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CENTER FOR VETERINARY MEDICINE

Biotechnology Notification File No. 000173
CVM Note to the File

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From: Rial Christensen, Ph.D.

To: Administrative Record, BNF No. 000173

Subject: Event MON 87429 Corn

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Purpose

This document summarizes the Food and Drug Administration (FDA) Center for Veterinary Medicine's (CVM, we) evaluation of biotechnology notification file (BNF) number 000173. Bayer CropScience LP (Bayer)[1] submitted a safety and nutritional assessment for a genetically engineered corn, transformation event MON 87429 (hereafter referred to as MON 87429 corn), and additional information afterwards. CVM evaluated the information in Bayer's submissions to ensure that regulatory and safety issues regarding the use of MON 87429 corn in animal food have been resolved prior to commercial distribution. FDA's Center for Food Safety and Applied Nutrition summarizes its evaluation of MON 87429 corn in human food in a separate document.

In CVM's evaluation, we considered all of the information provided by Bayer as well as publicly available information and information in the agency's files. Here we discuss the outcome of the consultation, but do not intend to restate the information provided in the final consultation in its entirety.

[1] Monsanto Company submitted the notice for BNF No. 000173. In a letter dated August 3, 2020, FDA was informed that Monsanto Company plant products "which were consulted on for food and feed safety and those still in the process" would be transferred to the legal entity Bayer CropScience LP, effective August 1, 2020.

Intended Effects

The intended effects of the modifications in MON 87429 corn are to confer tolerance to several herbicides. Bayer states that the parental corn variety was transformed with a *demethylase* gene from *Stenotrophomonas maltophilia*, which encodes the dicamba monooxygenase (DMO) protein that confers tolerance to dicamba herbicide. It also contains the *ft_t* gene, a modified version of the R-2,4-dichlorophenoxypropionate dioxygenase[2] gene from *Sphingobium herbicidovorans*, which confers tolerance to aryloxyphenoxypropionate acetyl coenzyme A carboxylase inhibitors ("FOPs" herbicides such as quizalofop) and to some synthetic auxin herbicides, including 2,4-dichlorophenoxyacetic acid (2,4-D). MON 87429 corn also expresses a copy of the *phosphinothricin N-acetyltransferase* gene from *Streptomyces viridochromogenes*, which imparts tolerance to glufosinate ammonium. Further, it contains the *aroA* gene from *Agrobacterium* sp. strain CP4, which encodes the CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein. The *aroA* gene is immediately downstream of an endogenous tassel specific regulatory element. The regulatory element targets CP4 EPSPS messenger ribonucleic acid (mRNA) for degradation in tassel tissues. Appropriately timed glyphosate applications induces non-viable pollen in MON 87429 corn, which aids plant breeding programs.

Regulatory Considerations

The purposes of this evaluation are (1) to assess whether Bayer has introduced into animal food a substance requiring premarket approval as a food additive and (2) to determine whether use of the new plant variety in animal food raises other regulatory issues with respect to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The Environmental Protection Agency (EPA) regulates herbicides under the FD&C Act and the Federal Insecticide, Fungicide, and Rodenticide Act. Under EPA regulations, the herbicide residues in MON 87429 corn are considered pesticide residues.

Genetic Modification and Characterization

Introduced DNA and Transformation Method

Bayer transformed immature embryos obtained from *Zea mays* L. line LH244 with plasmid PV-ZMHT519224 using disarmed *Agrobacterium tumefaciens* mediated transformation.[3] Bayer states that the transfer-DNA (T-DNA) region within the plasmid contained four expression cassettes between the left (LB) and right (RB) border sequences. These include:

- Cassette 1: *Phosphinothricin-N-acetyltransferase* (*pat*) gene from *Streptomyces viridochromogenes*, which is preceded by promoter, 5´ untranslated region (UTR), and intron sequences for a *ubiquitin* gene from *Erianthus ravennae* and followed by 3´ UTR sequence of the *fructose-bisphosphate aldolase* gene from *Setaria italica*.
- Cassette 2: *Demethylase* (*dmo*) gene from *Stenotrophomonas maltophilia* strain DI-6 that was codon optimized for expression in corn, which is preceded by promoter, 5´ UTR, and intron sequences for a *ubiquitin* gene from *Coix lacryma-jobi* and a codon-optimized chloroplast targeting sequence from the *Albino and*

[2] This is also known as a modified (R)-dichloroprop/alpha-ketoglutarate dioxygenase (RdpA).

