Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Pioneer Hi-Bred International, Inc. Petition (20-203-01p) for the Determination of Nonregulated Status for Insect Resistant and Herbicide-Tolerant DP23211 Maize

Finding of No Significant Impact

OECD Unique Identifier: DP-Ø23211-2

October 2023

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

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Overview

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) regulations at Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340) govern the movement (e.g., transport, environmental release) of organisms developed using genetic engineering that may pose a plant pest risk. APHIS recently revised 7 CFR part 340, publishing a final rule in the *Federal Register* on May 18, 2020.[1] The revisions to 7 CFR part 340 were implemented in phases: APHIS' new Regulatory Status Review (RSR) process, which replaced the prior "petition" for determination of nonregulated status process, became effective on April 5, 2021 for corn, soybean, cotton, potato, tomato, and alfalfa. The RSR process became effective for all crops as of October 1, 2021. As provided for in the final rule, "Until RSR is available for a particular crop…APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the [legacy] regulations at 7 CFR 340.6". Under the petition process, an organism developed using genetic engineering is no longer subject to the requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (PPA; 7 U.S.C. 7701 et seq.) if APHIS determines, through conduct of a Plant Pest Risk Assessment (PPRA), that it is unlikely to pose a plant pest risk (USDA-APHIS 2022a).

In July 2020, Pioneer Hi-Bred International, Inc. (Pioneer) submitted a petition (20-203-01p) to USDA-APHIS requesting that DP23211 maize (corn),[2] a plant developed using genetic engineering, and any progeny derived from it, no longer be regulated under 7 CFR part 340 (Pioneer 2020). Pioneer's petition for a determination of nonregulated status has been evaluated in accordance with the legacy regulations at 7 CFR 340.6, as it was received by APHIS in July, 2020, prior to full implementation of the final rule, discussed above.

Pioneer developed DP23211 corn for resistance to the insect pest western corn rootworm (WCR; *Diabrotica virgifera virgifera*), and the herbicide active ingredient (a.i.) glufosinate-ammonium.[3] WCR resistance is conferred using two different methods; RNA interference (RNAi), and a protein toxic to WCR. DP23211 corn produces a double-stranded ribonucleic acid (dsRNA), termed DvSSJ1 dsRNA, which interferes with production of DvSSJ1 protein via RNAi—a protein essential for gut epithelium function—and causes WCR death. WCR resistance is also conferred by DP23211 corn production of an insecticidal IPD072Aa protein that is likewise lethal to WCR when ingested.

As part of evaluation of Pioneer's petition USDA-APHIS developed an Environmental Assessment (EA) to consider the potential impacts of a determination of nonregulated status for DP23211 corn on the

[1] Federal Register / Vol. 85 / No. 96 / Monday, May 18, 2020 / page 29790: USDA-APHIS, Movement of Certain Genetically Engineered Organisms [https://www.aphis.usda.gov/brs/fedregister/BRS_2020518.pdf]

[2] Maize is the botanical term used globally for the cereal plant *Zea mays*. In the United States maize is commonly referred to as corn. Both terms are used interchangeably in this document. For consistency with the common plant name and petition APHIS uses the term maize, but also refers to corn in certain instances, such as in reference to food products.

[3] Note that "Resistance" to herbicides is defined by the Herbicide Resistance Action Committee (HRAC) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type. "Tolerance" is distinguished from resistance and defined by HRAC as the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. In reference to biotechnology-derived crops, the terms "resistance" and "tolerance" are often used interchangeably. Throughout this EA, APHIS will use the term "resistance" and "resistant", and "herbicide-resistant" (HR), when referring to biotech corn.

human environment.[4] The EA was prepared in compliance with the National Environmental Policy Act (NEPA, 42 U.S.C. § 4321 et seq.), the Council on Environmental Quality's (CEQ) NEPA-implementing regulations (40 CFR parts 1500-1508), and USDA and APHIS NEPA-implementing regulations (7 CFR part 1b, and 7 CFR part 372).

