the prey, pollution, habitat and/or dispersal (PPHD) of listed terrestrial vertebrates and plants are not expected based on the lack of effects of the pesticide on nontarget invertebrates that these species may rely on for ecosystem services, such as prey or pollination. Adverse effects to nontarget organisms attributed to *B. licheniformis* 414-01 are not expected, given the microbial active ingredient is not related to known plant pathogens, ubiquity in the environment, degradation due to ultraviolet radiation, wind, and rain, predominant soil directed and seed treatment use patterns, and low level of expected exposure for nontarget organisms. Therefore, EPA is making a "No Effect" determination under the Endangered Species Act (ESA) for listed species, including birds, mammals, amphibians, reptiles, plants, terrestrial invertebrates, and aquatic organisms (animals and plants), and their designated critical habitats from the proposed uses of *B. licheniformis* 414-01.

After reviewing the submitted and publicly available data and information for *B. licheniformis* 414-01, EPA has concluded that there is a reasonable certainty of no harm from residues of this new active ingredient and that the proposed uses will not cause any unreasonable adverse effects to human health or the environment. Therefore, EPA is proposing to register two manufacturing-use products (MP) and two EPs under FIFRA section 3(c)(5). A brief description of the active ingredient, composition, activity, and labeled uses for the EPs follows below.

414-02 (File Symbol: 70506-AEL)

Active ingredient:	*Bacillus licheniformis* strain 414-01 (.88%)
Activity:	Bionematicide
Uses:	Seed Treatment (At Plant and Commercial) and Soil Treatment via In-Furrow Application, Drip Chemigation, Transplant Water, Root Dip
Crops:	Roots and Tuber Vegetables (Crop Group 1), Legumes (Succulent or Dried) (Crop Group 6), Cucurbit Vegetables, Cereal Grains (Crop Group 15), Cottonseed (Crop Group 20), and Peanut

414-03 (File Symbol: 70506-AEA)

Active ingredient:	*Bacillus licheniformis* strain 414-01 (33%)
Activity:	Bionematicide
Uses:	Seed Treatment (At Plant and Commercial) and Soil Treatment via In-Furrow Application, Drip Chemigation, Transplant Water, Root Dip
Crops:	Roots and Tuber Vegetables (Crop Group 1) and Peanut

Furthermore, EPA is establishing a tolerance exemption for residues of *B. licheniformis* 414-01 in or on all food commodities when used in accordance with label directions and good agricultural practices.

2. Background

On August 3, 2022, EPA received an application from UPL NA, Inc. that proposed registration of new pesticide products containing *B. licheniformis* 414-01, a new microbial active ingredient. UPL NA, Inc. provided a combination of data and other information (e.g., scientific rationales bolstered by public literature) to support the registration of these pesticide products. In addition, UPL NA, Inc. submitted a petition proposing to establish an exemption from the requirement of a tolerance for residues of *B. licheniformis* 414-01 in or on all food commodities.

In the Federal Register of March 27, 2023 (88 FR 18133), EPA published a Notice of Receipt (NOR) that announced receipt of an application for registration of the pesticide products containing the new active ingredient, *B. licheniformis* 414-01. In the Federal Register of March 24, 2023 (88 FR 17780), EPA published a Notice of Filing (NOF) for the petition requesting an exemption from the requirement of a tolerance for residues of *B. licheniformis* 414-01. EPA is revising 40 CFR Part 180 to establish an exemption from the requirement of a tolerance for residues of *B. licheniformis* 414-01 in or on all food commodities when used in accordance with label directions and good agricultural practices.

3. Evaluation

In evaluating a pesticide registration application, EPA assesses a variety of studies to determine the likelihood of adverse effects (i.e., risk) from exposures associated with the use of the product. Risk assessments are developed to evaluate how the active ingredient might affect a range of nontarget organisms, including humans and terrestrial and aquatic wildlife (plants and animals).

