NBA
National Biosafety Authority

DECISION DOCUMENT FOR ENVIRONMENTAL RELEASE AND PLACING ON THE MARKET OF GENETICALLY MODIFIED PLANT

Tracking No: 2021-014-SARI-004-D **Date: 30th JUNE, 2022**

Decision on an Application from the Council for Scientific and Industrial Research (CSIR), Savanna Agricultural Research Institute (CSIR-SARI) for Environmental Release and Placing on the Market of Cowpea (*Vigna unguiculata* L. Walp.) Genetically Modified for Resistance to Maruca pod borer (*Maruca vitrata*) Event AAT-709AA-4 (hereafter referred to as cowpea event 709A) in Ghana.

Pursuant to Sections 4, 13, 17, 18, 19, 21, 22 and 23 of the Biosafety Act, 2011 (Act 831) and the relevant procedures under the Biosafety (Management of Biotechnology) Regulations, 2019 (L.I. 2383), the Board of the National Biosafety Authority (NBA) evaluated information submitted by the applicant- the Council for Scientific and Industrial Research (CSIR), Savanna Agricultural Research Institute (CSIR-SARI). This information addressed the safety of the insect resistance Cowpea event 709A. The Board of the NBA has determined that the genetically modified plant does not present an altered environmental risk or a food or feed safety concern when compared to conventional cowpea varieties in Ghana. **The Board has therefore approved the environmental release and placing on the market of Cowpea (*Vigna unguiculata* L. Walp.) Genetically Modified for Resistance to Maruca pod borer (*Maruca vitrata*) Event AAT-709AA-4 for ten (10) year period, renewable.**

Short summary of the genetically modified organism (GMO)

Id. of the Modified Plant:	Cowpea event 709A, OECD Unique Identifier AAT-709AA-4
Applicant:	Council for Scientific and Industrial Research (CSIR), Savanna Agricultural Research Institute (SARI)
Plant Species:	Cowpea. *Vigna unguiculata* L. Walp.
Modified Traits:	Insect resistance
Trait Introduction Method:	*Agrobacterium tumefaciens*-mediated transformation
Intended Use(s) of the Modified Plant:	Production of cowpea for human consumption (e.g., leaves and dried beans, including derived products) and for use in livestock feeding (e.g., fodder)

Application summary

The applicant noted that cowpea (*Vigna unguiculata* L. Walp.) is an important staple in the diet of more than 200 million households in sub-Saharan Africa (SSA) and provided information regarding its uses. Insect pests constitute one of the main constraints to cowpea production and many studies have shown that pesticide application at flowering and podding can increase yields up to two-fold. The *Maruca* pod borer (*Maruca vitrata*) is considered the most devastating insect of cowpea, accounting for yield losses ranging from 20–80 percent.

To address the challenge stated above, the applicant has developed pod borer resistant 709A cowpea event from *Agrobacterium tumefaciens,* intended to reduce pre-harvest losses and over-reliance on expensive, potentially damaging, and increasingly less effective chemical insecticides that are in routine use. Following the approval for environmental release and placing on the market of cowpea event 709A, the Cry1Ab insect resistance trait will be introgressed into additional farmer-preferred varieties suitable for variety evaluation and release.

Cowpea was genetically modified to express the trait of resistance to the legume pod borer, *Maruca vitrata*, (Lepidoptera: Crambidae). Transgenic cowpea event 709A was produced by *Agrobacterium tumefaciens*-mediated transformation resulting in the introduction of the *cry1Ab* gene from *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1, and the neomycin phosphotransferase ll encoding gene (*nptII*) from the Tn5 transposon of *Escherchia coli* strain K12 as a selectable marker. The Cry1Ab and neomycin phosphotransferase II (NPTII) proteins have a history of safe use in approved genetically modified crops in many countries.

The applicant provided data on the identity of cowpea event 709A, a detailed description of the transformation method, data and information on the insertion site, gene copy number and levels of gene expression in the plant and the role of the inserted genes and regulatory sequences. The newly produced proteins (Cry1Ab and NPTII) were identified and characterized.

The Cowpea event 709A was field tested in Nigeria in 2014 and 2015, and in Ghana in 2016. The Cowpea event 709A's agronomic and phenotypic characteristics, and nutritional components were observed in the field studies.