Pursuant to 40 CFR § 1501.6 agencies are required to prepare a Finding of No Significant impact (FONSI) and make the FONSI available to the public if the agency determines, based on the EA, to not prepare an environmental impact statement (EIS) because the proposed action will not result in significant impacts on the human environment.[5] Because the proposed action is not similar to one for which an EIS is normally prepared, nor is the nature of the proposed action without precedent, a 30-day public review of the FONSI, as described in 40 CFR § 1501.6(2), does not apply. This document describes the rationale for the FONSI and decision to approve of the petition. The EA in support of this FONSI is available online at www.regulations.gov [Docket No. APHIS–2020–0098], the APHIS website [(USDA-APHIS 2022b), see Petition No. 20-203-01p], and is incorporated by reference in its entirety.

Public Involvement

On November 3rd, 2020 APHIS announced in the *Federal Register* that it was making Pioneer'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.[6] APHIS accepted written comments on the petition for a period of 60 days, until midnight, January 4th, 2021. At the end of the comment period APHIS had received four comments on the petition. One comment was from an individual, which stated opposition to genetically engineered crops in general. Three comments were received from industry organizations, which generally supported approval of the petition.

On April 11th, 2023 APHIS published a notice in the *Federal Register* that it was making a draft EA, and draft plant pest risk assessment, available for public review and comment for a period of 30 days, ending midnight, May 11th, 2023. At the end of the comment period APHIS had received 3 comments on the draft EA. One comment submitted by an individual expressed concern about the insecticidal DvSSJ1 dsRNA in DP23211 corn, targeting Western corn rootworm. Another comment by an individual expressed opposition to biotechnology-derived crops, in general. A comment from the Tennessee Farm Bureau Federation expressed support for the deregulation of DP23211 corn.

APHIS provided a response to comments on the draft EA in Appendix 2 of the final EA. No issues were raised in public comments that suggested potentially significant environmental impacts could occur as a

[4] Human environment means comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment (40 CFR § 1508.1(m)).

[5] 40 CFR § 1501.3 – Determine the appropriate level of NEPA review: (a) In assessing the appropriate level of NEPA review, Federal agencies should determine whether the proposed action: (1) Normally does not have significant effects and is categorically excluded (§ 1501.4); (2) Is not likely to have significant effects or the significance of the effects is unknown and is therefore appropriate for an environmental assessment (§ 1501.5); or (3) Is likely to have significant effects and is therefore appropriate for an environmental impact statement. (b) In considering whether the effects of the proposed action are significant, agencies shall analyze the potentially affected environment and degree of the effects of the action.

[6] Federal Register, / Vol. 85, No. 213 / Tuesday, November 3, 2020, p. 69564. Pioneer Hi-Bred International, Inc.; Availability of a Petition for the Determination of Nonregulated Status for Insect Resistant and Herbicide Tolerant Maize [Docket No. APHIS–2020–0098]. Available at https://www.federalregister.gov/documents/2020/11/03/2020-24267/pioneer-hi-bred-international-inc-availability-of-a-petition-for-the-determination-of-nonregulated

result of cultivation of DP23211 corn, and utilization of DP23211 corn for production of food, animal feed, fuel ethanol, and industrial commodities.

APHIS considered all comments received in preparation of the draft and final EA. A full record of each comment received is available online at www.regulations.gov [Docket No. APHIS-2020-0098].

Alternatives Evaluated

NEPA implementing regulations (40 C.F.R. 1500–1508) require agencies to evaluate alternative actions that would avoid or minimize adverse impacts, or enhance the quality of the human environment, while meeting the purpose and need for Agency action (in this case, a regulatory decision). Two alternatives were evaluated in the EA: (1) No Action, denial of the petition, which would result in APHIS regulation of DP23211 corn, and (2) Preferred Alternative, approval of the petition, which would result in a determination of nonregulated status for DP23211 corn.