[3] Sidorov, V., and D. Duncan. 2009. *Agrobacterium*-mediated maize transformation: Immature embryos versus callus. Pages 47-58 in Methods in Molecular Biology: Transgenic Maize - Methods and Protocols. M.P. Scott (ed.). Humana Press, Inc, Totowa, New Jersey.

pale green 6 gene (*Apg6*) from *Arabidopsis thaliana*. Following the *dmo* gene is the 3´ UTR sequence of the *OsMT* gene from *Oryza sativa*.

- Cassette 3: Modified version of the R-2,4-*dichlorophenoxypropionate dioxygenase* (*ft_t)* gene from *Sphingobium herbicidovorans,* which is preceded by promoter and 5´ UTR for a *ubiquitin* gene from *Arundo donax* and a chloroplast targeting sequence from the *malate dehydrogenase* gene from *A. thaliana*. Following the *ft_t* gene is the 3´ UTR sequence from the gene coding for a no apical meristem (Nam) protein domain containing protein from *O. sativa*.
- Cassette 4: *aroA* gene from *Agrobacterium* sp. strain CP4, encoding the CP4-EPSPS protein that was codon optimized for expression in corn, which is preceded by promoter and leader sequence from 35S RNA of cauliflower mosaic virus, 5´ UTR leader sequence from the gene coding for chlorophyll a/b-binding protein of *Triticum aestivum*, intron and flanking UTR sequence of the *act1* gene from *O. sativa*, and a chloroplast target sequence from the *ShkG* gene from *A. thaliana*. Following the *aroA* gene is a modified partial 3´ UTR sequence of *Zea mays* complimentary deoxyribonucleic acid (cDNA) that contains male tissue specific small interference RNA (siRNA) target sequence. Following the siRNA target sequence is the 3´ UTR sequence of the *glycine-rich RNA binding-protein* (*Grp3*) gene from *O. sativa*.

Following transformation, immature embryos were grown in selection medium[4], transformed calli were placed into media conductive to shoot and root development, and plants were grown to maturity. These plants were self-pollinated and the R1 population was screened for the presence of T-DNA and absence of vector backbone sequences by polymerase chain reaction (PCR) and Southern blot analysis. Additional breeding steps were conducted to generate plants used in the characterization of the genetic insertion and inheritance studies.

Bayer characterized the number of T-DNA inserts, the number of insert junctions, the absence of vector backbone sequences, and organization and intactness of each insert that are present in MON 87429 corn using whole genome sequencing (WGS) and bioinformatics analyses. The parental cultivar, LH244, was used as the comparator in these analyses. Bayer reports a minimum average read depth of 86-fold. Bayer reports that a single copy of the T-DNA sequence was inserted into the corn genome and that MON 87429 corn does not contain sequences from the plasmid backbone region. Nucleotide sequencing, using MiSeq, of locus-specific overlapping PCR products demonstrated that the genetic elements within the inserted DNA were intact and that only T-DNA elements were present within the inserted DNA when compared to vector PV-ZMHT519224. The directed sequencing also included 1,029 bp of corn genome sequence that was upstream of the 5´ end of the inserted DNA and 1031 bp of sequence that was downstream of the 3´ end of the inserted DNA. The T-DNA insert replaced 54 bp of *Z. mays* genomic DNA. There also was a 29 bp insertion in the 5´ flanking sequence and a 31 bp insertion in the 3´ flanking sequence, which were not functional genetic elements. Bayer states that these types of changes are probably the result of double stranded break repair during the *Agrobacterium*-mediated transformation process.

[4] The selection media contained carbenicillin disodium salt to eliminate *A. tumefaciens* and glyphosate for selection of putative transformants.

The stability of the inserted T-DNA sequences in MON 87429 corn across multiple breeding generations and their appropriate comparators were evaluated by WGS. Bayer reports that the single locus of integration that was characterized in the R3 generation of MON 87329 corn is present in all five breeding generations of the MON 87429 corn. Within each back-crossed generation, Bayer collected phenotypic and genotypic segregation data to assess inheritance pattern and these data were analyzed using Chi square analysis. Bayer concludes that the inserted DNA segregated as a single locus according to the expected Mendelian principles.