Overall assessment of the agronomic data from multiple years of testing at locations in Ghana and Nigeria did not identify trends of significant differences between 709A and control cowpea, except for resistance to *Maruca* damage. Collectively, the comparative agronomic and phenotypic data support the conclusion that the genetic modification resulting in cowpea event 709A did not have an unintended, unexpected, effect on plant growth habit and general morphology, vegetative vigour, or grain yield.

Observed agronomic characteristics included germination, days to 50% flowering, plant height, pods per plant, *Maruca* damaged pods per plant, sucking insect damaged pods per plant, total seed per plant, *Maruca* damaged seed per plant, sucking insect damaged seed per plant, healthy seed per plant, and plant vigour.

There were also no indications that 709A cowpea would be more invasive or persistent in the environment, or have altered susceptibility to pests and diseases compared to the conventional cowpea. Except for the intended resistance to *Maruca* pod borer, the 709A cowpea is agronomically and phenotypically equivalent to conventional cowpea.

The compositional analysis compared the concentrations of major nutrient components in samples of whole grain, leaves, and fodder collected from cowpea event 709A and control cowpea. Whole grain, leaves, and fodder were measured for proximates (crude protein, crude fat, ash, and carbohydrates), calories and moisture. In addition, concentrations of key minerals and phytic acid were also determined in samples of whole grain.

Data were provided for the evaluation of the potential toxicity and allergenicity of the novel proteins to humans, livestock and other non-target organisms. The applicant also provided the NBA with an event-specific method for the detection and identification of cowpea event 709A.

Risk Assessment

Criteria

The Board of the NBA reviewed the risk assessment report from the Technical Advisory Committee (TAC) on the application in accordance with the criteria for assessing environmental safety of GMOs and assessing food and feed safety of GMOs as provided in the legislation. The risk assessment review considered the potential of the:

- cowpea event 709A to become a weed of agriculture, or to be invasive of natural habitats;
- gene-flow from cowpea event 709A to wild relatives whose hybrid offspring may become more weedy or more invasive;
- cowpea event 709A to become a plant pest;
- impact of cowpea event 709A and its gene products on non-target species, including humans;
- impact of cowpea event 709A on biodiversity;
- development of resistant *Maruca* population;
- impact of cowpea event 709A on human nutrition and health
- impact of cowpea event 709A on livestock nutrition and health; and
- impact of cowpea event 709A on workers and processors.

Development Method

Cowpea event 709A was developed through *Agrobacterium tumefaciens*-mediated transformation of cowpea cultivar IT86D-1010 using plasmid pMB4, which contained two gene expression cassettes within the T-DNA. This resulted in the introduction of the *cry1Ab* gene from *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1 and the neomycin phosphotransferase II encoding gene (*nptII*) from the Tn5 transposon of *Escherichia coli* strain K12 as a selectable marker.

Based on information provided by the applicant, and experience with the Cry1Ab and neomycin phosphotransferase II (NPTII) proteins, having a history of safe use in approved genetically modified crops in many countries, and the nature of the T-DNA, the Board of the NBA concluded that there are no safety concerns with respect to the development process.

New traits

Insect resistance: Cowpea event 709A was created to express a new trait of resistance to the cowpea pod borer, *Maruca vitrata*. No existing endogenous traits of the parent species were intentionally altered. Except for the intended resistance to *Maruca* pod borer, the 709A cowpea is agronomically, phenotypically and compositionally equivalent to the conventional cowpea.

The *nptII* gene from the Tn5 transposon of *Escherichia coli* strain K12 in Cowpea event 709A encodes the NPTII protein. To eliminate leaky expression of *nptII* in *Agrobacterium* and prevent selection of false-positive kanamycin-resistant plants, the *nptII* gene was interrupted with a modified catalase-1 (CAT-1) intron from castor bean (*Riccinus communis*). Transcription of the *nptII* gene is controlled by the S1 promoter from subterranean clover stunt virus (SCSV) and termination sequences are provided by the SCSV DNA segment 3. The *nptII* gene functions as a selectable marker immediately following transformation of plant cells during *in vitro* tissue culture.

