NATIONAL ENVIRONMENTAL POLICY ACT

FINDING OF NO SIGNIFICANT IMPACT

BASF Plant Science L.P. Petition (17-321-01p) for Determination of Nonregulated Status for LBFLFK Canola

OECD Unique Identifier: BPS-BFLFK-2

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this Finding of No Significant Impact (FONSI) to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) NEPA implementing regulations, and APHIS NEPA implementing procedures (7 CFR part 372). This FONSI sets forth APHIS' NEPA decision with respect to potential impacts to the human environment that could derive from a determination of nonregulated status for LBFLFK canola.

In November 2017, BASF Plant Science L.P. (BASF) submitted a petition (17-321-01p) to the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), requesting that genetically engineered (GE) LBFLFK canola, and any progeny derived from it, no longer be considered regulated articles under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). LBFLFK canola has been regulated by APHIS because it was developed using the plant pest *Agrobacterium rhizogenes*; a regulated article under 7 CFR part 340.2. BASF genetically engineered LBFLFK canola to produce long chain omega-3 polyunsaturated fatty acids (LC-PUFAs) not otherwise present in canola seed; namely, eicosopentaenoic acid (EPA) and docosahexaenoic acid (DHA). LBFLFK canola oil and whole seed are intended to provide additional sources of these omega-3 fatty acids to help meet human and food animal (e.g., livestock, poultry, farmed fish) dietary needs. LBFLFK canola was also engineered for resistance to imidazolinone based herbicides, which contain active ingredients such as imazamox.

As part of evaluation of BASF's petition APHIS conducted an Environmental Assessment (EA) to inform APHIS' decision regarding the regulatory status of LBFLFK canola. The EA evaluated the potential impacts of APHIS' regulatory decision on the quality of the human environment.[1] The EA did not identify any significant impacts that would derive from either an approval or denial of the petition. Therefore, the Agency has prepared this FONSI, pursuant to 40 CFR part 1508.13. This FONSI provides a summary of the EA and the reasons why APHIS' decision to

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR § 1508.14).

issue a determination of nonregulated status for LBFLFK canola will not have a significant impact on the human environment.

APHIS Regulatory Authority and the Coordinated Framework

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products.[2] Since 1986, the Environmental Protection Agency (U.S. EPA), Food and Drug Administration (FDA), and USDA have regulated GE organisms consistent with this framework. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are required to exercise oversight of GE organisms only when there is evidence of "unreasonable" risk.

In 2015, the U.S. EPA, FDA, and USDA began an effort to modernize the regulatory system for biotechnology products to accomplish three tasks: (1) clarify the current roles and responsibilities of the U.S. EPA, FDA, and USDA in the regulatory process; (2) develop a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology; and (3) commission an expert analysis of the future landscape of biotechnology products. The *Update to the Coordinated Framework for the Regulation of Biotechnology* was released on January 4, 2017.[3] The authorities and regulatory roles for USDA–APHIS, the U.S. EPA, and FDA are briefly summarized below.

USDA-APHIS

Protecting animal and plant health is among APHIS' primary strategic goals. APHIS provides leadership in ensuring the health and care of plants and animals. The agency's strategic goals help improve agricultural productivity and competitiveness, and contributes to the national economy and the public health. The USDA asserts that all methods of agricultural production (conventional, organic, or the use of GE varieties) can provide benefits to the environment, consumers, and farm income.

APHIS regulates GE organisms to ensure that they do not pose a plant pest risk pursuant to the Plant Protection Act (PPA) of 2000, as amended (7 USC §§ 7701 et seq.) and APHIS implementing regulations at 7 CFR part 340. APHIS regulations at 7 CFR part 340 govern the importation, interstate movement, and environmental release of GE organisms that may pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR § 340.2) and is also considered a plant pest; such as *Agrobacterium rhizogenes*. A GE organism is also regulated under 7 CFR part 340 when the APHIS administrator determines or has reason to believe that the GE organism is a plant pest. A

[2] An *Update to the Coordinated Framework for Regulation of Biotechnology* was released on January 4, 2017. See https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

[3] See https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

GE organism is no longer subject to the PPA or to the requirements of 7 CFR part 340 when APHIS determines that a GE organism is unlikely to pose a plant pest risk.