Bayer performed bioinformatics analyses using the nucleotide sequences obtained for the T-DNA insert and the bordering junction sequences to determine whether insertion of the introduced DNA created any potential open reading frames (ORF) that could encode for putative polypeptides. This analysis included nucleotide sequences for each of the six reading frames. Bayer evaluated the putative polypeptides against the TOX 2018 database[5] to determine the similarity of these putative polypeptides to known toxins. Analysis of the sequences spanning the junctions between the corn genome and inserted DNA revealed 14 putative peptides (eight amino acids or greater in length), and there were no unintended polypeptides within the insert. Bayer reports that none of these putative peptides share significant similarity or identity to known toxins or biologically active proteins that could affect animal health.

Protein Safety

Bayer used a weight of evidence approach to assess the safety of the four proteins expressed in MON 87429 corn. This approach included:

1.) documentation of the history of safe consumption of the expressed protein or its structural and functional homology to proteins that lack adverse effects on animal health;
2.) characterization of the physicochemical and functional properties of each expressed protein;
3.) examination of the similarity of each expressed protein to known allergens, toxins or other biologically active proteins known to have adverse effects on humans and animals;
4.) evaluation of the susceptibility of each expressed protein to the digestive enzymes pepsin and pancreatin;
5.) evaluation of the stability of each expressed protein after heat treatment;
6.) quantification of the expression of each of these proteins in plant tissues; and, if justified,
7.) investigation of potential animal toxicity through an animal assay.

Bayer highlights that the DMO protein has been expressed in several commodity crops and includes by reference information on safety of DMO protein isoforms in these crops.[6] In addition, the multistep approach to address the safety of these proteins is

[5] The Tox_2018 database contains 28,344 sequences and was selected using a keyword search of the National Center for Bioinformatics Information GenBank protein database, release 223, and filtered to remove likely non-toxin proteins.

[6] Completed consultations for DMO proteins that are highly similar (identical in structure of the catalytic site, function, immunoreactivity, and substrate specificity) to those produced in MON 87429 corn include BNF No. 000125 (soybean), BNF No. 000135 (cotton), and BNF No. 000148 (corn). Detailed safety assessments on the DMO proteins were provided in BNF No. 000125 and BNF No. 000135.

provided in the scientific literature.[7] Bayer notes that there were minor amino acid differences between the DMO proteins expressed in these crops, but these modifications are not anticipated to have an effect on the structure of the catalytic site, functional activity, immunoreactivity, or specificity of the protein. Because of these slight differences, Bayer assessed the specificity of the two isoforms of the DMO protein that are expressed in MON 87429 corn using dicamba and a structurally related compound, *o*-anisic acid, as substrates in an *in vitro* assay.[8] Bayer reports that dicamba was demethylated, whereas *o*-anisic acid was not catabolized by *Escherichia coli*-produced MON 87429 DMO protein, and Bayer concludes that MON 87429 DMO protein has high specificity for dicamba as a substrate. Bayer also concludes that previous safety assessments are applicable to DMO protein that is expressed in MON 87429 corn and that these data support a conclusion that animal food products containing MON 87429 corn DMO protein pose no meaningful risk to animal health.

Bayer highlights that the PAT and CP4 EPSPS proteins expressed in MON 87429 corn are identical to the proteins that have been expressed in several commodity crops and includes by reference information on safety of these proteins in these crops.[9] In addition, the multistep approach to address the safety of the PAT protein is provided in the scientific literature.[10] Bayer notes that PAT protein produced in MON 87429 corn is identical to the PAT protein present in MON 87419 corn (BNF 0000148). The CP4 EPSPS protein in MON 87429 corn is identical to the CP4 EPSPS protein present in consultations that have completed FDA's consultation process. In addition, Bayer highlights the multistep approach that addresses the safety of the CP4 EPSPS protein is provided in the scientific literature.[11] Bayer notes that the conclusions of these safety assessments are applicable to the PAT and CP4 EPSPS proteins expressed in MON 87429 corn. Based on the results obtained from the protein safety assessments, Bayer concludes that animal food products containing PAT and CP4 EPSPS proteins that are expressed in MON 87429 corn pose no meaningful risk to animal health.

Bayer utilized an endogenous corn regulatory element to target CP4 EPSPS messenger ribonucleic acid (mRNA) for degradation in tassel tissues, which results in glyphosate-

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[7] Wang, C., K.C. Glenn, C. Kessenich, E. Bell, L.A. Burzio, M.S. Koch, B. Li and A. Silvanovich. 2016. Safety assessment of dicamba mono-oxygenases that confer dicamba tolerance to various crops. Regul. Toxicol. Pharmacol. 81:171-182.