No Action: Deny the Petition

APHIS considered a "No Action Alternative" as required by CEQ regulations (40 CFR § 1502.14 (c)). For APHIS, no action in this context means no change in regulated status. Under the No Action Alternative APHIS would deny the petition request for nonregulated status and DP23211 corn would remain regulated under 7 CFR part 340. Any movement or environmental release of DP23211 corn would require an APHIS permit.

Preferred Alternative: Approve the Petition for Nonregulated Status

Under this alternative APHIS would approve the petition request. DP23211 corn and progeny derived from it would no longer be subject to APHIS regulation under 7 CFR part 340. Permits issued by APHIS would no longer be required for movement or environmental release of DP23211 corn.

Finding of No Significant Impact

APHIS developed topics for consideration in the EA based on issues identified in public comments on the petition, prior EAs for biotechnology-derived corn varieties, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Zea* and *Tripsacum* species. The following topics were identified as relevant to the scope of the impacts analysis in the EA (40 CFR § 1501.9–Scoping):

- Agricultural Production: Acreage and areas of corn production, agronomic practices and inputs
- Physical Environment: Soils, water resources, air quality
- Biological Resources: Soil biota, animal communities, plant communities, gene flow and weediness, biodiversity
- Public health and worker safety
- Food animal health and welfare
- Domestic economy and international trade

- Potential impacts on threatened and endangered species
- Compliance of the Agency's regulatory status decision with Executive Orders, and environmental laws and regulations to which the action is subject.

In evaluating the potential significance of impacts on the human environment APHIS considered those requirements outlined in sections 102(2)(C) of NEPA, 40 CFR § 1501.3–Determine the appropriate level of NEPA review, 40 CFR § 1502.16–Environmental consequences, and 40 CFR § 1502.24–Environmental review and consultation requirements, and 40 CFR § 1502.15–Affected environment, which are summarized below. The potential impacts/effects identified and discussed in the EA include those that may be both beneficial and adverse; on balance the agency believes that the potential impacts of approval of the petition would be largely beneficial to U.S. corn production and corn-based food, feed, and fuel ethanol markets (40 CFR § 1508.1(g)).

1. *Potential adverse environmental effects that cannot be avoided should the proposal be implemented*

Commercial crop production of any type, whether a conventional, organic, or biotechnology-based cropping system always has some degree of impact on the environment, as discussed in the EA. Potential introduction of pesticides and fertilizers to surface water, soil erosion, and loss of biodiversity and wildlife habitats are examples of impacts that can potentially derive from commercial crop production. The degree of environmental impacts can be minor or noticeably adverse, depending on a variety of factors that include the type and quantity of agronomic inputs and practices employed, geography and proximity of surface waters to crops, local biota, weather, prevalence and diversity of insect pests and weeds, and crop type being produced. With around 360,000 corn farms comprising some 90 million acres of land in the United States the scale of potential impacts, namely in an aggregate sense, requires integration of crop production with sustainability and conservation practices, for biotechnology-derived, conventionally bred, and organic crops alike. Implementing such practices can often result in significant mitigation of environmental impacts, however, not all impacts can be fully attenuated and accepting some degree of environmental impact/change in meeting the market demand for corn-based food, feed, fuel, and industrial commodities is inevitable (Robertson and Swinton 2005; NRC-IM 2015).

On approval of the petition, and subsequent grower adoption of DP23211 corn, the agronomic practices and inputs that would be used in the cultivation of DP23211 corn, and any contribution of these practices and inputs to impacts on soils, water quality, or air quality, is expected to be similar to that of other corn crops currently cultivated. It is expected that DP23211 corn would be produced on lands already converted to cropland—replace other HR/IR corn crops currently cultivated. Hence, adoption of DP23211 corn is not expected to have any effect on wildlife habitats or biodiversity. The EA did not identify any significant changes to agronomic practices and inputs, nor in DP23211 corn physiology, that would have effects on plant diseases or insect pests, or their management (USDA-APHIS 2022a).

There are various federal, state, and private sector collaborative initiatives to support sustainable agricultural practices and help alleviate the collective impacts of crop production on the physical environment, as well as biological resources—these are summarized the EA.

