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David Heron, Ph.D.
Global Regulatory Advisor
Moolec Science, SA

Animal Plant
Health Inspection
Service

RSR number: 23-234-01rsr

Biotechnology
Regulatory
Services

RE: Regulatory Status Review of soybean developed using genetic engineering for accumulation of a meat protein

4700 River Road
Riverdale
MD 20737

Dear Dr. Heron:

Thank you for your letter dated August 22nd, 2023, requesting a Regulatory Status Review (RSR) for soybean developed using genetic engineering (modified soybean). In your letter, you described that the soybean was modified to impart accumulation of a meat protein via genetic engineering.

The Plant Protection Act of 2000 (7 U.S.C. §§ 7701 et seq.) provides USDA authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests to protect agriculture, environment, and the economy of the United States. USDA, through the Animal and Plant Health Inspection Service (APHIS), regulates the “Movement of Organisms Modified or Produced through Genetic Engineering” as described in 7 CFR part 340.

Consistent with 7 CFR 340.4, APHIS reviewed your modified soybean to determine whether it is subject to the regulations in 7 CFR part 340. Specifically, APHIS reviewed the modified soybean to determine whether there is a plausible pathway by which the soybean would pose an increased plant pest risk relative to the plant pest risk posed by an appropriate soybean comparator. Based on information you provided, publicly available resources, and APHIS’ familiarity with soybean and knowledge of the trait, phenotype, and mechanism of action, APHIS considered the (1) biology of nonmodified soybean and its sexually compatible relatives; (2) the trait and mechanism-of-action of the modification; and (3) the effect of the trait and mechanism-of-action on the (a) distribution, density, or development of the plant and its sexually compatible relatives, (b) production, creation, or enhancement of a plant pest or a reservoir for a plant pest, (c) harm to non-target organisms beneficial to agriculture, and (d) weedy impacts of the plant. APHIS did not identify any plausible pathway by which your modified soybean would pose an increased plant pest risk relative to comparator soybean plants. APHIS has determined your soybean is unlikely to pose an increased plant pest risk relative to its comparators. Once APHIS determines that a plant product is unlikely to pose an increased plant pest risk relative to its comparator, and, thus, is not a plant pest or a plant that requires regulation because it is capable of introducing or disseminating a plant pest, APHIS has no authority to regulate it under 7 CFR part 340. Accordingly, your soybean is not subject to the regulations under 7 CFR part 340. APHIS’ determination that this modified plant is not subject to the regulations extends to any progeny of the modified plant that is derived from crosses with other non-modified plants or other modified plants that are also not subject to the regulations in 7 CFR part 340.

Please be advised that APHIS’ decision applies to the soybean developed using genetic engineering exactly as described in your letter. If at any time you become aware of any information that may affect our review of your modified soybean, including, for example, new information that shows the trait, phenotype, or mechanism of action is different than described in your letter, you must contact APHIS for further review of the plant at RSRrequests@usda.gov.

Please be advised that your plant product, while not regulated under 7 CFR part 340, may be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, you may contact the PPQ general number for such inquiries at 877-770-5990. Your plant product may also be subject to other regulatory authorities such as the U.S.

Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA). Please contact EPA and FDA to enquire about the regulatory status of your product.

Sincerely,

A handwritten signature in black ink, appearing to read 'BJ', with a stylized flourish extending to the right.

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

April 18, 2024

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ACCESSWIRE

Moolec Becomes First Molecular Farming Company to Achieve USDA Approval for Plant-Grown Animal Proteins

Provided by Accesswire
Apr 22, 2024 4:00am

LUXEMBOURG / ACCESSWIRE / April 22, 2024 / Moolec Science SA (NASDAQ:MLEC) ("The company"), a Molecular Farming food-ingredient company, announced today that the Animal and Plant Health Inspection Service ("APHIS") of the U.S. Department of Agriculture ("USDA") has concluded its Regulatory Status Review ("RSR") for Moolec's genetically engineered ("GE") soybean Piggy Sooy™. See post online here: <https://www.aphis.usda.gov/sites/default/files/23-234-01rsr-response.pdf> [1].



USDA Piggy Sooy

The USDA-APHIS RSR determines that Moolec's genetically engineered soybean, accumulating animal meat protein, is unlikely to pose an increased plant pest risk relative to non-engineered soybeans. Therefore, it is not subject to the APHIS regulation that governs the movement of organisms modified or produced through genetic engineering (as described in 7 CFR part 340).