[8] Bayer reported in BNF No. 000125 that endogenous plant compounds, including ferulic acid, sinapic acid, syringic acid, and vanillic acid, were not catabolized by DMO protein, even though they were structurally similar to dicamba.

[9] Completed consultations for PAT protein, which has specificity for glufosinate, include BNF No. 000023, No. 000029 (corn), No. 000038 (sugar beet), No. 000046 (canola), No. 000055 (soybean), and No. 000148 (corn); completed consultation for CP4 EPSPS protein, which has specificity for glyphosate, include BNF No. 000126 (corn).

[10] Hérouet, C., D.J. Esdaile, B.A. Mallyon, E. Debruyne, A. Schulz, T. Currier, K. Hendricks, R.-J. van der Klis, and D. Rouan. 2005. Safety evaluation of the phosphinothricin acetyltransferase proteins encoded by the *pat* and *bar* sequences that confer tolerance to glufosinate-ammonium herbicide in transgenic plants. Regul. Toxicol. Pharmacol. 41:134-149.

[11] Harrison, L.A., M.R. Bailey, M.W. Naylor, J.E. Ream, B.G. Hammond, D.L. Nida, B.L. Burnette, T.E. Nickson, T.A. Mitsky, M.L. Taylor, R.L. Fuchs, and S.R. Padgette. 1996. The expressed protein in glyphosate-tolerant soybean, 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4, is rapidly digested in vitro and is not toxic to acutely gavaged mice. J. Nutr. 126:728-740; Nair, R.S., R.L. Fuchs, and S.A. Schuette. 2002. Current methods for assessing safety of genetically modified crops as exemplified by data on Roundup Ready soybeans. Toxicol. Pathol. 30:117-125.

induced non-viable pollen phenotype.[12] Thus, MON 87429 corn can be used in hybrid seed production. Bayer verified that the mRNA degrading sequence did not produce secondary effects (absence of unintended effects on endogenous gene regulation).

Bayer notes that MON 87429 corn also expresses a modified version of the R-2,4-dichlorophenoxypropionate dioxygenase (FT_T) protein. The multistep approach described above was used to assess the safety of the FT_T protein. Bayer highlights that the donor organism, *Sphingobium herbicidovorans*, is a common gram-negative non-motile, non-spore forming soil bacterium that is ubiquitously present in the environment. Bayer states that there is widespread animal exposure to *S. herbicidovorans* without any known adverse safety effects. Bayer states that the FT_T protein is 295 amino acids and it shares 89% sequence identity with the wild type RdpA protein that is produced by *S. herbicidovorans*.[13] Bayer used *in silico* analyses and *in vitro* assays to verify that 32 endogenous plant small molecules plus cinnamate that have structural similarity with 2,4-D were not substrates for the FT_T protein.[14] Bayer also tested 11 herbicidal compounds as positive controls. FT_T protein activity on the herbicidal compounds range from 3-100% (relative to activity of quizalofop). Bayer concludes that the FT_T protein was optimized for quizalofop and 2,4-D catalytic activity and has improved temperature stability.

To obtain sufficient quantities of the FT_T protein for conducting safety assessment studies, Bayer produced the FT_T protein in *E. coli*. Bayer confirmed the identity and biochemical equivalence of the FT_T proteins expressed in *E. coli* and MON 87429 corn, using several analytical techniques.[15] Using the *E. coli* expressed FT_T protein, Bayer demonstrated that FT_T protein was cleaved within 0.5 minutes in simulated gastric fluid and 5 minutes in simulated intestinal fluid, and FT_T protein was denatured when exposed to ≥75°C for 15 minutes. Bayer states that there was no evidence of acute toxicity in mice that were dosed orally at 2000 milligrams of FT_T protein/kilogram of body weight. Bayer also demonstrated that MON 87429 corn and *E. coli* expressed FT_T proteins were not glycosylated. Bayer concludes that these data collectively support the conclusion that expression of FT_T protein in MON 87429 corn poses no meaningful risk to animal health.

