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EPA issues proposed registration decision for Biotalysâ?? EVOCA Biofungicide

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Biotalys is pleased to announce that the United States Environmental Protection Agency (EPA) has issued its proposed registration decision to approve the companyâ??s first biofungicide, EVOCA. The agency will now initiate the final phase in its regulatory review, allowing stakeholders such as growers and industry associations 15 days to provide feedback before finalizing its regulatory decision.

The EPA has also posted a final rule exempting EVOCAâ??s active ingredient residues on treated crops from tolerance requirements, indicating that no maximum residue limits will apply and highlighting the product candidateâ??s exemplary safety profile.

EVOCA is a precision biocontrol solution that targets the fungal pathogens botrytis (grey mold) and powdery mildew in high-value fruits and vegetables without harming beneficial organisms or the environment. The product candidate offers growers a new mode of action to manage resistance to existing fungicides, as was recognised by the Fungicide Resistance Action Committee (FRAC), a panel of renowned industry experts.

â??The EPAâ??s recommendation to approve EVOCA marks a pivotal moment for Biotalys, and the advancement of the first protein-based biofungicide of its kind for approval in the United States. This achievement underscores Biotalysâ?? pioneering leadership in agricultural innovation and provides the company with a significant first-mover advantage in transforming how growers protect their crops safely and sustainably,â?• said Kevin Helash, CEO of Biotalys.

â??Our protein-based platform has the potential to transform crop protection by delivering next generation biological solutions with new modes of action, developed to create targeted, consistent and scalable products to meet farmersâ?? needs, as demonstrated today by the EPAâ??s publication,â?• he added.

â??This significant milestone reflects the dedication and expertise of the entire Biotalys team,â? Helash concluded. â??EVOCA is just the beginning for Biotalys, and we look forward to bringing our pipeline of fungicides and insecticides to the market in the coming years.â?•

An approval of EVOCA paves the way for the regulatory submission of EVOCA NG, the next-generation version of the product candidate, and Biotalysâ?? anticipated first commercial launch. The company expects the review process for EVOCA NG to be significantly shorter as the product contains the same active ingredient as EVOCA and features enhanced formulation and production methods.