"Moolec embraced Nasdaq's slogan 'Rewrite Tomorrow' and took it literally! We achieved an unprecedented milestone in biotechnology with the first-ever USDA-APHIS approval of this kind," stated Gastón Paladini, Moolec Science's CEO & Co-Founder. "We are unlocking the power of plants by leveraging science to overcome climate change and global food security concerns. I am very proud of the Moolec team, creating value for shareholders and the planet at the same time."

This milestone reinforces Moolec's B2B go-to-market strategy for Piggy Sooy™ product, an innovative, functional, and nutritious ingredient. By adding a well-known animal meat protein (porcine myoglobin) to the standard soybean proteins, the company expects to provide food manufacturers with a unique ingredient that will have a positive carbon and water footprint.

Martin Salinas, Chief of Technology & Co-Founder at Moolec, enthusiastically announced: "We believe this milestone sets the stage for a revolution in the food-industrial biotech landscape, paving the way for expedited adoption of Molecular Farming technology by other industry players. Also, this compelling advancement signifies a stride in enhancing our operational efficiency, transforming our methods of raw material sourcing, and optimizing our downstream crushing and processing operations."

In June 2023, the company announced that Piggy Sooy™ seeds had achieved high levels of expression of pork protein (up to 26.6% of the total soluble protein) and had patented their technology. The company clarifies that Piggy

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Brian Calisto
Sector Director

Analyst Note | Brian Calisto | Jun 5, 2023

As expected, Apple's Worldwide Developer Conference (WWDC) Vision Pro, the company's augmented reality headset, will maintain our \$150 fair value estimate for the stock. We have enough units of these devices to move the market away from being dominated by the far more pervasive iPhone.

At first glance, we're impressed with the company's hardware and its operating system. Yet we didn't see

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Sooy™ development is set to keep moving forward completing the necessary consultation with the United States Food and Drug Administration ("FDA"). Moolec declares to be engaged in the consultation process with the FDA, representing the next pivotal regulatory milestone preceding the commercial availability of Piggy Sooy™ ingredient.

About Moolec Science SA

Moolec is a science-based ingredient company leader in the use of Molecular Farming technology for food and dietary supplementation markets. The Company's mission is to create unique food ingredients by engineering plants with animal protein genes. Its purpose is to redefine the way the world produces animal proteins, for good and for all. Moolec's technological approach aims to have the cost structure of plant-based solutions with the nutrition and functionality of animal-based ones. Moolec's technology has been under development for more than a decade and is known for pioneering the production of a bovine protein in a crop for the food industry. The Company's product portfolio and pipeline leverages the agronomic efficiency of broadly used target crops, like soybean, pea, and safflower to produce oils and proteins. Moolec also has an industrial and commercial R&D capability to complement the company's Molecular Farming technology. Moolec secures a growing international patent portfolio (25+, both granted and pending) for its Molecular Farming technology. The Company is run by a diverse team of Ph.Ds and Food Insiders, and operates in the United States, Europe, and South America. For more information, visit moolecscience.com and ir.moolecscience.com.

Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements may be identified by the use of words such as "forecast," "intend," "seek," "target," "anticipate," "believe," "expect," "estimate," "plan," "outlook," and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Such forward-looking statements with respect to performance, prospects, revenues, and other aspects of the business of Moolec are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that these statements are based on a combination of facts and factors, about which we cannot be certain. We cannot assure you that the forward-looking statements in this press release will prove accurate. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially from expected results, including, among others, changes in applicable laws or regulations, the possibility that Moolec may be adversely affected by economic, business and/or other competitive factors, costs related to the scaling up of Moolec's business and other risks and uncertainties, including those included under the header "Risk Factors" in Moolec's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission ("SEC"), as well as Moolec's other filings with the SEC. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, you should not put undue reliance on these statements.

Contacts:

- Press & Media inquiries: comms@moolecscience.com
- Investor Relations inquiries: MoolecIR@icrinc.com | ir@moolecscience.com

[1] In the first paragraph of the USDA-APHIS online response letter, please note that the term "gene editing" should be understood as "genetic engineering" due to an unintentional error that may be addressed in the coming days.