2. *The relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity*

Long-term agricultural productivity depends on the sustainable utilization of natural resources over continued production cycles—namely topsoils, groundwater, beneficial insect populations such as plant pest predators, the plants that support beneficial insects, and products such as fertilizers that derive from natural resources. DP23211 corn is agronomically equivalent to other dent corn cultivars and production utilizes the same types, and same/similar quantities of resources, as all other conventional and biotech dent corn varieties. There would be reductions, to some extent, in fossil fuel and applied insecticide use—the utilization of the natural resources from which fuels and insecticides are derived. As a plant incorporated protectant (PIP) based IR corn variety targeting *Diabrotica virgifera virgifera*, and reduced insecticide use, there could be a reduction in adverse impacts on non-target species, including beneficial predator and parasitoid species (Bale et al. 2008; Barratt et al. 2018). The novel RNAi (DvSSJ1 dsRNA) and IPD072Aa MOAs could facilitate management of development of insect resistance by broadening the variety of PIP MOAs in crops. These aspects of DP23211 corn would be expected to be of potential benefit to sustaining the long-term productivity of U.S. corn cropping systems, in association with the efficacy of implemented IWM and IPM programs.

3. *Irreversible or irretrievable commitments of resources that would be involved in the proposal should it be implemented*

The production of corn and the food, feed, fuel, and industrial products derived from corn involves the irreversible and irretrievable utilization of resources. For example, corn production involves the irreversible consumption of nonrenewable petroleum-based products (e.g., fuels necessary to operate equipment, cleaning agents, pesticide additives/adjuvants). Crude oil cannot be replaced once utilized for energy or other purposes. Some crop production systems may utilize wind or solar energy sources—renewable sources. Topsoil and phosphorus are also considered nonrenewable. Over the long-term, continued crop production on the same site can contribute to wind and water erosion. Materials such as aluminum, steel, wood, and plastics would be consumed as part of the process of crop production. Some of the materials used are non-renewable and could be irreversibly utilized if not recycled (plastics, metals). Crop production inherently entails the irretrievable conversion of natural habitat, and relocation of associated wildlife to other landscapes.

DP23211 corn is physiologically and agronomically equivalent to other dent corn varieties, apart from the HR and IR traits. Renewable and nonrenewable resources utilized for DP23211 corn production would differ little from that of other dent corn varieties. Any irreversible or irretrievable commitment of resources in DP23211 corn production would be the same as or similar to that of other dent corn cropping systems. It is expected that DP23211 corn would be produced on lands already converted and utilized for commercial crop production. As an IR crop variety utilizing PIPs, reductions in fossil fuel use could occur in production of the crop, relative to non-IR corn varieties on which insecticides are sprayed. Fossil fuels are commonly used in the manufacture, transportation, and soil and foliar application of insecticides to commercial corn crops.

4. *Whether the action would violate or conflict with federal or state laws, Executive Orders, or local requirements governing protection of the environment and environmental justice*

Based on the data reviewed in the EA, approval of the petition would not lead to circumstances that resulted in non-compliance with any federal or state laws, local ordinances, or Executive Orders providing protections for the environment, public health, underserved communities, or minority or low income populations. The U.S. Environmental Protection Agency (EPA) regulates the use of pesticides on DP23211 corn, as well as worker safety. Pioneer completed a food safety consultation with the FDA in 2022; based on the information Pioneer presented to the FDA, the FDA had no further questions concerning the safety of human or animal food derived from DP23211 corn, noting that it is Pioneer's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements (US-FDA 2022).

5. *Possible conflicts between the proposed action and the objectives of federal, regional, state, tribal, and local land use plans, policies, and controls for the area concerned*

As reviewed in the final, EA, there are no conflicts with approval of the petition, and subsequent commercial production of DP23211 corn with federal, state, tribal, or local government oversight of land uses and policies. Any cultivation of DP23211 corn in the United States would require compliance with federal, state, or local government land management authorities (e.g., local ordinance, zoning). Tribal entities are recognized as independent governments and agricultural activities on tribal lands would only be conducted if approved by the tribe. APHIS conducted outreach to tribal nations informing tribes of Pioneer's petition. APHIS received one reply from the Ysleta del Sur Pueblo Tribe, stating that this project will not adversely affect traditional, religious, or culturally significant sites.