Based on these assessments, EPA evaluates and approves language for each pesticide label to ensure the directions for use and safety measures are appropriate to mitigate any potential risk. In this way, the pesticide label communicates essential limitations and mitigations that are necessary for public and

environmental safety. In fact, FIFRA section 12(a)(2)(G) states that it is unlawful for any person to use a registered pesticide in a way that conflicts with the label.

3.1 Assessment of Human Health Exposure and Risk

To assess risks to human health from the use of microbial pesticides, EPA typically requires a wide range of studies, including Tier I acute toxicity/pathogenicity data (oral, pulmonary, and injection), cell culture data, reports of hypersensitivity incidents, acute toxicity data (oral, dermal, and inhalation), and irritation data (dermal and eye). Tier II and III testing (e.g., sub-chronic toxicity/pathogenicity) is triggered only when there is indication, usually through lower tier testing, that a microbial pesticide has unusual toxicological characteristics, such as infectivity or being suspected as or known to be a carcinogen.

3.1.1 Product Characterization

The data and information provided to address the product analysis data requirements for the pesticide product containing *B. licheniformis* 414-01 have been classified as acceptable.

3.1.2 Toxicological Data and Information

All Tier I mammalian acute toxicology data requirements were satisfied through a combination of guideline studies and scientific rationales.

Scientific rationales were submitted for the acute oral toxicity/pathogenicity and acute injection toxicity/pathogenicity on the technical grade of the active ingredient (TGAI). Acute pulmonary toxicity/pathogenicity testing conducted with TGAI demonstrated a pattern of clearance from the organs of treated animals. The spleen and lung samples did not achieve complete clearance by the end of the study, but a pattern of clearance was eventually observed in these tissues. An extended pattern of clearance is common with some strains of *Bacillus* and other spore forming organisms which are generally more resistant to the host's immune system when administered intra-tracheally. The acute oral toxicity and primary dermal irritation tests conducted on the TGAI containing 100% of the active ingredient *B. licheniformis* 414-01*,* were classified as EPA Toxicity Category IV[1] and the acute eye irritation was classified as EPA Toxicity Category III. There was no report of hypersensitivity incidents or other adverse effects during research, development, manufacturing, or handling of the microbial active ingredient or the pesticide products.

Scientific rationales were submitted for the product-specific acute oral, inhalation, and dermal toxicity data requirements for the end-use product (EP), 414-03 (dry powder), and the manufacturing product (MP) 414-01. The acute oral, acute dermal, acute inhalation toxicity, and the acute eye irritation were classified as EPA Toxicity Category IV, and the primary dermal irritation was classified as EPA Toxicity Category III.

Scientific rationales were submitted for the product-specific acute oral, inhalation, and dermal toxicity data requirements for the EP, 414-02 (liquid). The acute oral, acute dermal, acute inhalation toxicity, and the acute eye and primary dermal irritation were classified EPA Toxicity Category IV.

Since data on *B. licheniformis* 414-01 were sufficient to demonstrate no additional toxicity or irritation is expected as a result of the active ingredient and *B. licheniformis* 414-01 demonstrated a pattern of clearance from the organs of the test animals in toxicity/pathogenicity data, no adverse effects of concern are expected concerning the proposed pesticide uses of *B. licheniformis* 414-01.

[1] See Section III of Chapter 7 of the Label Review Manual for a complete description of the Toxicity Categories.

3.1.3 Aggregate Exposure and Risk Characterization

EPA did not identify any adverse effects of concern in toxicological tests performed with *B. licheniformis 414-01*; therefore, EPA did not conduct a quantitative exposure assessment. The following information summarizes the findings for *B. licheniformis* 414-01.