FDA

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the *Federal Register* on May 29, 1992 (57 FR 22984). Pursuant to this policy, the FDA uses what is termed a voluntary consultation process to ensure that human food and animal feed safety issues and other regulatory issues are resolved prior to commercial distribution of bioengineered foods. To help developers of food and feed derived from GE crops comply with their obligations pursuant under Federal food safety laws, the FDA encourages them to participate in a voluntary consultation process. BASF states they will consult with the FDA as to the safety of food and feed products derived from LBFLFK canola.

EPA

The U.S. EPA regulates pesticide use, including plant-incorporated protectants pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Any pesticide used with LBFLFK canola must comply with EPA labeled use and other requirements. The U.S. EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, pursuant to FFDCA. BASF states they will petition the U.S. EPA to update the label for Beyond® herbicide to allow for field application on LBFLFK canola.

APHIS' Response to Petitions for Nonregulated Status

APHIS regulations at 7 CFR part 340 provide that any person may submit a petition to APHIS requesting that, because the GE organism does not pose a plant pest risk, it should not be regulated by APHIS. As required by 7 CFR 340.6, APHIS must respond to petitioners with a regulatory status decision. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to regulation under 7 CFR part 340.

Public Involvement

On March 30, 2018 APHIS announced in the *Federal Register* that it was making BASF's petition available for public review and comment to help identify potential environmental and interrelated economic issues that APHIS should consider in evaluation of the petition.[4] APHIS accepted written comments on the petition for a period of 60 days, until midnight May 29, 2018. At the end of the comment period APHIS had received 8 comments on the petition. Five comments (four from the agricultural sector and one from an individual) were in support of BASF's petition. Three comments (two from the same individual, and one from the Center for

[4] Federal Register, / Vol. 83, No. 62 / Friday, March 30, 2018 / Notices / p. 13722 - BASF Plant Science, LP; Availability of Petition for Determination of Nonregulated Status of Canola Genetically Engineered for Altered Oil Profile and Resistance to an Imidazolinone Herbicide. Available at https://www.regulations.gov/docket?D=APHIS-2018-0014

Biological Diversity) were opposed to any approval of BASF's petition. A full record of each comment received is available online at www.regualtions.gov.[5]

On April 4, 2019 APHIS announced in the Federal Register it was making available the draft EA and PPRA for a 30-day public review and comment period.[6] At the end of the comment period APHIS had received 2 public comments. One comment from the U.S. Canola Association was in support of the petition. One comment from an individual was opposed to approval of the petition. Among the comments received, no new information was presented to APHIS that contributed to or altered the analyses presented in the EA. A full record of each comment received is available online at www.regulations.gov, Docket ID: APHIS-2018-0014.

The Environmental Assessment and Scope of Analysis

An EA was prepared consistent with CEQ regulations (40 CFR parts 1500-1508) and USDA-APHIS NEPA implementing procedures (7 CFR part 372). APHIS developed a list of topics for consideration in the EA based on issues identified in prior EAs for GE canola varieties, public comments submitted on the petition and draft EA for LBFLFK canola, other EAs and EISs evaluating petitions for nonregulated status, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Brassica* species. The following topics were identified as relevant to the scope of analysis (40 CFR part 1508.25):

Agricultural Production

- Acreage and Areas of Canola Production
- Agronomic Practices and Inputs

Environmental Considerations

- Soil Quality
- Water Resources
- Air Quality
- Soil Biota
- Animal and Plant Communities
- Herbicide Resistant Weeds
- Gene Flow and Weediness of Canola
- Biodiversity

Human Health

- Consumer Health and Worker Safety

Animal Health

- Animal Feed/Livestock Health

Socioeconomics

- Domestic Economic Environment and International Trade

In addition to evaluation of potential direct and indirect impacts, potential cumulative impacts relative to these topics were also considered. Additionally potential impacts on threatened and endangered species, as well as adherence of the regulatory decision to executive orders, and

[5] See https://www.regulations.gov/docket?D=APHIS-2018-0014

[6] Federal Register / Vol. 84, No. 65 / Thursday, April 4, 2019 / Notices / p. 13243: Environmental Assessments; Availability, etc.: BASF Plant Science, LP, Canola Genetically Engineered for Altered Oil Profile and Resistance to an Imidazolinone Herbicide. Available at https://www.regulations.gov/document?D=APHIS-2018-0014-0011

environmental laws and regulations to which the regulatory status decision may be subject were analyzed.