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[12] Yang, H., Y. Qi, M.E. Goley, J. Huang, S. Ivashuta, Y. Zhang, O.C. Sparks, J. Ma, B.M. van Scoyoc, A.L. Caruano-Yzermans, J. King-Sitzes, X. Li, A. Pan, M.A. Stoecker, B.E. Wiggins, and M.J. Varagona. (2018) Endogenous tassel-specific small RNAs-mediated RNA interference enables a novel glyphosate-inducible male sterility system for commercial production of hybrid seed in *Zea mays* L. PLoS ONE 13(8):e0202921. https://doi.org/10.1371/journal.pone.0202921.

[13] A total of 30 amino acid substitutions were made to the protein resulting in a protein with improved enzyme kinetics (increased Vmax) and substrate affinity (reduced Km) for 2,4-D and thermal stability, relative to RdpA protein. Cited in the work of Larue, C.T., M. Goley, L. Shi, A.G. Evdokimov, O.C. Sparks, C. Ellis, A.M. Wollacott, T.J. Rydel, C.E. Halls, B. Van Scoyoc, X. Fu, J.R. Nageotte, A.M. Adio, M. Zheng, E.J. Sturman, G.S. Garvey, and M.J. Varagona. 2019. Development of enzymes for robust aryloxyphenoxypropionate and synthetic auxin herbicide tolerance traits in maize and soybean crops. Pest Manag. Sci. 75:2086-2094.

[14] Bayer concludes that substrates for the FT_T protein in MON 87429 corn require three structural features, a phenoxy group, a terminal carboxylate, and an available site for oxidation between the phenoxy group and the terminal carboxylate. Bayer identified endogenous plant small molecules based on a search of the NAPRALERT database (https://napralert.org) using these structural criteria.

[15] The analytical techniques discussed in the submission include sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE), Western hybridization analysis, N-terminal amino acid sequence analysis using nano liquid chromatography mass spectrometry/mass spectrometry (nano LC-MS/MS), and peptide mass fingerprint analysis (nano LC-MS/MS analysis of trypsin digested peptides).

Expression Levels of Proteins in MON 87429 Corn

Bayer quantified DMO, PAT, CP4 EPSPS, and FT_T protein levels in various tissues of MON 87429 corn. The study included five field trial sites with four replicate plots at each site. Forage, leaves, grain, and pollen tissue samples were collected from MON 87429 corn plants from each replicated plot at all field sites treated with dicamba, glufosinate ammonium, quizalofop, and 2,4-D herbicides. Samples were prepared for and analyzed using multiplexed immunoassay. Bayer reports that mean DMO protein level in MON 87429 corn across all sites was highest in leaves at 35 micrograms/gram of tissue dry weight (DW) and lowest in grain at 2.4 micrograms/gram DW. The mean PAT protein level in MON 87429 corn across all sites was highest in leaves at 5.8 micrograms/gram DW and lowest in grain at 0.84 micrograms/gram DW. The mean CP4 EPSPS protein level in MON 87429 corn across all sites was highest in leaves at 54 micrograms/gram DW and lowest in grain at 0.63 micrograms/gram DW micrograms/gram DW. The mean CP4 EPSPS protein level in pollen across all sites was below the limits of quantitation of the assay, consistent with the intended effect of tissue specific expression of the CP4 EPSPS protein. The mean FT_T protein level in MON 87429 corn across all sites was highest in leaves at 440 micrograms/gram DW and lowest in grain at 47 micrograms/gram DW.

Bayer concludes that each of the newly expressed enzymes in MON 87429 corn was fully characterized to confirm amino acid sequence, function, and specificity. Bayer cited information in scientific literature for DMO, PAT, and CP4 EPSPS proteins and demonstrated that the FT_T protein was rapidly digested with pepsin and pancreatin and was denatured when exposed to a temperature of 75 to 95°C. Additionally, Bayer notes that the risk to animals following dietary exposure to these proteins from consumption of animal food derived from MON 87429 corn is very low. Based on this information, Bayer concludes that dietary exposure to DMO, PAT, CP4 EPSPS, and FT_T proteins in MON 87429 corn poses no meaningful risk to animal health.

Animal Food Use

Corn (*Zea mays* L.) is a commodity crop grown worldwide for various uses, including human and animal food. In the United States, the world's leading producer of corn, several different types of corn are cultivated, including field corn (e.g., yellow dent and white dent), sweet corn, and popping corn. Corn grain and by-products of corn processing may be included in diets for most animal species. Corn silage is a readily digestible, high energy, fermented forage product. It is fed primarily to ruminants (e.g., cattle, sheep, and goats). For animal nutrition, corn is considered to be an important source of energy, essential fatty acids, and some of the essential amino acids.