Food Exposure and Risk Characterization: Based on the proposed uses, dietary exposure to *B. licheniformis* 414-01 on food commodities is a possibility, however *B. licheniformis* is a ubiquitous environmental microbe that is common in soils and in bird feathers such as ducks and sparrows. Since many food crops undergo postharvest processing (e.g., washing to remove soil and surface residues and peeling), it is unlikely that significant amounts of these microorganisms would remain on treated crops. Should the microorganism remain on some food commodities, results of the guideline mammalian toxicological testing with a maximum hazard dose of *B. licheniformis* 414-01 demonstrated a lack of significant adverse effects (i.e., toxicity, pathogenicity, and/or infectivity). Based on characteristics of *B. licheniformis* 414-01 and lack of adverse effects from toxicity and pathogenicity studies, EPA considers any risk from dietary exposure to *B. licheniformis* 414-01 to not be of concern.

Drinking Water Exposure and Risk Characterization: Although the EP containing *B. licheniformis* 414-01 is intended for commercial seed treatment and agricultural uses, significant drinking water exposure to *B. licheniformis* 414-01 resulting from these uses is not expected. As a rhizosphere-competent strain, *B. licheniformis* 414-01 is mainly associated with the roots of growing plants and is not expected to percolate through soil to reach ground water. Within the proposed pesticide products, *B. licheniformis* 414-01 will be applied by seed treatment and soil-directed applications. These application methods reduce the likelihood of offsite airborne movement (i.e., spray drift) of the active ingredient to nearby surface waters. However, if *B. licheniformis* 414-01 were to somehow make it into drinking water, it would be subject to municipal treatment processes and would likely not survive the conditions water goes through before being distributed for consumption by humans (e.g., pH adjustments and chlorination). Should the microorganism remain in drinking water, results of the guideline mammalian toxicological testing with a maximum hazard dose of *B. licheniformis* 414-01 demonstrated a lack of significant adverse effects (i.e., toxicity, pathogenicity, and/or infectivity). Based on characteristics of *B. licheniformis* 414-01 and lack of adverse effects from toxicity and pathogenicity studies, EPA considers any risk from drinking water exposure to *B. licheniformis* 414-01 to not be of concern.

Non-Occupational and Residential Exposure and Risk Characterization: Based on the proposed uses for *B. licheniformis* 414-01, there is minimal risk for indirect residential exposure, as no residential uses are on the proposed EP labels. Since *B. licheniformis* 414-01 will be applied in agricultural settings by seed treatment and direct soil applications, other non-occupational exposures through drift or other measures are considered very unlikely. Should the microorganism remain on some food commodities, results of the guideline mammalian toxicological testing with a maximum hazard dose of *B. licheniformis* 414-01 demonstrated a lack of significant adverse effects (i.e., toxicity, pathogenicity, and/or infectivity). Based on characteristics of *B. licheniformis* 414-01 and lack of adverse effects from toxicity and pathogenicity studies, EPA considers any risk from non-occupational and residential exposure to *B. licheniformis* 414-01 to not be of concern.

3.1.4 Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, EPA consider "available information concerning the cumulative effects of [a particular pesticide's] … residues and other substances that have a common m mechanism of toxicity". *B. licheniformis* 414-01 is not toxic and does not have a common mechanism of toxicity with other substances. Consequently, FFDCA section 408(b)(2)(D)(v) does not apply.

3.1.5 Determination of Safety for U.S. Population, Infants, and Children

U.S. Population: For all the reasons discussed previously, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *B. licheniformis* 414-01. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

Infants and Children: FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

As discussed previously, EPA has concluded that *B. licheniformis* 414-01 is not toxic, pathogenic, or infective to mammals, including infants and children. Because there are no threshold levels of concern to infants, children, and adults when *B. licheniformis* 414-01 is used in accordance with label directions and good agricultural practices, EPA determined that the additional margin of safety is not necessary to protect infants and children.