Alternatives Evaluated in the EA

NEPA implementing regulations (40 C.F.R. § 1502.14) require agencies to evaluate all alternatives that appear reasonable and appropriate to the purpose and need for the Agency's action (in this case, a regulatory decision). Two alternatives were evaluated in the EA for BASF's petition: (1) No Action, denial of the petition, which would result in the continued regulation of LBFLFK canola, and (2) a determination of nonregulated status for LBFLFK canola, approval of the petition, the Preferred Alternative.

No Action: Continuation as a Regulated Article

One of the alternatives that must be considered by APHIS is a "No Action Alternative," pursuant to CEQ regulations at 40 CFR part 1502.14. No Action in this instance means no change in regulatory status. Under the No Action Alternative APHIS would deny the petition request for nonregulated status and LBFLFK canola and progeny derived from LBFLFK canola would remain regulated articles under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would be required for the introduction of LBFLFK canola. Because APHIS concluded in its PPRA that LBFLFK canola is unlikely to pose plant pest risk (USDA-APHIS 2019), choosing this alternative would not be an appropriate response to BASF's petition, nor satisfactorily meet the purpose and need for making a science based regulatory status decision consistent with the requirements of 7 CFR part 340.

Preferred Alternative: Determination of Nonregulated Status for LBFLFK Canola

Under this alternative LBFLFK canola and progeny derived from it would no longer be subject to APHIS regulation under 7 CFR part 340 because it was determined that, based on the scientific evidence before the Agency, LBFLFK canola is unlikely to pose a plant pest risk (USDA-APHIS 2019). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of LBFLFK canola. This alternative best satisfies the purpose and need to respond appropriately to the petition for nonregulated status, pursuant to the requirements of 7 CFR part 340.6 and the Agency's statutory authority under the PPA.

Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS evaluated several other alternatives for consideration in the EA in light of the Agency's statutory authority under the PPA and APHIS implementing regulations at 7 CFR part 340, but dismissed them from detailed analysis in the EA. The additional alternatives considered are summarized in the EA along with the reasons for dismissal from detailed analysis.

Environmental Consequences of APHIS' Selected Action

The EA provides analyses of the alternatives APHIS considered, to which the reader is referred for specific details. The following table summarizes the potential environmental impacts of the No Action and Preferred Alternative.

Table Error! No text of specified style in document.**-1. Summary of Potential Impacts for the Alternatives Considered**		
Analysis	**No Action Alternative: Continue to Regulate LBFLFK Canola as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for LBFLFK Canola**
Meets Purpose and Need	No	Yes
Unlikely to pose a plant pest risk	Addressed by the use of regulated field trials.	Determined by the plant pest risk assessment (USDA-APHIS 2019).
Agricultural Production		
Acreage and Areas of Canola Production	Denial of the petition would have no effect on the areas or acreage utilized for canola production. Fluctuations in production areas and acreage would be relative to climate, pest and disease pressures, market demand for canola oil and meal, as well as availability of soybean oil and meal.	The potential impact of approval of the petition on the total number of U.S. acres planted to canola is difficult to determine with any degree of accuracy. Because LBFLFK canola oil, enriched in EPA and DHA, would be a new commodity, it may entail use of additional cropland for production. Market forces, grower choices, consumer preference, and demand for vegetable and fish oils rich in EPA and DHA, across all markets (i.e., feed, food, and nutraceuticals), will, in combination, determine the market share and scale of adoption of LBFLFK canola. Among these factors, consumer preference for a GE vegetable oil enriched in omega-3 fatty acids is uncertain.
Agronomic Practices and Inputs	Agronomic practices and inputs used in canola crop production would remain unchanged.	Studies evaluating the phenotypic and agronomic properties of LBFLFK canola indicate agronomic practices and inputs would be the same as for other varieties of canola (BASF 2018). As discussed above, if LBFLFK canola entails the use of additional cropland for production, there would be a commensurate increase in pesticide inputs, subject to U.S. EPA requirements.
Use of GE Canola	Approximately 90% of the U.S. canola crops are GE herbicide resistant (HR) varieties. Denial of the petition would have no effect on the planting of existing varieties of GE canola.	Approval of the petition would provide for cultivation of a GE canola with modified nutritional properties – subject to voluntary consultation with the FDA.
Physical Environment		
Soils	Agronomic practices, inputs, and other factors potentially impacting soils would be unaffected by denial of the petition. Growers will continue management practices, such as crop rotation, conservation tillage, and pest and weed management strategies that maximize crop yield, preserve soil quality, and avoid soil erosion.	The agronomic practices and inputs are the same for both LBFLFK and existing canola varieties – potential direct and indirect impacts to soils would be unchanged.
Water Resources	Denial of the petition would have no effect on water resources in the United States.	Because the agronomic practices and inputs utilized for LBFLFK canola production would be no different than those currently

