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Will Your Microbial Pesticide Pass the Test?

Preparing for New Pre-Market Authorization Requirements in the EU

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The global biopesticide industry is forecast to grow 14.7% by 2025[1] with Europe as the fastest growing market. Biopesticides formulated with bacteria, fungi, or viruses as active ingredients are expected to drive the majority of Europe's growth as consumers demand safer, more sustainable agricultural products. While identifying and characterizing microorganisms is a key component of the risk assessment required for microbial pesticides by the EU's pre-market authorization process, the European Food Safety Authority (EFSA) has not historically specified a method for obtaining this data. This may soon change.

EFSA is strongly considering establishing whole genome sequencing (WGS) as the state-of-the-art method to unequivocally identify and characterize microorganisms in biopesticide products. Based on the public consultation EFSA initiated in January 2020, WGS data may soon be required for microbial active substance approval in the EU. In anticipation of this change, we encourage new microbial pesticide applicants to proactively ensure that genomes of their microbial strains are sequenced, annotated, and analyzed according to EFSA recommendations. If needed, applicants can partner with technical and regulatory experts to ensure that risk assessments are performed in a scientifically sound and harmonized way and that conclusions on the identity and characteristics of microorganisms are robust enough to meet EU pre-market authorization requirements in a timely manner.

Identifying and Characterizing Microbial Ingredients

The identification and characterization of microorganisms used in a microbial pesticide's formulation can provide a key point for making risk assessment decisions. In the EU, the microorganisms to be included in a microbial pesticide should be assessed at strain level in compliance with specific data requirements outlined in part B of the Annex to Commission Regulation (EU) No. 283/2013. This is important because the toxicological properties of different strains belonging to the same species of microorganism may vary.

Unequivocal identification and characterization of microbial strains used in microbial pesticides is crucial. This is particularly important for certain bacterial groups, including Bacillus subtilis species complex, B. cereus group, and Burkholderia cepacia complex. These groups are tight assemblages of closely related species or strains that typically harbor strains with biocontrol potential as well as their pathogenic relatives. There are several techniques in molecular biology to identify and characterize microorganisms, each with their benefits and limitations. However, the most reliable way to unequivocally identify and characterize a microorganism at strain level is through WGS.

[1] https://www.researchandmarkets.com/reports/5116567/biopesticides-market-by-type-bioinsecticides

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Preparing Whole Genome Sequencing Data

With rapid developments in next generation sequencing technologies, sequencing an entire microbial genome is low cost. Still, a major challenge is the annotation, analysis, and contextual interpretation of the information contained in a microbial genome. Therefore, applicants seeking approval of microbial active ingredients in the EU are advised to seek expert support to ensure that the genomes of their microbial strains are sequenced, annotated, and analyzed according to EFSA recommendations. This can help potential applicants for microbial pesticides authorization in the EU prepare genome data of their active ingredients according to EFSA recommendations and better facilitate a smooth, scientifically sound risk assessment process.

How Exponent Can Help

Exponent's team of regulatory consultants has technical expertise in microbiology and molecular biology and can help microbial pesticide manufacturers assess existing WGS data and reports for compliance with EFSA recommendations. We can also help manufacturers select contract laboratories with capabilities to perform WGS of microbial strains; analyze data according to EFSA standards; and ensure that raw data are submitted in the recommended standard formats. We have the expertise to interpret data within the appropriate regulatory and scientific contexts and summarize reports for inclusion in dossiers.

Oluwatobi Oni, Ph.D.
Chemical Regulation & Food Safety
Senior Scientist
London (UK)
+44 (0) 2035 851 286
ooni@exponent.com

Michael Watson, Ph.D.
Chemical Regulation & Food Safety
Senior Scientist
Harrogate (UK)
+44 (0) 1423 853243
mwatson@exponent.com

Mark Briggs, Ph.D.
Chemical Regulation & Food Safety
Senior Managing Scientist
Harrogate (UK)
+44 (0) 1423 853210
mbriggs@exponent.com