3.1.6 Occupational Exposure and Risk Characterization

Based on the agricultural use pattern proposed for *B. licheniformis* strain 414-01 there is potential for occupational exposure to applicators and other handlers through the oral, dermal, ocular, and inhalation routes. However, the supporting mammalian toxicological testing has shown a lack of irritation, toxicity, infectivity, or pathogenicity associated with the active ingredient. The labels for the EPs 414-02 and 414-03 require that applicators and other handlers must wear PPE, such as a long-sleeved shirt, long pants, waterproof gloves, socks, shoes, and minimum of a National Institute for Occupational Safety and Health (NIOSH)-approved particulate respirator or a NIOSH-approved powered air-purifying respirator. The respirator is required for handlers of the EP because repeated exposure to high concentrations of microbial proteins can cause allergic sensitization, and these types of workers in commercial and agricultural settings may be subject to these conditions. Since occupational and post-application exposure to *B. licheniformis* strain 414-01 are not expected to exceed any toxicity thresholds when workers follow the precautions and requirements identified on the EPs, EPA considers any risk from occupational exposure to *B. licheniformis* 414-01 to not be of concern.

3.1.7 Human Health Conclusions

Based on the available toxicology and exposure data and information, EPA concludes that use of *B. licheniformis* 414-01 will not result in unreasonable adverse effects to humans from aggregate exposure to residues of *B. licheniformis* 414-01 resulting from the proposed pesticide uses of the EPs containing *B. licheniformis* 414-01 when EPA-approved product label instructions are followed. EPA does not expect dietary (food and drinking water), spray drift, or occupational risks of concern from the proposed uses of *B. licheniformis* 414-01 as an active ingredient. Data and other information demonstrated that *B. licheniformis* 414-01 is not associated with any adverse effects (i.e., toxicity, pathogenicity, or infectivity). In addition, residues of *B. licheniformis* 414-01 will be covered by an exemption from the requirement of a tolerance in or on all food commodities when used in accordance with label directions and good agricultural practices.

The database of studies required to support the assessment of risk to human health is complete. For more information on the human health risk assessment of *B. licheniformis* 414-01, please see the supporting

documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2023-0146" at www.regulations.gov).

3.2 Assessment of Ecological Exposure and Risk

To assess risks to the environment from the use of microbial pesticides, EPA initially requires a wide range of studies, including Tier I testing done on the following nontarget organisms: birds (oral and inhalation), mammals, freshwater fish and invertebrates, estuarine/marine fish and invertebrates, plants, insects, and honey bees. Testing is organized in a tiered structure, where Tier I studies test worst-case exposure scenarios and higher tiers (Tiers II through IV) generally encompass definitive risk determinations and longer-term greenhouse or field testing. Higher tier testing is implemented only when unacceptable effects are seen at the Tier I screening level. All data requirements may be addressed with guideline studies or scientific rationales.

For *B. licheniformis* 414-01, the database of studies and information required to support the assessment of risk to the environment is adequate for making a safety determination for the proposed uses, based on the EP labels provided. UPL NA, Inc. submitted guideline studies and scientific rationales to address the data requirements, all of which were determined by EPA to be acceptable to address the data requirements and make a risk determination. Based on these data and acceptable scientific rationales, adverse effects to birds, mammals, nontarget plants, nontarget insects and honey bees, and freshwater fish and invertebrates are not anticipated from the use of the EPs containing the active ingredient *B. licheniformis* 414-01 when applied via seed and soil application methods and from foliar uses on peanuts.

The database of studies required to support the assessment of risk to ecological exposure is complete. For more information on the environmental risk assessment of *B. licheniformis* 414-01, please see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2023-0146" at www.regulations.gov). A summary of the information reviewed for *B. licheniformis* 414-01 follows.