Table Error! No text of specified style in document.**-1. Summary of Potential Impacts for the Alternatives Considered**		
Analysis	**No Action Alternative: Continue to Regulate LBFLFK Canola as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for LBFLFK Canola**
		used, sources of potential impacts on water resources, namely NPS pollutants in agricultural run-off, would not be expected to substantially differ. There are no novel impacts to water resources identified with cultivation of LBFLFK canola. The U.S. EPA provides label use restrictions and guidance for pesticides, to include imidazolinone based herbicides, that are intended to prevent impacts to surface and groundwater.
Air Quality	Emission sources, namely tillage and machinery combusting fossil fuels, and the level of emissions associated with canola production would be unaffected by denial of the petition.	Because agronomic practices and inputs would remain unchanged, no changes to emission sources (i.e., tillage, fossil fuel burning equipment, the application of fertilizers and pesticides) are expected. An increase in acreage used for LBFLFK canola production would result in a commensurate increase in NAAQS emissions, however, the probability and extent of increased acreage is highly uncertain. In general, approval of the petition is unlikely to result in a significant increase in production area and associated emissions of NAAQS pollutants.
Biological Resources		
Soil Biota	Potential impacts on soil biota would be unaffected by denial of the petition.	Commercial production of LBFLFK canola and LBFLFK hybrid crops are not expected to present any impacts to soil biota. Same or functionally similar elongase and desaturase enzymes, and the fatty acids they synthesize, are inherent to a variety of soil biota.
Animal Communities	Potential impacts on animal communities would be unaffected by denial of the petition.	Approval of the petition, and subsequent commercial production of LBFLFK canola, would not be expected to affect animal communities adjacent to or within LBFLFK canola cropping systems any differently from that of current canola cropping systems. All wildlife consume or synthesize, and are comprised of, fatty acids found in LBFLFK canola seed, to include the LC-PUFA EPA, and to some extent DHA. It is unlikely that LBFLFK canola seed presents any risks to wildlife. Acetohydroxyacid synthase (AHAS) enzymes are ubiquitous in plants and microbes. It is highly unlikely the modified AHAS in LBFLFK canola presents any risks to wildlife.
Plant Communities	Potential impacts on plant communities would be unaffected by denial of the petition. Plants (other than crop plants) in	Because the agronomic practices and inputs that will be used for LBFLFK canola production are the same as for other canola