6. *Energy requirements and conservation potential of various alternatives and mitigation measures*

The energy requirements involved with the full life cycle of DP23211 corn production and marketing would differ little from that of other commercial corn crops. USDA-NRCS provides guidance on energy management in crop production via practices such as integrated pest management, precision agriculture, irrigation water and nutrient management, and crop residue management (USDA-NRCS 2020). Energy conservation estimation tools are also provided to help growers estimate costs and saving associated with irrigation, nitrogen use, and tillage.

7. *Natural or depletable resource requirements and conservation potential of various alternatives and mitigation measures*

Natural resources relative to crop production that are depletable (non-renewable, or renew slowly) include petroleum-based products (e.g., diesel fuel, gasoline, plastics, lubricants), fertilizer phosphorus, groundwater, and soils. There are no natural resource requirements unique to the production and marketing of DP23211 corn. Use of natural resources in DP23211 corn production would be no different than that of other corn varieties. Natural resource conservation opportunities, such as those provided or funded by the USDA, would be available to growers of DP23211 corn, summarized below in item 9.

8. *Urban quality, historic and cultural resources, and the design of the built environment, including the reuse and conservation potential of various alternatives and mitigation measures*

DP23211 corn would be cultivated on lands allocated or zoned for agricultural uses, which may occur in proximity to historic or cultural resources. This would not be expected to directly or indirectly result in alteration of the character or use of historic properties protected under The National Historic Preservation Act, nor result in any loss or destruction of cultural or historical resources. As discussed in the EA, there are no weediness/invasiveness characteristics associated with DP23211 corn that would impact historical properties. The design of the built environment in relation to crop production activities would be resolved at the state and local levels of governance (e.g., city, county, and/or state authorities governing land use).

9. *Means to mitigate adverse environmental impacts*

There are a number of federal, state, and private sector collaborative initiatives to help farmers alleviate the impacts of crop production on the physical environment, as well as biological resources. Some of the ongoing USDA and partner programs supporting agricultural sustainability and natural resources conservation (e.g., National Water Quality Initiative, Natural Resources Conservation Programs) are discussed in the EA (USDA-APHIS 2022b). Each contribute in some way to environmental stewardship and long-term farm sustainability.

10. *Economic and technical considerations, including the economic benefits of the proposed action*

DP23211 corn could provide for effective plant pest and weed management, achieving optimal yields, and efficient provision of food, feed, fuel, and industrial commodities. The economic impacts associated with the introduction of DP23211 corn into commerce are potentially beneficial (USDA-APHIS 2022b).

IR crops have proven effective in control of insect pests, thus the extent of adoption in the United States—IR corn comprised 84% of U.S. corn crop acreage in 2022 (USDA-ERS 2022a). From 1996-2018, IR corn targeting corn boring pests provided a 7% increase in yield, and increased farm income of $81/ha ($32/acre) (Brookes and Barfoot 2018). IR corn targeting WCR, specifically, provided a 5% increase in yield, and increased farm income $78/ha ($31.6/acre) (Brookes and Barfoot 2018). At the aggregate level, the global gross farm income gains from using IR corn in 2018 was $4.5 billion (Brookes and Barfoot 2018).

The average gross farm income benefit from using HR corn (after deduction of cost of technology) has been around $30.1/ha ($12.5/acre). During the 1996-2018 timeframe, the aggregate income benefit from using HR corn in the United States has been estimated to be around $10.8 billion (Brookes and Barfoot 2018). In 2018, the total global farm income gain from using HR corn was $1.66 billion with the cumulative gain over the period 1996–2018 being $17 billion (Brookes and Barfoot 2018).

11. *The degree to which the action may adversely affect endangered or threatened species protected under the Endangered Species Act*

As discussed in the EA, a determination of nonregulated status of DP23211 corn, and subsequent commercial production of this corn variety, would have no effect on listed species or species proposed for listing, nor would it affect designated habitat or habitat proposed for designation.

