

NATIONAL ENVIRONMENTAL POLICY ACT

FINDING OF NO SIGNIFICANT IMPACT

Regarding Deregulating a Petition (17-236-01p) Under 7 CFR part 340

from: Nuseed Americas Inc.

DHA Canola

OECD Unique Identifier: NS-B50027-4

**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 finding with respect to potential impacts to the human environment that could derive from a determination of nonregulated status for DHA canola.

Nuseed Americas Inc. (Nuseed), submitted a petition (17-236-01p) to the USDA APHIS, requesting that genetically engineered (GE) canola referred to as DHA canola, and any canola lines derived from crosses of DHA canola and conventional canola, or nonregulated GE canola, no longer be considered regulated articles under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). DHA canola has been genetically engineered to produce omega-3 fatty acids, namely eicosopentaenoic acid (EPA) and docosahexaenoic acid (DHA). DHA canola has been regulated by APHIS because it was developed using *Agrobacterium tumefaciens*; a regulated article under 7 CFR part 340.2.¹

As part of evaluation of Nuseed's petition, APHIS conducted an Environmental Assessment (EA) to inform APHIS' decision regarding the regulatory status of DHA canola. The EA evaluates the potential impacts of APHIS' regulatory decision on the quality of the human environment.² The EA did not identify any significant impacts that would derive from either an approval or a denial of the petition. Therefore, the Agency has prepared this FONSI, pursuant to 40 CFR part 1508.13, which provides a summary of the EA, and the reasons why APHIS' decision to issue a determination of nonregulated status for DHA canola will not have a significant impact on the human environment.

¹ Disarmed *Agrobacterium* is commonly used in the genetic modification of plants. Disarmed means the *Agrobacterium* is non-virulent.

² Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR part 1508.14).

APHIS Regulatory Authority

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 part 340.2) and is also considered a plant pest; such as *Agrobacterium tumefaciens*. A GE organism is also regulated under 7 CFR part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have sufficient information to determine if the GE organism is unlikely to pose a plant pest risk. A 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.

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 part 340.6, APHIS must respond to petitioners with a regulatory status decision. If APHIS determines, based on a Plant Pest Risk Assessment (PPRA) and other relevant information 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 December 11, 2017, APHIS announced in the *Federal Register* that it was making Nuseed's petition available for public review and comment to help identify potential environmental and interrelated economic impacts that APHIS should consider in evaluation of the petition.³ APHIS accepted written comments on the petition for a period of 60 days, until midnight February 9, 2018. At the end of the comment period APHIS had received a total of 4 comments – 2 were from individuals, and 2 were from the canola industry. APHIS evaluated the comments and integrated the concerns raised into the EA. All comments received on the petition are available for public review at www.regulations.gov, Docket ID: APHIS-2017-0096.

On June 26, 2018, APHIS announced in the *Federal Register* it was making available the draft EA and PPRA for a 30-day public review and comment period.⁴ At the end of the comment period APHIS had received 2 public comments on the petition, one from the U.S. Canola Association and 1 from the Global Organization for EPA and DHA Omega-3s. Both were in support of Nuseed's petition for a determination of nonregulated status for DHA canola. No new information was presented to APHIS in the comments that contributed to or altered the analyses presented in the draft EA, thus, neither comment was deemed substantive in the sense that they

³ Federal Register, Vol. 82, No. 236, Monday, December 11, 2017, p. 58167 - Nuseed Americas Inc., Availability of Petition for Determination of Nonregulated Status of Canola Genetically Engineered for Altered Oil Profile [Docket No. APHIS-2017-0096, www.regulations.gov].

⁴ Federal Register / Vol. 83, No. 123 / Tuesday, June 26, 2018 / Notices / Nuseed Americas Inc.; Availability of a Draft Plant Pest Risk Assessment and Draft Environmental Assessment for Canola Genetically Engineered for Altered Oil Profile, p. 29742

warranted a formal response from APHIS. Comments received on the draft EA are available for public review at www.regulations.gov, Docket ID: APHIS-2017-0096.⁵

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

⁵ <https://www.regulations.gov/docket?D=APHIS-2017-0096>

Alternatives Evaluated in the EA

The EA considered two alternatives in responding to Nuseed’s petition, to either deny or approve the request for nonregulated status, and analyzed the potential environmental, human health, and socioeconomic impacts that may result from the two alternatives.