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	canola fields are considered weeds as they can impact crop yield and quality. Weeds are managed using a variety of methods, including tillage and herbicides. The U.S. EPA regulates and determines how pesticides can be used. U.S. EPA pesticide use requirements are intended to be protective of non-target plant communities and other plants, such as those in adjacent fields.	varieties, potential impacts on plant communities would be the same as that for the No Action Alternative.
Gene Flow and Weediness	Pollen may flow from GE canola to sexually-compatible wild relatives i.e., *Brassica* spp. The progeny of this gene flow (hybrids) could spread to other areas and lead to the establishment of additional feral hybrid populations. Because of the general ecological requirements of *Brassica* spp., the establishment of feral hybrid populations is more likely in sites that are subject to frequent disturbances. Pollen dispersal is most likely to areas 300 feet or less from pollen sources. Rarely, outcrosses may occur at distances up to 2 miles away. APHIS recognizes interspecific and intraspecific hybridization will occur, although probably at a low frequencies. Gene flow is most likely to occur among *B. napus* crops grown in adjacent areas, and *B. napus* crops and wild relative *B. rapa* species.	LBFLFK canola, if grown for commercial purposes, would present the same potential risk for gene flow, specifically the propensity and frequency of gene flow, as current canola varieties. Accordingly, a determination of nonregulated status for LBFLFK canola and its progeny would not be expected to present more or less risk for gene flow to wild relative species as do current canola varieties. Based on the PPRA, APHIS concluded that it is unlikely that gene introgression from LBFLFK canola to other organisms with which it can interbreed will increase their weediness (USDA-APHIS 2019).
Biodiversity	LBFLFK canola could be grown in field trial settings under permit or notification. Because of the relatively small acreages and short periods required for field trials compared to that of commercial-scale crop production, it is unlikely that LBFLFK field trials would impact biodiversity.	Because LBFLFK canola is agronomically the same as currently cultivated canola varieties, potential impacts on biodiversity would be the same as under the No Action Alternative.
Human and Animal Health		
Human Health	Denial of the petition would have no effect on human health.	Approval of the petition would provide for the use of LBFLFK canola products in the food industry. BASF states they will consult with the FDA as to the safety of food products derived from LBFLFK canola. The U.S. EPA regulation of pesticides, and worker protection standards, would be no different than that of the No Action Alternative.
Animal Health and Welfare	Denial of the petition would have no effect on animal health and welfare. LBFLFK	LBFLFK canola oil and whole seed would provide a supplemental source of omega-3

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Analysis	**No Action Alternative: Continue to Regulate LBFLFK Canola as a Plant Pest**	**Preferred Alternative: Approve the Petition for Nonregulated Status for LBFLFK Canola**
	canola would remain a regulated article and would not be available as an animal feed. Current canola based feed for livestock will remain unchanged.	fatty acids in the production of animal feed, to include feeds for use in the aquaculture industry. BASF states they will consult with the FDA as to the safety of feed products derived from LBFLFK canola.
Socioeconomics		
Domestic Economic Environment	Denial of the petition would have no effect on the U.S. domestic canola oil, meal, or biodiesel markets.	Approval of the petition would not be expected to present any significant impacts to domestic markets. To the extent LBFLFK canola augmented current marine sources of EPA and DHA and the oil and seed valued commodities in the food and feed industries, benefits to domestic markets would be expected. It is assumed that growers would adopt and produce LBFLFK canola commensurate with market demand for GE vegetable oil and whole seed enriched in DHA and EPA.
International Trade	Denial of the petition would have no impacts on the trade of canola commodities.	U.S. canola imports and exports would be unaffected by a determination of nonregulated status to LBFLFK canola.
Cumulative Impacts		
Agriculture, Physical and Biological Resources, Public Health, Socioeconomic	No significant cumulative impacts on agronomic practices and inputs, the acreage and areas of canola production, the physical environment and biological resources, development of pest and weed resistance, gene flow and weediness, human and animal health, domestic markets, or international trade were identified.	LBFLFK canola production would entail the use of pesticides and fertilizers, and to some extent tillage, which will contribute to potential cumulative impacts on water, soil, and air quality, as does current canola production. If total U.S. canola acreage increases due to LBFLFK canola adoption in the market, there would be a commensurate increase in the contribution of agricultural inputs (pesticides and fertilizers) as well as NAAQS emissions, relative to the amount of increased acreage. If LBFLFK canola is accepted by consumers, there may be a marginal increase in canola acreage, with commensurate cumulative effects on total agricultural inputs and NAAQS emissions, and the impacts these may present to water and air quality, and soil resources.
Coordinated Framework		
U.S. Regulatory Agencies	Denial of the petition would have no effect on the roles of the FDA and U.S. EPA in oversight of LBFLFK canola.	BASF intends to consult with the FDA on the food and feed safety of LBFLFK canola. BASF will petition the U.S. EPA to update the label for Beyond® herbicide to allow for field application on LBFLFK canola.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Compliant	Compliant

Finding of No Significant Impact

The analyses in the EA indicate that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of granting nonregulated status to LBFLFK canola. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA finding is based on the following context and intensity factors (40 CFR part 1508.27).