3.2.1 Terrestrial Animals and Plants

Birds, Mammals, Reptiles, and Amphibians: No hazards were identified for these organisms. Oral exposure may occur through consumption of treated foods and touching treated surfaces (i.e., soil, seeds, insects, and drainage water) following pesticide application. However, scientific rationale was sufficient to conclude that effects to birds are not anticipated as a result of exposure to *B. licheniformis* 414-01 since *B. licheniformis* 414-01 and other related strains are not known to be pathogenic to birds and frequently found on avian feathers. No mortality, pathogenicity, or toxicity was observed at 5,000 mg/kg-bw, which is lower than the LD_{50}, in the acute oral toxicity study in rats, and results of the acute injection toxicity/pathogenicity study of rats showed no mortality, infectivity, or pathogenicity. Based on the demonstrated lack of effects in the submitted rationale for avian oral toxicity and acute toxicological studies performed on rats, and the maximum estimated environmental concentrations (EECs), direct and indirect effects to birds and mammals are not expected as a result of the soil/seed applications of *B. licheniformis* 414-01. In summary, although exposure to *B. licheniformis* 414-01 is possible, EPA does not expect direct and indirect effects to birds and wild mammals as a result of the soil directed and seed treatment application of the proposed EPs containing *B. licheniformis* 414-01, as labeled. Generally, EPA uses bird toxicity data as a surrogate for terrestrial-phase amphibians and reptiles, the lack of toxicity shown or expected for vertebrates generally (including birds, mammals, and fish) indicate that low toxicity to terrestrial-phase amphibians and reptiles can be reasonably expected.

Nontarget Plants: No hazards were identified for nontarget plants. Although exposure to *B. licheniformis* 414-01 may occur during pesticide application and/or runoff, *B. licheniformis* 414-01 is not taxonomically related to any known plant pathogens and a literature search did not identify any

phytotoxicity caused by *B. licheniformis* 414-01. Additionally due to dilution and ubiquity of *B. licheniformis* strain 414-01 in the soil, exposure will not affect nontarget, soil dwelling invertebrates. *B. licheniformis* 414-01 during application or runoff, EPA does not expect any adverse effects to nontarget plants as a result of the application of the proposed EPs containing *B. licheniformis* 414-01, as labeled.

Nontarget Invertebrates: Nontarget insects and honey bees may be exposed to *B. licheniformis* 414-01 during foliar application to peanuts at the pegging stage, routine ground soil applications, and contact with treated seed and soil or be directly exposed during foraging and where applications are actively occurring.

In a 13-day acute oral toxicity/pathogenicity study on honey bees the EEC was determined to be 3.8×10^6 CFU/mL, which is below the No Observed Adverse Effect Concentration (NOAEC) of 6×10^8 CFU/mL; therefore, *B. licheniformis* 414-01 was considered not toxic or pathogenic to honeybees. Literature supports that *Bacillus licheniformis* has also been used a probiotic for honeybee hives and no effects against honeybees and pollinators were reported. Based on the seed treatment and soil directed applications, the soil EEC is low and at 1.0×10^3 CFU/cm^3, which is lower than existing background levels of *Bacillus* species in the soil. Due to the seed and soil treatment uses, the applied active ingredient will be diluted in the soil resulting in a low EEC and *B. licheniformis* 414-01 is ubiquitous in soil environments along with other similar microbes, thus, exposure is not expected to result in effects to nontarget insects. Also, the product labels state that the active ingredient is primarily toxic or pathogenic to specific target pests, such as, nematodes. Additionally, degradation of *Bacillus licheniformis* strain 414-01 will occur in the field and even further reduce exposure, due to ultraviolet radiation, wind, and rain, as is expected for most biological pesticides.

3.2.2 Aquatic Animals and Plants

Indirect exposure of *B. licheniformis* 414-01 to aquatic organisms (freshwater and estuarine/marine fish and invertebrates) and semi-aquatic plants may occur via intense runoff events that occur soon after application or through spray drift from foliar application on peanuts when applications occur near water bodies. The worst-case aquatic EEC that may result from drift was estimated assuming direct application to water on a one-acre wetland resulting in 1.2×10^3 CFU/mL of water. Exposure from drift and runoff would be a much lower exposure scenario compared to the direct water application of the active ingredient. Also, this concentration is expected to quickly decline since *B. licheniformis* is not known to proliferate in water. However, this active ingredient is not expected to be any different than background levels in these water bodies given the dilution of the EPs and the predominant soil/seed treatment use pattern. Additionally, direct applications of *B. licheniformis* 414-01 to water are not permitted on the proposed labels, thus, the worst-case aquatic EEC is a highly conservative estimate.