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Related Files

[Moolec Becomes First Molecular Farming Company to Achieve USDA Approval for Plant-Grown Animal Proteins - 2024.04.22](#)

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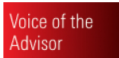
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The Office of
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March 20, 2024

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March 20, 2024

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Re: *In re: Paraquat Products Liability Litigation*,
Case No. 21-md-3004-NJR

Counsel:

I represent the Minnesota Department of Agriculture in connection with the subpoenas served by plaintiffs in the above captioned matter.

This letter serves as an omnibus objection to the subpoenas, as set forth below.

Objection to the Place of Production: Most of the subpoenas purport to require production of documents in locations other than St. Paul, Minnesota. While the production of documents is likely to be electronic, the Department objects to a production of any physical documents at a location other than St. Paul.

Objections to the Timing of Production:

The Department began receiving subpoenas on March 6, and has received approximately 48 subpoenas so far with the majority being received between March 11 and March 18. Given the number of subpoenas the Department has received, the Department will not be able to produce documents on or before April 19.

Improper Service:

The Department notes that the vast majority of subpoenas it has received were not properly served, with most simply being mailed to the Department. The Department reserves its right to contest service if any motion is filed with respect to any subpoena.

Objections to Definitions and Instructions:

The definitions and instructions included in the subpoenas are substantially identical. Certain of the definitions and instructions are clearly inappropriate in the context of a third-party subpoena, many others are not consistent with the Federal Rules of Civil Procedure, and still others purport to impose unreasonable constructions on the language of the subpoenas themselves. In particular:

- Definition 8 purports to require production of any document in the possession, custody, or control of the Department's "present and former partners, members, associates, attorneys,

employees, agents, and representatives thereof.” The Department will limit its production to those documents actually within its own possession, custody, or control.

- Instruction 1 purports to control the format of the Department’s production. The Department will produce its documents in a format of its own choosing, taking into account the reasonable needs of your clients and the burdens on the Department.
- Definitions 1 and 2, and Instruction 3 contains various demands that words be given unnatural meanings. The Department will give the words “and,” “or,” and “each,” their natural meanings. The Department objects to the instruction to construe singular as plurals and vice versa, and will construe such words consistent with their natural meanings. The Department objects to the instruction to construe past tense verbs as present tense and vice versa, and will give construe such words consistent with their natural meaning. The Department objects to the instruction to construe “negative terms to include the positive and vice versa.” The instruction is nonsensical. To the extent the Department encounters negative or positive terms it will give such terms their natural meaning.
- Instruction 4 purports to require the Department to provide detail on responsive documents that it no longer possesses. The Department objects and will not provide such detail, which is not required by applicable rules.
- Instruction 5 purports to specify the manner in which the Department will assert any claims of privilege or other protections. The Department objects, and will provide reasonable disclosures on these issues, consistent with the requirements of the applicable rules. At present, the Department is not asserting any privileges.
- Instruction 6 purports to impose an obligation to supplement responses to the subpoena. The Department will not provide supplemental responses, which are not required of subpoena respondents – something you should know. *See, e.g., Discover Fin. Servs. v. Visa U.S.A., Inc.*, 2006 WL 8460949 *2 n.1 (S.D.N.Y. Aug. 3, 2006); *Alexander v. F.B.I.*, 192 F.R.D. 37, 38 (D.D.C. 2000).

Documents the Department will Produce:

As set forth above and below, the Department objects to various elements of the subpoenas. For clarity, the Department will search for and produce the following:

- Licensing data sufficient to show the licensing and/or registration status of sufficiently identified persons or entities;
- Current, publicly available training materials created by the Department for restricted use pesticide licenses.

Common Objections to Production Requests:

Licensing Data:

The subpoenas broadly seek production of all documents of any nature in any way related to licensing. These requests are overbroad and too vague to allow any meaningful response. The Department will produce records sufficient to show the licensing status of any individual or entity that the subpoena proponent has identified with sufficient specificity to allow the records to be located. The Department notes that many large entities have multiple sites, and multiple licenses. For these entities, the subpoena proponent will need to identify the specific location for which they seek licensing data. The Department will correspond separately on this issue as it reviews the subpoenas.

Licensing Requirements:

The Department is unsure how data about the requirements for obtaining a license is relevant to the issue of whether a plaintiff was or was not exposed to Paraquat. There are no Paraquat-specific licensing requirements.

Your clients can find the current licensing requirements here: <https://www.mda.state.mn.us/pesticide-fertilizer/pesticide-applicator-licensing>. The Department objects to the production of other documents relating to these requirements as unreasonably burdensome.