Context

The term "context" means identification of the locations and resources that could potentially be affected by the Agency's petition decision. The EA identified the areas in which canola is grown and may be cultivated in the United States, and those aspects of the human environment potentially affected by the Agency's regulatory decision. This decision has the potential to affect GE and non-GE canola cropping systems; environments adjacent to and associated with LBFLFK canola cropping systems; canola oil and meal post-harvest processing systems; and domestic and foreign canola commodity markets. The areas affected by a determination of nonregulated status for LBFLFK canola are localized to those of commercial canola crops, canola seed processing facilities, and the transport routes associated with pre-planting and harvested seed distribution. In the United States, canola is currently produced in 34 states, and canola croplands comprise around 2.0 million acres. Around 80% to 90% of U.S. canola production occurs in North Dakota (depending on the year), with significantly less production occurring in other states. Canola production is largely concentrated in the Northwestern United States, where a cooler climate is more amenable to optimizing yields (ideal temperature for canola is between 53° and 86° F).

Currently, around 90% of U.S. canola acreage is comprised of GE herbicide resistant (HR) varieties, hence, a small percentage of canola crops are comprised of non-GE cultivars. As of 2016 (latest data) there were only 4 USDA certified organic canola farms in the United States, two in Pennsylvania, one Indiana, and one in Iowa (USDA-NASS 2017).

Because LBFLFK canola oil would be a new commodity, marketed as a specialty canola oil containing EPA and DHA, production may eventually involve the use of additional cropland for production. Any increase in cropland would entail a commensurate increase in pesticide use, subject to U.S. EPA requirements. The potential impact of approval of the petition on the total number of U.S. acres planted to canola is difficult to determine with any degree of accuracy. Market forces, consumer preference, and demand for vegetable and fish oils comprised of EPA and DHA, across all markets (i.e., feed, food, and nutraceuticals), will determine the market share and scale of adoption of LBFLFK canola. Among these factors, consumer preference for a GE vegetable oil containing omega-3 fatty acids is uncertain. It is anticipated that initial use may be limited to the livestock and aquaculture feed industries. In general, it is possible that, if LBFLFK canola eventually becomes a preferred source of food oil and animal feed, as well as a source for production of EPA/DHA supplements, an increase in canola acreage could follow.

Intensity

Within the context discussed above, intensity means the degree or severity of potential impacts. As recommended by CEQ (40 CFR part 1508.27), the following were considered in evaluating intensity and making this NEPA determination.

1. *Impacts that may be both beneficial and adverse.*

   The EA evaluated the potential impacts of approval and denial of the petition, this included impacts that would be potentially adverse, as well as beneficial; these are summarized below.

   Potentially Beneficial: Approval of the petition could potentially result in market availability of a canola oil comprised of omega-3 fatty acids, namely EPA and DHA. A substantive body of scientific literature describes the health benefits of EPA and DHA and the challenge for most individuals in the United States to acquire a recommended dietary intake of 250 to 1000 mg/day for adults, and from 40 to 250 mg/day for children, adolescents, and infants older than six months (Weylandt et al. 2015; NIH 2017). Adequate intake of EPA and DHA is recommended by many health authorities to prevent or treat chronic diseases (Russell and Bürgin-Maunder 2012; Calder 2014; NIH 2017). To the extent this canola variety helps provide the food and feed industries an additional supply of vegetable oil comprised of EPA and DHA, there may be benefits to public health – relative to consumer preference, and uses of LBFLFK canola oil by the food and feed industries.