No hazards have been identified for aquatic plants exposed to *B. licheniformis* 414-01 and the active ingredient is not taxonomically related to any known plant pathogens. *Bacillus licheniformis* strain 414-01 is not known to be a pathogen of freshwater or estuarine/marine organisms and the species is used as a probiotic in fish aquaculture indicating that pathogenicity is not expected for aquatic organisms.

Based on the limited exposure of *B. licheniformis* 414-01 in the aquatic environment due to the predominant seed and soil only use pattern of the proposed EPs and concentrations of the active ingredient will not be different than background levels in these water bodies, EPA does not expect any discernible direct effects to fish, aquatic invertebrates, and aquatic plants as a result of the application of the proposed EPs containing *B. licheniformis* 414-01, as labeled.

3.2.3 Endangered Species Conclusion

EPA has no reasonable expectation for any proposed use of *B. licheniformis* 414-01 to cause discernible direct effects to threatened or endangered (listed) species, including birds, mammals, amphibians,

reptiles, plants, terrestrial invertebrates, and aquatic organisms (plants and animals), or their designated critical habitats from the proposed uses of *B. licheniformis* 414-01. Although exposure to is expected through spray drift and runoff; based on the degradation of *B. licheniformis* 414-01 and predominant soil/seed treatment uses, exposure is expected to be minimal. Submitted data indicate if exposure was to occur, EPA does not expect *B. licheniformis* 414-01 to cause effects to listed endangered species or their critical habitats based on lack of toxicity/pathogenicity observed in testing on nontarget birds, mammals, plants, honeybees, and nontarget insects. Expected exposure to aquatic organisms is lower than that of the maximum EEC and concentrations of the active ingredient will not be different than background levels in these water bodies given the dilution of the active ingredient and predominant soil/seed treatment use pattern. Further, *B. licheniformis* 414-01 is ubiquitous in the soil environments and are not known to be pathogenic to plants and/or aquatic organisms.

Although risk is predicted to be low for all nontarget organisms from foliar application due to lack of toxicity, a spatial analysis was conducted to confirm lack of exposure for listed species from the uses on peanuts (the only listed crop proposed via foliar application) due to the possible exposure for invertebrates (particularly soft bodied invertebrates) on the treated field given the mode of action on nematodes. Foliar use has a higher level of exposure for on-field nontarget invertebrates and from application also drift off field. EPA conducted spatial analysis with the Use Data Layer (UDL) Overlap tool to demonstrate the output of the potential overlap (or co-occurrence) of listed terrestrial invertebrate species and use sites. Generally, EPA does not consider overlap percentages that are less than 1% as significant overlap. There are only five listed insects (*Oarisma poweshiek*, *Desmocerus californicus dimorphous*, *Hesperia dacotae, Elaphrus virdis, Icarcia icarioides fenderi*) that have greater than 1% but less than 5% overlap with the UDL regarding use on peanuts; however, these species' habitats do not coincide with peanut operations (where peanuts are predominantly grown). In addition, EPA expects that the overlap indicated in the output from the UDL Overlap tool is due to other crops (e.g., hops, sugar beet, sunflowers) included in the Other Row Crops UDL in addition to peanuts, and these other crops may grow in these areas where the listed species occur. Although nontarget invertebrates may be exposed to *B. licheniformis* 414-01 from foliar application on peanuts, given the lack of toxicity/pathogenicity to honeybees in laboratory testing and the unlikelihood of listed invertebrates being on or near the treated peanut field from foliar application, EPA does not expect effects to these listed nontarget terrestrial invertebrates as a result of the foliar application on peanuts from the proposed EPs containing *B. licheniformis* 414-01.

