U.S. FOOD & DRUG ADMINISTRATION

April 10, 2025

William Urquhart, Ph.D.
Global Regulatory Manager
Bayer CropScience LP
700 Chesterfield Parkway West
Chesterfield, Missouri 63017

RE: Biotechnology Notification File No. BNF 000198

Dear Dr. Urquhart:

This letter addresses Bayer CropScience LP (Bayer) and KWS SAAT SE & Co. KGaA (KWS)'s consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered sugar beet, KWS20-1. According to information Bayer and KWS have provided, KWS20-1 sugar beet is genetically engineered to express dicamba mono-oxygenase (DMO) for tolerance to dicamba herbicide; phosphinothricin-N-acetyltransferase (PAT) for tolerance to glufosinate-ammonium herbicide; and CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) for tolerance to glyphosate herbicide. The administrative record for this consultation has been placed in a file designated BNF 000198. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, Bayer and KWS submitted to FDA a summary of its safety and nutritional assessment of KWS20-1 sugar beet, which FDA received on June 6, 2023. Bayer and KWS submitted additional information, received by FDA on June 7, 2024, and November 26, 2024. These communications informed FDA of the steps taken by Bayer and KWS to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Bayer and KWS have conducted, it is our understanding that Bayer and KWS have concluded that human and animal food from KWS20-1 sugar beet are not materially different in composition, safety, and other relevant parameters from sugar beet-derived human and animal food currently on the market, and that genetically engineered KWS20-1 sugar beet does not raise issues that would require premarket review or approval by FDA.

It is Bayer and KWS's responsibility to obtain all appropriate clearances, including those from the United States Environmental Protection Agency and the United States Department of Agriculture (USDA), before marketing human or animal food derived from KWS20-1 sugar beet.

On July 29, 2016, the National Bioengineered Food Disclosure Law (Public Law 114-216) charged the USDA's Agricultural Marketing Service with developing a national mandatory system

for disclosing the presence of bioengineered material in human food. Food manufacturers, importers, and retailers of KWS20-1 sugar beet are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Bayer and KWS have presented to FDA, we have no further questions concerning human or animal food derived from KWS20-1 sugar beet at this time. However, as you are aware, it is Bayer and KWS's continuing responsibility to ensure that foods marketed by the firms are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000198 and copies of FDA's memoranda summarizing the information in BNF 000198 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

MARK A. HARTMAN -S

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Mark A. Hartman
Director
Office of Food Chemical Safety,
Dietary Supplements, and Innovation
Human Foods Program