Composition

Scope of Analysis

Bayer analyzed the nutrient composition of MON 87429 corn and a conventional corn variety (control) that were grown and harvested under similar conditions. Compositional analyses of grain and forage samples were reported for components listed in the Organisation for Economic Cooperation and Development (OECD) corn composition consensus document.[16]

[16] Organisation for Economic Cooperation and Development. 2002. Consensus document on compositional considerations for new varieties of maize (*Zea mays*): Key food and feed nutrients, anti-nutrients, and secondary plant metabolites. OECD ENV/JM/MONO 25. OECD, Paris, France.

Study Design

Bayer conducted field trials in 2017 at five locations in the United States. A randomized complete block design with four replicate plots was used at each field site. The MON 87429 corn plots were treated with dicamba, glufosinate ammonium, quizalofop, and 2,4-D. Forage samples were harvested at R5 growth stage and were shipped on dry ice from the field sites to Bayer. A subsample for compositional analysis was obtained from forage and grain samples and stored at not less than -20°C prior to nutrient analyses.

Components that were analyzed in forage samples included crude protein, crude fat, ash, carbohydrates by calculation,[17] acid detergent fiber (ADF), neutral detergent fiber (NDF), calcium, and phosphorus. Nutrient analyses in grain included the above mentioned components plus total digestible fiber, 18 amino acids, 22 fatty acids, nine minerals, seven vitamins, three secondary metabolites, and two anti-nutrients. Bayer noted that 13 of the fatty acids, sodium, and furfural were not statistically analyzed because more that 50% of the observations fell below the lower limits of quantitation. Results were all expressed on a dry matter basis prior to statistical analyses. Moisture of forage and grain were not statistically analyzed. Bayer statistically compared each component for MON 87429 corn with the control across-locations using a linear mixed model with site and replicate as random factors. T-test analyses were used to test at the level of $P \leq 0.05$ for differences between MON 87429 corn and control. Differences between MON 87429 corn and control were evaluated in context of variation within the conventional control germplasm grown across multiple sites and of natural variability defined by values for conventional corn varieties in the International Life Sciences Institute (ILSI) Crop Composition Database (CCDB) or in the scientific literature.

Results of Analyses – Forage

Bayer reported that there were no statistically significant differences between MON 87429 corn and control for any of the analyzed components. Bayer also notes that all of these components fell within the natural variability that is observed for corn forage components.

Results of Analyses – Grain

Bayer reports that there were no statistically significant differences between MON 87429 corn and control for most of the analyzed components. Statistically significant differences between MON 87429 corn and the control were reported for total fat, 3.76 and 3.88% for MON 87429 and control, respectively, and for six (palmitoleic, stearic, oleic, linoleic, linolenic, and behenic acids) of the nine fatty acids that were present in the grain samples.[18] Statistically significant differences were also reported for copper, iron, magnesium, and alpha-tocopherol. However, Bayer notes that for all of these components, the mean difference between MON 87429 corn and the control was less than the range of values for the control. The mean values for all of these components were also within the range of values observed in the ILSI-CCDB and scientific literature. Bayer concludes that the observed statistically significant differences between MON 87429 corn and the control are not biologically meaningful from an animal food safety perspective.

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[17] Percent carbohydrates = 100% - (% protein + % fat + % moisture + % ash).
[18] Bayer highlights that linoleic, oleic, and palmitic acids account for 96% of the total fatty acids in corn.

Summary of Compositional Analyses

Bayer states that expression of the four proteins that impart tolerance to different herbicides does not meaningfully alter the nutrient composition of MON 87429 corn. Bayer concludes that these results support the conclusion that forage and grain obtained from MON 87429 corn are compositionally equivalent to the control in the levels of key nutrients and anti-nutrients.

Conclusion

CVM evaluated Bayer's submissions to determine whether MON 87429 corn raises any safety or regulatory issues with respect to its use in animal food. Based on the information provided by Bayer and other information available to the agency, CVM did not identify any safety or regulatory issues under the FD&C Act that would require further evaluation at this time.

Bayer concludes that MON 87429 corn and the animal foods derived from it are as safe as and are not materially different in composition or any other relevant parameter from other corn varieties now grown, marketed, and consumed. At this time, based on Bayer's data and information, CVM considers Bayer's consultation on MON 87429 corn for use in animal food to be complete.

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