Due to lack of toxicity to birds, mammals and nontarget plants, nontarget insects at estimated exposure levels, and unlikelihood of listed terrestrial invertebrates being on or near the treated peanut field, and exposures to aquatic organisms that are below the concentrations that would elicit any effects, there is a reasonable expectation of no discernible effects to these taxa. Therefore, EPA is making a "No Effect" determination under the Endangered Species Act (ESA) for listed birds, mammals, amphibians, reptiles, plants, terrestrial invertebrates, aquatic organisms (animals and plants), and their critical habitats under the Endangered Species Act.

4. Benefits and Public Comments

Biopesticides are pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals. Microbial pesticides, a class of biopesticides, consist of microorganism (e.g., bacterium, fungus, virus, or protozoan) as the active ingredient may have the following benefits:

- Usually are inherently less harmful than conventional pesticides.
- Generally affect only the target pest and closely related organisms, in contrast to broad-spectrum conventional pesticides that may affect many different organisms (e.g., birds, insects, and mammals).
- Often effective in very small quantities and often decompose quickly, thereby resulting lower

exposure and largely avoiding the pollution problems caused by conventional pesticides.
- Can greatly decrease the use of conventional pesticides while crop yields remain high, when used as a component of integrated pest management programs.
- Can offer another tool for pest management in areas where pesticide resistance, niche markets, environmental concerns, and organic preference limit the use of conventional pesticides.

Like other microbial pesticides, *B. licheniformis* 414-01 aligns with the potential benefits above and could fill particular needs in unique markets. For example, *B. licheniformis* 414-01 works by colonizing the rhizosphere and releasing its enzymes (i.e. chitinase) to impair the various stage of nematode development, including egg hatching, mobility and increased nematode mortality. The unique and multiple modes of action of the pesticide may help resistance management and be useful in IPM programs. Furthermore, the proposed EPs containing *B. licheniformis* 414-01 are applied through limited application methods at low application rates resulting in low exposure to nontarget organisms and in the environment.

Thus far, EPA has provided the public two opportunities to comment (1) on the *B. licheniformis* 414-01 pesticide product and (2) the associated tolerance exemption petition through information presented in the Federal Register (FR). For these two comment periods opened with FR publication (i.e., NOR and NOF), EPA received no comments relevant to these actions.

Because UPL NA, Inc.'s pesticide product contains *B. licheniformis* 414-01, a new active ingredient, and involves this active ingredient's first food and outdoor uses, EPA is opening a 15-day public comment period. EPA is taking this action in accordance with a policy, first implemented in October 2009, designed to provide a more meaningful opportunity for the public to participate in major registration actions.

5. Proposed Registration Decision

The *B. licheniformis* 414-01 database is comprised of scientific literature and information that fulfill the data requirements and support the labeled uses. In considering the assessed risk to human health and the environment, EPA concludes that *B. licheniformis* 414-01 meets the regulatory standard under FIFRA. Therefore, EPA is proposing to grant the registration of the *B. licheniformis* 414-01 pesticide products under FIFRA section 3(c)(5).

EPA is proposing to register one MP containing *B. licheniformis* 414-01 at 100%, one MP containing *B. licheniformis* 414-01 at 33%, and two EPs containing *B. licheniformis* 414-01 at .88% and 33%, respectively. The EPs will be applied by soil treatment and/or seed on a variety of food and non-food crops in agricultural settings against nematodes that attack the root systems of corn, cottonseed, foliar use on peanut, potato sorghum, soybean, sugar beet, and wheat. For the new active ingredient, an exemption from the requirement of a tolerance will be established for all food commodities when used in accordance with label directions and good agricultural practices.

The risk assessments and other documents supporting this decision can be found in the associated regulatory docket (search for "EPA-HQ-OPP-2023-0146" at www.regulations.gov).