Regulatory Status Review under 7 CFR part 340 for Soybean with Pork Protein
Submitted August 22, 2023, by Moolec Science SA

1. Requestor:

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2. This RSR request contains Confidential Business Information (CBI).

Justification Statement for Confidential Business Information:
This request by Moolec Science SA for Regulatory Status Review under 7 CFR part 340 contains confidential business information (CBI) which includes one or more of the following: trade secrets and commercial or financial information obtained from a person and privileged or confidential. Public disclosure of the information designated as CBI in this communication would pose serious harm to Moolec Science SA. Moolec Science SA is claiming this exemption from disclosure pursuant to the provisions of the FOIA Improvement Act of 2016 (Public Law No. 114-185), which can be found online at https://www.foia.gov/foia-statute.html .

Moolec Science SA recognizes that the Freedom of Information Act (FOIA) requires federal agencies to withhold information from disclosure that the agency reasonably foresees would harm an interest protected by a FOIA exemption or where such disclosure is prohibited by law. Under FOIA Exemption 4 "trade secrets and commercial or financial information obtained from a person and privileged or confidential" is exempt from disclosure, where information is "confidential" if customarily and actually treated as private, and especially if provided to the government under an assurance of privacy (5 U.S.C. 552(b)(4)).

This Regulatory Status Review Request contains information that is treated as confidential by Moolec Science SA. Disclosure of this information is likely to harm various interests of Moolec Science SA, including the competitive position and intellectual property of Moolec Science SA.

Moolec Science SA treats as private and maintains as confidential the information about the genetic sequences transferred to the soybean plants, because disclosure of this information could directly provide our competitors with commercially valuable knowledge of the precise genetic sequences that Moolec Science SA has found to be most desirable to provide the desired plant characteristics. Disclosure of this information may also jeopardize the intellectual property of Moolec Science SA, because patents are pending and have not been published. The sequence information in question is maintained by Moolec Science SA in document control systems that have strict clearance procedures to control access to the information.

3. Description of the comparator plant:

Scientific name: *Glycine max*
Common Name: Soybean

Soybean has been the subject of extensive monographs that describe its biology, genetics, and agronomic production practices as a crop. The Organisation for Economic Cooperation and Development published a 19-page consensus document in 2000, and it can be found online (https://www.oecd.org/env/ehs/biotrack/46815668.pdf).

In July 2021, The Canadian Food Inspection Agency published an updated version of its biology document entitled "The Biology of Glycine max (L.) Merr. (Soybean)" (https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology-documents/glycine-max-l-merr-/eng/1330975306785/1330975382668).

Under the provisions of the regulations found at 7 CFR part 340, USDA-APHIS has published numerous Environmental Assessments for environmental releases and determinations of nonregulated status for a wide range of genetically engineered (GE) soybean plants. None of these APHIS Environmental Assessments concluded that the GE version of the soybean posed a plant pest risk greater than posed by its non-GE comparator soybean. These Environmental Assessments did not cite any evidence in the scientific literature to support a conclusion that gene flow from any GE soybean to sexually compatible relatives is likely to result in offspring with increased weediness or were likely to pose an increased plant pest risk as compared to the non-GE soybean. These APHIS Environmental Assessments cover more than 30 years of agency assessments, and they are publicly available via the agency's web site or through requests under the provisions of the Freedom of Information Act.

Soybean is not a parasitic plant and is not listed on the APHIS list of plant parasitic genera (https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/plant-pests/SA_Noxious_Weeds/parasitic-plant-genera-list). Because soybean is not a parasitic plant, it does not meet the definition of plant pest in APHIS regulation 7 CFR part 340 (see the definition of plant pest in 7 CFR part 340.3). The only plants that fall under this definition of "plant pest" are parasitic plants.

There are no scientifically substantiated studies that describe a plausible pathway by which soybean plants can be modified by genetic engineering to make it into a parasitic plant.

Soybean is not on the list of Federal Noxious Weeds (https://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist.pdf).

4. Genotype of the modified plant.
The genotype of the modified soybean plants is achieved by inserting the sequences of the constructs described below in to the genome of soybean. Plants are transformed with two constructs: (1) a selectable marker and (2) either Moolec02 or Moolec03. Annex 1 includes the sequence insertion information, as well as annotation of the constructs in Tables 1 – 3. Table 1 annotates the selectable marker construct, and Tables 2 and 3 annotate the constructs Moolec02 and Moolec03, respectively.

5. Description of new intended trait of the modified soybeans
Intended Phenotype: The intended phenotype is the accumulation of a pork meat protein in the soybean seed. The specific pork meat protein is described in Table 1 below. The intended phenotype of for the selectable marker is described in the "Component Function" column in Table 1 below. Annex 2 has NCBI references relevant to the intended phenotype.

Description of Mechanism of Action (MOA): Expression of the constructs Moolec02 or Moolec03 results in the accumulation of a pork meat protein in the soybean seed. Expression of the selectable marker gene is used in the laboratory to identify successfully transformation. The specific selectable marker gene encodes an enzyme that inactivates the specific antibiotics (description in Table 1 below).

Table 1: Selectable Marker

Nucleotide position	Component Name	Component Donor	Component Function	
0 – 13	Linker	Synthetic	Links construct components (no function in plant)	
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	Linker	Synthetic	Links construct components	CBI-DELETED

Table 2: Moolec02

Nucleotide position	Component Name	Component Donor	Component Function	
0 – 26	Linker	Synthetic	Links construct components (no function in plant)	
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	Linker	Synthetic	Links construct components	CBI-DELETED

Table 2: Moolec03

Nucleotide position	Component Name	Component Donor	Component Function	
0 – 26	Linker	Synthetic	Links construct components (no function in plant)	
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	[ ]	[ ]	[ ]	CBI-DELETED
[ ]	Linker	Synthetic	Links construct components	CBI-DELETED

Annex 1: Sequences of the genetic construct insertions into soybean

Selectable Marker

[

CBI-DELETED

CBI-DELETED

]

Moolec02
[

CBI-DELETED

]

Moolec03

[

CBI-DELETED

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Annex 2: NCBI Reference Numbers

1. [

CBI-DELETED

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2. [

CBI-DELETED

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