Training Materials:

The Department is (again) unsure how data about training requirements is relevant to the issue of whether a plaintiff was or was not exposed to Paraquat.

Nonetheless, the Department does not object to the production of current training materials created by the Department that were made available to the general public, and will produce those

documents. The Department objects to the production of *all* documents relating to training as unduly burdensome.

Use Reports:

The Department does not require applicators to report on their specific uses of restricted pesticides. It also does not require applicators to furnish contracts relating to applications, or records of sales or purchases of restricted use pesticides. As a result, the Department has no such records available for production.

In its enforcement actions, the Department does sometimes require applicators to furnish information on the restricted use pesticides they used leading to the enforcement matter. There is no way for the Department to review its enforcement records for such reports other than with a document by document search of the files. Even if such usage reports existed, the records would generally lack sufficient detail to establish whether a particular individual was or was not exposed to Paraquat. The Department's enforcement files are also generally classified as not public data under the Minnesota Government Data Practices Act and Minnesota Statutes, Chapter 18B.

For all these reasons, the Department objects to conducting searches for restricted pesticide usage reports, or documents relating to sales, purchases, or applications of restricted use pesticides.

Time Periods:

The Department notes that its document retention period for most types of records that have been requested is six years.

Additional Objections to Production Requests:

Certain subpoenas have additional requests beyond those appearing in the bulk of the subpoenas. With respect to those subpoenas, the Department provides the following information and objections:

Studies:

Certain subpoenas seek studies regarding Paraquat. The Department has not conducted studies of Paraquat. Any studies the Department might possess would be generally available to the public. The Department objects to searching its files for the ad hoc presence of such studies.

Examination Materials:

Certain subpoenas seek license examination materials. The Department objects to the production of examination materials, which cannot be released publicly for obvious reasons, and which are also

March 20, 2024

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generally classified as protected data pursuant to Section 13.34 of the Minnesota Government Data Practices Act.

Contacts at Other Entities:

Certain subpoenas seek documents showing contacts at other agencies or entities that may possess relevant documents. The Department objects to this request as an improper subject for third-party discovery, vague, and as imposing undue burden for the Department. The Department has no readily available document identifying other entities that may possess documents relevant to the plaintiffs' claims.

Service of Additional Subpoenas:

Having put the plaintiffs on notice of the plainly improper nature of many of the definitions and instructions in their subpoenas, the Department also provides the plaintiffs with notice that it will not respond to any additional subpoenas that repeat the improper definitions or instructions.

Rule 45(d) requires attorney serving subpoenas to avoid imposing undue burden or expense on a subpoena respondent. Serving subpoenas with clearly improper definitions and instructions violates this rule. Subpoena respondents should not be burdened with the task of culling through improper definitions and instructions to preserve their objections. Service of additional subpoenas with these improper definitions and instructions will be met with a flat refusal to respond to the subpoena unless and until an appropriate subpoena is served.

Sincerely,

OLIVER J. LARSON
Assistant Attorney General

(651) 757-1265 (Voice)
(651) 297-1235 (Fax)

cc: Doug Spanier, Esq.
Chris McNulty, Esq.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

In re: PARAQUAT PRODUCTS
LIABILITY LITIGATION

This Document Relates to All Cases.

Case No. 3:21-md-3004-NJR

MDL No. 3004

CASE MANAGEMENT ORDER NO. 21
RELATING TO LIMITED THIRD-PARTY DISCOVERY

ROSENSTENGEL, Chief Judge:

On May 15, 2023, the Court entered Case Management Order No. 18 relating to Deceased Plaintiffs' Submissions and Cases Based on Implausible Theories of Proof (CMO 18). (Doc. 4242.) CMO 18 reflects the Court's concern "about the presence of cases on its docket that present implausible or far-fetched theories of liability, and therefore would not have been filed but for the availability of this multidistrict litigation." (CMO 18 at 3.) The Court identified four categories of cases that present implausible theories of liability: "(i) a plaintiff states that they have no information concerning their exposure to paraquat (as opposed to a different product); or (ii) a plaintiff has no medical evidence to support a diagnosis of Parkinson's disease; or (iii) a plaintiff claims to have used paraquat in a form in which it never existed (e.g., in powder or pellet form); or (iv) there are other evidentiary issues such as those that led to the voluntary dismissal of the bellwether plaintiffs." (*Id.* at 4.)