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. Under the No Action Alternative, APHIS would deny the petition. DHA canola and progeny derived from DHA canola would continue to be regulated articles under 7 CFR part 340. Because APHIS concluded in its PPRa that DHA canola is unlikely to pose a plant pest risk (USDA-APHIS 2018) this is not APHIS’ preferred alternative. Choosing this alternative would not be an appropriate response to the petition for nonregulated status, nor satisfactorily meet the purpose and need for making a regulatory status decision pursuant to the requirements of 7 CFR part 340.

Preferred Alternative: Determination of Nonregulated Status for DHA Canola

Under this alternative DHA 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, DHA canola is unlikely to pose a plant pest risk (USDA-APHIS 2018). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DHA canola. Under this alternative, growers may have future access to DHA canola and progeny derived from it if the developer decides to commercialize DHA canola, and other requisite federal and state requirements are met. 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, the Agency’s statutory authority under the PPA, and the biotechnology regulatory policies described for the Coordinated Framework.

Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS evaluated several 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 these alternatives from detailed analysis in the EA. The alternatives considered are described 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 briefly summarizes the potential environmental impacts of the alternatives evaluated in the EA.

Summary of Potential Impacts for the Alternatives Considered		
Attribute/Measure	No Action Alternative: Continue to Regulate DHA Canola as a Plant Pest	Preferred Alternative: Approve the Petition for Nonregulated Status for DHA Canola
Meets Purpose and Need	No	Yes
Unlikely to pose a plant pest risk	Addressed through confinement conditions for regulated field trial authorizations.	Determined by the plant pest risk assessment (USDA-APHIS 2018).

Summary of Potential Impacts for the Alternatives Considered		
Attribute/Measure	No Action Alternative: Continue to Regulate DHA Canola as a Plant Pest	Preferred Alternative: Approve the Petition for Nonregulated Status for DHA Canola
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. There may be fluctuations in production areas and acreage 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 DHA 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 DHA canola. Among these factors, consumer preference for a GE vegetable oil enriched in omega-3 fatty acids is uncertain. Nuseed estimates that the market share of DHA canola oil in the fish oil food ingredient market is likely to be low initially, increasing over time and with market acceptance to as high as ~20% after 10 years (Nuseed 2017).
Agronomic Practices and Inputs	Agronomic practices and inputs used in canola crop production would remain unchanged.	Studies evaluating the phenotypic, phenologic, and agronomic properties of DHA canola indicate agronomic practices and inputs would be the same as for other varieties of canola (Nuseed 2017).
Physical Environment		
Soils	Agronomic practices, inputs, and other factors potentially impacting soils would be unaffected by denial of the petition.	The agronomic practices and inputs are the same for both DHA 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 DHA canola is agronomically similar to currently cultivated canola, approval of the petition and subsequent commercial production of DHA canola would present the same potential risks to water resources as currently cultivated canola varieties.
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.	Sources of potential impacts on air quality are the same as those under the No Action Alternative.
Biological Resources		
Soil Biota	Potential impacts on soil biota would be unaffected by denial of the petition.	Commercial production of DHA canola and DHA hybrid crops are not expected to present any risk to soil biota. Same or functionally similar elongase and desaturase

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		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. Canola fields can contain several animal species. Some species (such as insect crop pests) may need to be controlled using a range of tools. These tools may be deployed within integrated pest management strategies. The U.S. EPA regulates pesticides and determines whether they pose an unreasonable risk to animals. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its U.S. EPA-approved label.	Potential impacts on animal communities would be the same as that under the No Action Alternative. Fatty acids are vital to the normal development and function of all organisms. The vast majority of fatty acids among eukaryotes and prokaryotes are common across taxa as are biosynthesis pathways. All wildlife consume or synthesize, and are comprised of, fatty acids found in DHA canola seed, to include the LC-PUFA EPA, and to some extent DHA. It is unlikely that DHA canola seed presents any risk to wildlife.
Plant Communities	Potential impacts on plants would be unaffected by denial of the petition. Plants (other than crop plants) in 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 plants, such as those in adjacent fields.	Potential impacts on plants would be the same as that for the No Action Alternative.
Gene Flow and Weediness	Environmental releases of GE canola would be subject to confinement conditions which serve to minimize gene flow to sexually compatible species. If gene flow were to occur, progeny could spread to other areas and lead to the establishment of feral populations. Because of the general ecological requirements of <i>Brassica</i> spp., the establishment of feral 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 <i>B.</i>	Based on the PPRa, APHIS concluded that gene introgression from DHA canola to other organisms with which it can interbreed will not increase their weediness (USDA-APHIS 2018). Consequently, the Preferred Alternative is not expected to substantially differ from the No Action Alternative in regard to the potential environmental impacts associated with gene flow and weediness.