   Potentially Adverse: The agronomic practices and inputs used for cultivation of LBFLFK canola would be the same as those used for other canola varieties. Thus, cultivation of LBFLFK canola would have the same potential for impacts on water, soil, and air quality as that of currently cultivated canola. For water, these risks would be relative to the proximity of surface waters to LBFLFK canola crops. As discussed above, if cultivation of LBFLFK canola entails increased canola acreage, there would be a commensurate increase in pesticide use, and contribution to the cumulative emissions of NAAQS pollutants. Any use of pesticides would be subject to U.S. EPA as well as state requirements (e.g., (US-EPA 2017a, b)). The potential impacts of agricultural activities on air, water, and soil quality are well understood. As discussed in the EA, there are various federal and state cooperative initiatives to help mitigate these impacts.

2. *The degree to which the proposed action affects public health or safety.*

   Potential impacts on public health are considered generally beneficial. BASF states they will initiate a consultation with the FDA as to the safety of food and feed products derived from LBFLFK canola. The HR trait in LBFLFK canola is conferred through the introduced transgene and enzyme product acetohydroxy acid synthase (AHAS), derived from *Arabidopsis thaliana*, a plant in the Brassicaceae family (same family as LBFLFK canola). As reviewed in the EA, it is unlikely the AHAS enzyme present in LBFLFK canola presents any risk to human health. Any pesticide used in cultivation of LBFLFK canola would need to be used pursuant to U.S. EPA registration, label specifications, and other requirements.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

   The EA concluded it is unlikely that historic or cultural resources, park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas would be significantly impacted by a determination of nonregulated status for LBFLFK canola. Feral populations of LBFLFK canola may establish along seed transport routes and in environments proximate to LBFLFK canola crop fields. However, invasion of park lands, wetlands, wild and scenic areas, or ecologically critical areas by LBFLFK canola or feral hybrids is considered unlikely. APHIS conducted a PPRA and concluded that it is unlikely that LBFLFK canola will become weedy or invasive. The PPRA also concluded it unlikely that gene introgression from LBFLFK canola into wild *Brassica* species will increase the weediness of LBFLFK canola hybrids (USDA-APHIS 2019). Consequently, cultivation of LBFLFK canola is not expected to present any risks to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

   Approval of BASF's petition is not an action considered highly controversial in nature. The EA concluded that the agronomic practices and inputs that would be used for LBFLFK canola production are no different than those utilized for production of current canola varieties. Thus, the potential sources of impacts, and the nature of potential impacts on physical and biological resources that could derive from LBFLFK canola production are no different than that of currently cultivated canola. The fatty acids present in the seed of LBFLFK canola, to include EPA, and to some extent DHA, serve vital structural and functional purposes in most animal species studied (Stanley-Samuelson et al. 1988; Swanson et al. 2012; Calder 2014); these fatty acids present no risk to plants, animals, and other taxa. While the United States has no official Recommended Daily Allowance for EPA or DHA, there is a general consensus among health professionals that a daily individual intake of 250 to 1000 mg/day EPA/DHA for adults and from 40 to 250 mg/day for infants older than six months, and children and adolescents, is required for optimal health and disease prevention (Calder 2014; Weylandt et al. 2015; NIH 2017).

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

   The vital physiological roles and health benefits of EPA and DHA are well recognized and evaluated in the EA relative to LBFLFK canola production. Imazamox resistant canola varieties are already produced in the United States, such as those sold under the Clearfield® brand. Market forces, consumer preference, and demand for vegetable and fish oils comprised of EPA and DHA, across all markets (i.e., feed, food, and nutraceuticals), will determine the market share and scale of adoption of LBFLFK canola. Among these factors, consumer preference for a GE vegetable oil enriched in omega-3 fatty acids is uncertain. Consequently, the potential impact of approval of the petition on any potential increase in acreage planted to canola is difficult to determine with any

degree of accuracy. While there is some uncertainty in this respect, this does not present any unique or unknown impacts on physical or biological resources that were not evaluated in the EA and considered by the Agency.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