Since CMO 18 was issued, the Court has reiterated its concern about the existence of many implausible and unsubstantiated claims on the docket in this MDL. During the

August 2023 hearing on motions filed pursuant to Federal Rule of Evidence 702, the Court clarified CMO 18 and ordered that the parties' "time in the coming weeks . . . be focused on getting [the] docket cleaned up." (Doc. 4795 at 184:9-10; *id.* at 183:14-17 (explaining that CMO 18 ordered "examination and clean up of the docket").) On January 22, 2024, the Court issued Case Management Order No. 20 (CMO 20), selecting certain cases for limited discovery to address the Court's concern "that a significant number of plaintiffs in the MDL . . . do not plausibly allege exposure to paraquat." (Doc. 5102 at 2.) In the two weeks following the issuance of CMO 20, nine of the 25 Plaintiffs who were selected for limited discovery voluntarily dismissed their complaints. This prompted the Court to issue Case Management Order No. 20A (CMO 20A), where it selected nine additional Plaintiffs for limited discovery. (Doc. 5127.) As stated in CMO 20A, "[t]hese dismissals . . . only reinforced the Court's concern about the proliferation of non-meritorious claims on the docket of this MDL." (*Id.* at 1.)

The Court asked the Special Master to review and analyze the documentary evidence of Plaintiffs' use of and/or exposure to paraquat as shown in their Plaintiff's Assessment Questionnaires ("PAQ"). The Special Master has advised the Court that many Plaintiffs in the MDL have not produced any documentary evidence in support of their exposure allegations, despite the opportunity to do so in the PAQ itself, as well as requests for the same types of documents made by Defendants to certain Plaintiffs in letters sent to Plaintiffs' counsel. This may be because such proof does not exist, or it may instead be because the relevant documentary evidence is in the possession, custody, or control of a third-party. Until now, the Court has not required Plaintiffs to request or

produce such documentary evidence. *See* Section XXIII of the Plaintiff's Assessment Questionnaire ("For purposes of this Plaintiff's Assessment Questionnaire, you are not required to obtain records from third party entities")¹

In light of the foregoing, the Court directs *each Plaintiff in this MDL* to serve third-party subpoenas pursuant to Federal Rule of Civil Procedure 45 seeking documentary evidence providing proof of use and/or exposure to paraquat. Each Plaintiff is encouraged to serve any and all subpoenas he or she believes are necessary to establish documentary proof of his or her use of and/or exposure to paraquat. The Court likewise directs each Plaintiff to produce—by uploading to the PAQ portal—any documentary evidence providing proof of use and/or exposure currently in their possession, custody, or control that has not already been uploaded to the PAQ portal. This additional limited third-party discovery will provide Plaintiffs an opportunity to better determine the strength of their claims, as well as expose non-meritorious claims. Additional information about Plaintiffs in this MDL also will assist the Court in facilitating the expeditious, economical, and just resolution of this litigation, which has been the Court's goal since the MDL's inception. (*See* Doc. 16.)

The Court **ORDERS** that the third-party subpoenas be served by **March 11, 2023**. The subpoenas **SHALL** specify a return date of **21 days from service**. Any documents received in response to the subpoenas **SHALL** be uploaded to the PAQ portal within **10 days** of production to Plaintiffs' counsel by the third-party. So long as all documents

¹ *See* Plaintiff's Assessment Questionnaire, available at <https://www.ilsd.uscourts.gov//documents/Paraquat/PlaintiffAssmntQuestionnaire.pdf>.

received in response to a subpoena are uploaded to the PAQ portal, they do not otherwise need to be served on defense counsel or the Special Master. Given the expected number of forthcoming subpoenas, Lead Counsel for all parties **SHALL** confer regarding the notice requirements under Rule 45(a)(4) and refer any disputes to the Special Master.

Finally, it is this Court's preference to adjudicate any discovery disputes concerning this CMO. Should a dispute arise in connection with a subpoena issued pursuant to this CMO, the Plaintiff serving the subpoena **SHALL** promptly notify this Court and inform the presiding Judge of this Court's preference to decide it.

IT IS SO ORDERED.

DATED: February 26, 2024

The image shows a handwritten signature in black ink that reads "Nancy J. Rosenstengel". The signature is written in a cursive style and is positioned above a horizontal line. To the right of the signature, there is a faint circular seal of the United States District Court for the District of Columbia.

NANCY J. ROSENSTENGEL
Chief U.S. District Judge