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	<i>napus</i> crops grown in adjacent areas, and <i>B. napus</i> crops and wild relative <i>B. rapa</i> species.	
Biodiversity	Denial of the petition would have no effect on biodiversity in commercial canola cropping systems.	Because DHA 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 impact on human health.	As part of the FDA consultation process, Nuseed submitted a safety and nutritional assessment for food and feed derived from DHA canola to the FDA in March, 2017. If the petition is approved, DHA canola may become available to the commercial market. This would be considered a potential public health benefit, relative to potential uses of DHA canola oil by consumers and industry. A determination of nonregulated status for DHA canola would not be expected to have any impact on the U.S. EPA regulation of pesticides, or worker protection standards; potential risks and protections for workers would be no different than that of the No Action Alternative.
Animal Health and Welfare	Denial of the petition would have no impact on animal health and welfare. DHA canola will remain a regulated article, will not be available as an animal feed, and current canola based feed for livestock will remain unchanged.	DHA canola oil and whole seed would provide a supplemental source of omega-3 fatty acids in the production of animal feed, to include feeds for use in the aquaculture industry. Producers of livestock and farmed fish would be expected to utilize DHA canola oil and whole seed to the extent they determined it provided, as a dietary component, optimal quality beef, swine, poultry, and farmed fish.
Socioeconomics		
Domestic Economic Environment	Denial of the petition would have no impact on the U.S. domestic canola oil, meal, or biodiesel markets.	A determination of nonregulated status for DHA canola is not expected to adversely impact domestic conventional, organic, or GE canola markets. DHA canola would be adopted to the extent DHA canola oil provided benefits in meeting market demand for food and feed with omega-3 fatty acids.
International Trade	Currently available canola and canola seed would be exported subject to market	U.S. canola imports and exports would be unaffected by a determination of

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Attribute/Measure	No Action Alternative: Continue to Regulate DHA Canola as a Plant Pest	Preferred Alternative: Approve the Petition for Nonregulated Status for DHA Canola
	demand. There would be no impacts on trade under the No Action Alternative.	nonregulated status to DHA canola. Nuseed will seek international regulatory approvals in Australia, New Zealand, Canada, Mexico, Japan, South Korea, China, European Union, and other countries as required.
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.	DHA 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 DHA 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 DHA canola is accepted by consumers, there may be a marginal increase in canola acreage, with commensurate cumulative impacts on total agricultural inputs and NAAQS emissions, and the risk these may present to water and air quality, and soil resources.
Coordinated Framework		
U.S. Regulatory Agencies	Denial of the petition would have no impact on the roles of the FDA and U.S. EPA in oversight of DHA canola.	Nuseed is consulting with the FDA on the food and feed safety of DHA canola. Changes to U.S. EPA registration of pesticides used on DHA canola would be unnecessary.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. 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 action. 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 action has the potential to affect GE and non-

GE canola cropping systems; environments adjacent to and associated with DHA canola cropping systems; canola oil and meal post-harvest processing systems; and domestic and foreign commodity markets. The areas affected by a determination of nonregulated status of DHA canola are localized to those of commercial canola crops, canola seed processing – namely crushing facilities, and the transport routes associated with planting and harvested seed distribution. In the United States, canola is currently produced in 34 states (USDA-NASS 2014), and canola croplands comprise around 2.0 million acres (USDA-NASS 2018). 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, 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 DHA canola oil would be a new commodity, marketed as a specialty canola oil containing EPA and DHA, production may entail use of additional cropland for production. 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 rich in EPA and DHA, across all markets (i.e., feed, food, and nutraceuticals), will determine the market share and scale of adoption of DHA canola. Among these factors, consumer preference for a GE vegetable oil containing omega-3 fatty acids is uncertain. Nuseed estimates that the market share of DHA canola oil in the fish oil food ingredient market is likely to be low initially, increasing over time and with market acceptance to as high as ~20% after 10 years (Nuseed 2017). It is anticipated that initial use may be limited to the livestock and aquaculture feed industries. In general, it is possible that, if DHA canola eventually becomes a preferred source of food oil and meal, 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, those 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 > 500 mg/day of EPA and DHA (Tacon and Metian 2013; Calder 2014;