   Approval of BASF's petition would not establish a precedent for future actions, nor would it represent a decision in principle about a future decision. Approval of the petition is based upon an independent determination of whether LBFLFK canola poses a plant pest risk pursuant to 7 CFR part 340 (USDA-APHIS 2019), and an environmental analysis consistent with NEPA and CEQ implementing regulations. APHIS has reviewed and approved petitions for nonregulated status since 1992, to include 11 petitions for GE canola varieties. All petitions submitted were reviewed independent of the other, and determinations of regulatory status issued in part based on plant pest risk assessments and relevant NEPA analyses specific for the GE organism subject of the petition. Each petition that APHIS receives is for a particular GE organism-trait combination and undergoes an independent review to determine if the regulated article may pose a plant pest risk. The requirements for petitions for nonregulated status, which include APHIS' response requirements, are described in 7 CFR part 340.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

   The potential cumulative impacts of agricultural activities on air, water, and soil quality are well recognized. The agronomic practices and inputs used for LBFLFK canola production would be no different than those currently used, consequently, the types of potential cumulative impacts that derive from these practices and inputs, namely those on the physical environment and biological resources, are the same under both alternatives. The only potential difference between the alternatives would be relative to any increase in acreage used for LBFLFK canola crop production, discussed above, and how this may expand the range of potential cumulative impacts. The EA considered this outcome and concluded that, while LBFLFK canola crop production would contribute to cumulative impacts as does production of current canola varieties, a determination of nonregulated status for LBFLFK canola is not a decision that is likely to result in any significant cumulative impacts on the human environment. APHIS has not identified any changes in the agronomic practices and inputs used for cultivation of LBFLFK canola, or its progeny, that would present any novel risks to the physical environment or biological resources. The EA did not identify any adverse cumulative impacts on human or animal health, or domestic or international markets.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*

   The EA concluded that approval of the petition is not an action that would directly or indirectly alter the character or use of properties protected under the National Historic Preservation Act. It would have no impact on districts, sites, highways, structures, or objects listed in, or eligible for listing in, the National Register of Historic Places, nor

cause any loss or destruction of significant scientific, cultural, or historic resources. LBFLFK canola would be cultivated on lands zoned for agricultural uses. The crop production practices used in the cultivation of canola do not introduce significant visual impairments, or noise, in a manner that would impact the use and enjoyment of historic properties in areas proximate to canola fields. Any farming activities that may be undertaken on tribal lands are only conducted under the tribe's approval; tribes have control over any potential conflict with cultural resources on tribal properties.

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

   APHIS analyzed the potential effects of LBFLFK canola on threatened and endangered species and critical habitat. APHIS concluded that approval of the petition for nonregulated status for LBFLFK canola, and any subsequent commercial production of this canola variety, will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the U.S. Fish and Wildlife Service and National Marine Fisheries Services are not required.

10. *Whether the action threatens a violation of federal, state, or local law or requirements imposed for the protection of the environment.*

    The EA evaluated the federal, state, and local laws and regulations, executive orders, and policy related to APHIS' decision on BASF's petition. The EA concluded that approval of the petition would not lead to circumstances that resulted in non-compliance with federal, state, or local laws and regulations providing protections for environmental and human health. The U.S. EPA will regulate the use of pesticides on LBFLFK canola, and BASF states they will consult with the FDA as to the food and feed safety of canola oil and meal derived from LBFLFK canola.

NEPA Decision and Rationale

I have carefully reviewed the EA and determined that the analyses and conclusions support a Finding of No Significant Impact (FONSI) from the deregulation of LBFLFK canola.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." Based upon our evaluation and analysis, the Preferred Alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect the health and value of American agriculture and natural resources using a science-based regulatory framework that allows for the safe development and use of GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations pursuant to 7 CFR part 340. As APHIS has not identified any plant pest risks associated with LBFLFK canola, the continued status of LBFLFK canola as a regulated article would be inconsistent with the plant pest provisions of the PPA, APHIS regulations at 7 CFR part 340, and the biotechnology regulatory policies of the

Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of LBFLFK canola will not have any significant impacts on the human environment.

Ibrahim M. Shaqir
Acting Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

8/1/2019
Date

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