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

Approval of the petition and subsequent availability of DP23211 corn to producers, and DP23211 corn products to commercial markets, would not present any risks to public health or worker safety. It is unlikely that DP23211 corn, a dent corn variety (e.g., *Zea mays* var. *indentata*), would be directly consumed by humans. Direct consumption of corn is generally limited to sweet corn (*Zea mays* convar. *saccharata* var. *rugosa*), popcorn (*Zea mays* var. *everta*), and flint corn (*Zea mays* var. *indurata*) (e.g., polenta). Dent corn is produced primarily for animal feed and industrial uses such as fuel ethanol production, although some specialty dent corn varieties may be used for grits, and processed into food products such as tortilla chips, corn syrup, corn oil, etc. Only certain hybrid dent corn varieties with specific starch properties are used for food purposes.

As reviewed in EA, the introduced traits, the DvSSJ1 dsRNA, and the IPD072Aa, PAT, and PMI proteins, would present negligible risks to human health in the event of inadvertent consumption of DP23211 corn grain. Pioneer completed a food safety consultation with the FDA in 2022; the FDA had no questions concerning the safety of food products derived from DP23211 corn (US-FDA 2022).

13. *Whether the affected environment includes reasonably foreseeable environmental trends and planned actions in the affected areas.*

Approval of the petition would provide for the commercial production of DP23211 corn, subject to any FDA, EPA, state, or tribal requirements. As of May 2023, APHIS has issued determinations of nonregulated status in response to 41 petitions for biotechnology-based corn varieties, most of these are insect and/or herbicide resistant. APHIS maintains a publicly available list of petitions and determinations of nonregulated status on its website (USDA-APHIS 2022c). As of 2022, over 90% of U.S. corn acreage is comprised of biotechnology-based varieties (USDA-ERS 2022b).

Advances in biotechnologies are expected to refine the precision with which crop varieties will be developed, and lead to a greater diversity of commercial crop varieties (NAS 2016). While it is difficult to predict the scope of improved crop varieties that will emerge in the coming decades, beneficial traits likely to be utilized and adopted by growers include improved tolerance to abiotic stresses such as drought and temperature extremes; increased efficiency in plant physiological processes such as photosynthesis and nitrogen use; resistance to fungal, bacterial, and viral diseases; and new types of herbicide resistance (NAS 2016).

For biotechnology-based plants that APHIS has determined are not subject to 7 CFR part 340, all of which were evaluated for potential plant pest risks, and potential environmental impacts via NEPA analyses (USDA-APHIS 2022c), the scientific literature indicates that the cultivation of the presently commercialized biotech HR and IR corn plants have not resulted in any adverse environmental impacts that are unique, differ from conventional corn crops and cropping systems

(e.g., (Sanvido et al. 2007; NRC 2010; NAS 2016; Brookes and Barfoot 2017)). To date, biotechnology-derived crops, which undergo evaluation by USDA, the EPA, and FDA under the Coordinated Framework (ETIPCC 2017; USDA-APHIS 2020), have been found to have no more or fewer adverse effects on the environment than non-biotech crops produced conventionally (NRC 2010; NAS 2016; Brookes and Barfoot 2020).

NEPA Decision and Rationale

I have evaluated the information provided in the EA, and compliance of approval or denial of the petition with applicable laws, regulations, and policy, as well as public comments on the petition. Based on this evaluation, summarized above, I have not identified any significant impacts on the human environment that would derive from approval of the petition. Because APHIS did not identify any plant pest risks associated with DP23211 corn, the regulation of DP23211 corn 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 these reasons APHIS will implement the Preferred Alternative, approval of the petition. The Preferred Alternative is not a federal action significantly affecting the quality of the human environment under NEPA. Accordingly, an EIS is not required and environmental review pursuant to NEPA and CEQ implementing regulations is concluded with this FONSI.

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Bernadette Juarez — Date

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