NIH 2017). Adequate consumption of EPA and DHA is recommended by many health authorities to prevent or treat chronic diseases (Russell and Bürgin-Maunders 2012; Calder 2014; NIH 2017). To the extent this canola variety could provide the food and feed industries an additional supply of vegetable oil comprised of EPA and DHA, benefits to public health would be expected – relative to consumer preference, and potential uses of DHA canola oil by the food and feed industries.

Potentially Adverse: The EA concluded that cultivation of DHA canola, would have the same potential impacts on water, soil, and air quality as that of currently cultivated canola. For water, these risks would be relative to proximity of surface waters to DHA canola crops. For air, there would be a contribution to the cumulative emissions of NAAQS pollutants, as there is with current canola crop production. Any use of pesticides would be subject to U.S. EPA as well as state requirements (e.g., (US-EPA 2017a, b)).

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

As discussed above, potential impacts on public health are considered generally beneficial. In March 2017, Nuseed submitted a safety and nutritional assessment for food and feed derived from DHA canola to the FDA (Nuseed 2017). Approvals for commercial production are being sought by Nuseed in Australia, New Zealand, Canada, Mexico, Japan, South Korea, China, European Union, and other countries as required (Nuseed 2017).

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 DHA canola. Feral populations of DHA canola may establish along transport routes and in environments proximate to DHA canola crop fields. However, invasion of park lands, wetlands, wild and scenic areas, or ecologically critical areas by DHA canola or feral hybrids is considered unlikely. APHIS conducted a PPRA and concluded that it is unlikely that DHA canola will become weedy or invasive, and that it is similarly unlikely that gene introgression from DHA canola into wild *Brassica* species will increase the weediness of any DHA canola hybrids (USDA-APHIS 2018). Consequently, a determination of nonregulated status for DHA canola is not expected to have significant impacts on 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 Nuseed's petition for nonregulated status for DHA canola is not an action considered highly controversial in nature. The EA concluded that the agronomic practices and inputs that would be used for DHA 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 DHA canola production are no different than that of currently cultivated canola. The fatty acids present in the seed of DHA 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); they present no risk to plants, animals, and other taxa. There are no novel or unique impacts on the human environment, nor any considered controversial, that would derive from approval of the petition.

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

The potential impacts of canola crop production on the human environment are well understood and thoroughly evaluated in the EA. Because DHA canola oil, comprised of EPA and DHA, would be a new commodity, it may entail use of additional cropland for production. Market forces, consumer preference, and demand for vegetable and fish oils rich in EPA and DHA, across all markets (i.e., feed, food, and nutraceuticals), will determine the market share and scale of adoption of DHA canola. Among these factors, consumer preference for a GE vegetable oil enriched in omega-3 fatty acids is uncertain. Nuseed estimates that the market share of DHA canola oil in the fish oil food ingredient market is likely to be low initially, increasing over time and with market acceptance to as high as ~20% after 10 years (Nuseed 2017). Consequently, the potential impact of approval of the petition on any potential increase in U.S. acres 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 discussed 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 Nuseed's petition would not establish a precedent for future actions that would result in significant impacts on the human environment, nor would it represent a decision in principle about a future decision. Approval of the petition is based upon an independent determination of whether DHA canola is unlikely to pose a plant pest risk (USDA-APHIS 2018) pursuant to 7 CFR part 340, and an environmental analysis consistent with NEPA and CEQ implementing regulations. APHIS has reviewed and approved petitions for nonregulated status since 1992, to include 10 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 specific 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, applicable to both APHIS and the petitioner, are described in 7 CFR part 340. These requirements have been reviewed above under the sections summarizing APHIS' regulatory authority, and APHIS' requirements to respond to petitions for nonregulated status.

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

The EA discusses potential cumulative impacts on agricultural practices and inputs; human and animal health; physical and biological resources; as well as on selection for herbicide-resistant weed populations. Impacts from the cultivation of DHA canola would not be considered cumulatively significant and no different from that which occurs with currently cultivated canola varieties.

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. DHA 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 DHA canola on threatened and endangered species and critical habitat in Chapter 6 of the EA. APHIS concluded that approval of the petition for nonregulated status for DHA 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 Nuseed'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 DHA canola, and Nuseed is consulting with the FDA as to the food and feed safety of canola oil and canola meal derived from DHA canola.

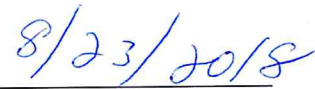
NEPA Finding and Rationale

I have carefully reviewed the EA prepared for this NEPA finding and the input from the public involvement process. In light of the FONSI, APHIS will implement Alternative 2 as described in the EA (Determination that DHA canola is No Longer a Regulated Article). This alternative meets APHIS’ purpose and need to allow the safe development and use of GE organisms, and is consistent with the plant pest provisions of the PPA.

As stated in 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.” The Preferred Alternative has been selected for implementation taking into consideration a number of environmental, economic, and social 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. As a result of the analyses conducted in the EA and summarized in this FONSI, I have concluded that granting nonregulated status to Nuseed’s DHA canola will have no significant impacts on the human environment as a result of making a determination of nonregulated status.



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References

- Calder PC. 2014. *Very long chain omega-3 (n-3) fatty acids and human health*. European Journal of Lipid Science and Technology 116, pp. 1280-1300. Retrieved from <http://dx.doi.org/10.1002/ejlt.201400025>
- NIH. 2017. *Omega-3 Fatty Acids: Fact Sheet for Health Professionals* U.S. Department of Health & Human Services, National Institutes of Health. Retrieved from <https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional/>
- Nuseed. 2017. *Petition [17-236-01p] for Determination of Nonregulated Status for DHA Canola. OECD Unique Identifier: NS-B5ØØ27-4*. Retrieved from <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>
- Russell FD and Bürgin-Maunders CS. 2012. *Distinguishing Health Benefits of Eicosapentaenoic and Docosahexaenoic Acids*. Marine Drugs 10, pp. 2535-2559. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3509534/>
- Stanley-Samuelson DW, Jurenka RA, Cripps C, Blomquist GJ, and de Renobales M. 1988. *Fatty acids in insects: Composition, metabolism, and biological significance*. Archives of Insect Biochemistry and Physiology 9, pp. 1-33. Retrieved from <http://dx.doi.org/10.1002/arch.940090102>
- Swanson D, Block R, and Mousa SA. 2012. *Omega-3 Fatty Acids EPA and DHA: Health Benefits Throughout Life*. Advances in Nutrition 3, pp. 1-7. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3262608/>
- Tacon AGJ and Metian M. 2013. *Fish Matters: Importance of Aquatic Foods in Human Nutrition and Global Food Supply*. Reviews in Fisheries Science 21, pp. 22-38. Retrieved from <https://doi.org/10.1080/10641262.2012.753405>
- US-EPA. 2017a. *Pesticide Registration (PR) Notice 2017-1: Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling*. Retrieved from <https://www.epa.gov/sites/production/files/2016-05/documents/pr-2016-x-guidance-pesticide-registrants-resistance-management.pdf>
- US-EPA. 2017b. *Pesticide Registration (PR) Notice 2017-2, Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship*. Retrieved from <https://www.epa.gov/pesticide-registration/prn-2017-2-guidance-herbicide-resistance-management-labeling-education>
- USDA-APHIS. 2018. *Plant Pest Risk Assessment: Nuseed Petition (17-236-01p) for Determination of Non-regulated Status of DHA Canola* Retrieved from <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>

USDA-NASS. 2014. *2012 Census of Agriculture: United States Summary and State Data, Volume 1, Geographic Area Series, Part 51 [AC-12-A-51]*. Retrieved from <https://www.agcensus.usda.gov/Publications/2012/>

USDA-NASS. 2017. *Certified Organic Survey: 2016 Summary, September 2017*. Retrieved from http://usda.mannlib.cornell.edu/usda/current/OrganicProduction/OrganicProduction-09-20-2017_correction.pdf

USDA-NASS. 2018. *Crop Production, 2017 Summary, January, 2018*. Retrieved from <http://usda.mannlib.cornell.edu/usda/current/CropProdSu/CropProdSu-01-12-2018.pdf>