A truncated version of the *cry1Ab* gene, from *Bacillus thuringiensis* subs. *kurstaki* strain HD-1, in Cowpea event 709A encodes the Cry1Ab protein. The nucleotide sequence of the *cry1Ab* gene was codon-optimized for plant expression and encodes a 615-amino acid protein (68.9 kDa) corresponding to the trypsin-resistant insecticidally active core protein following cleavage of the 1155-amino acid native Cry1Ab protoxin (GenBank accession no. M60856.1). The *cry1Ab* gene is under the control of the promoter and 5' UTR of the RUBISCO SSU from *Arabidopsis thaliana* with transcription termination sequences derived from the tobacco (*Nicotiana tabacum*) RUBISCO SSU. Expression of *Cry1Ab* confers resistance to the lepidopteran pest *Maruca vitrata*, also known as cowpea pod borer.

Expression of both *Cry1Ab* and *nptII* is controlled by constitutive promoters and accumulation of some amount of each protein would be expected in all plant tissues. In samples obtained from T5 generation IT86D-1010 plants containing cowpea event 709A, the highest concentrations of Cry1Ab were measured in leaf tissue (1.9–8.1 µg/g), while the concentrations in dry seed, green cotyledons, pods, and flowers were lower, ranging between 1.95–5.2 µg/g. Measurable amounts of Cry1Ab were also found in samples of roots, pollen, and anthers taken from 709A plants. The average concentrations of NPTII protein in samples of leaves, flowers, pods, green cotyledons, pollen, anthers, and roots obtained from 709A plants grown in the greenhouse were similar, ranging from 0.16–0.35 µg/g. The highest amounts of NPTII protein were found in dry seed samples, with an average concentration of 1.5 µg/g. As expected, no quantifiable amounts of Cry1Ab and NPTII protein were found in any tissue samples derived from the control (unmodified plants).

Considering variability due to differences in promoters used to drive gene expression and in sampling and testing methodologies, the highest concentrations of Cry1Ab measured in 709A plant tissues (leaf, pod, and flower tissue) were consistent with what had been observed for different genetically modified maize lines expressing Cry1Ab protein.

The potential dietary exposure to new or novel proteins (Cry1Ab and NPTII) in the diet was assessed. The maximum potential human daily dietary exposures to Cry1Ab and NPTII proteins from 709A cowpea were estimated to be *ca.* 2.4 and 1.3 µg/kg body weight, respectively. This is based on the highest amount of these proteins measured in grain (seed) and a maximum daily cowpea intake of 0.812 g/kg body weight. More realistic estimates of exposure are likely to be significantly less considering that the estimated cowpea consumption is based on amounts available for consumption, which also include stocks held by private traders or the public sector, wastages after harvest and before consumption, and quantity used in livestock feed. Additionally, it is unlikely that 100 percent of daily cowpea consumption will be substituted with 709A cowpea.

Conservative estimates of dietary exposure to Cry1Ab and NPTII proteins for livestock animals consuming forage, hay, and seed derived from 709A cowpea were also developed. The highest exposures to newly-expressed proteins in 709A cowpea would be for lambs consuming diets containing up to 100 percent fodder, where daily dietary intakes for Cry1Ab and NPTII were estimated at *ca.* 1.76 and 0.06 mg/kg body weight, respectively. However, because it is unlikely that all of the cowpea fodder in a feed ration would be substituted with 709A cowpea, more realistic dietary exposures are likely to be less.

The applicant provided information on weight-of-evidence supporting the lack of identifiable hazards associated with Cry1Ab protein as below:

- The known function and specificity of Cry1Ab in binding to specific receptors on the brush border membrane of midgut epithelial cells only in target lepidopteran insect species, thereby resulting in cell lysis and septicemia causing insect death. This activity does not occur in mammals, other vertebrates, or other orders.
- Bioinformatic analyses showed that the Cry1Ab protein does not display significant amino acid sequence similarity to known or putative protein mammalian toxins or allergens.

- The Cry1Ab protein is rapidly degraded in SGF containing pepsin, with more than 90 percent degradation within two minutes as assessed by SDS-PAGE and western immunoblot analysis.
- The Cry1Ab protein is not acutely toxic in mice at dosages up to 4,000 mg/kg body weight, the highest dosage tested.

The applicant also provided information on weight-of-evidence supporting the lack of identifiable hazards associated with NPTII protein as below:

- The known function of NPTII in catalyzing the ATP-dependent phosphorylation of the 3'-hydroxyl group of the amino-hexose portion of certain aminoglycosides is not similar to the activities of known protein toxins.
- Bioinformatic analyses showed that the NPTII protein does not display significant amino acid sequence similarity to known or putative protein toxins or allergens.
- The NPTII protein is rapidly degraded in SGF containing pepsin and SIF containing pancreatin. No intact NPTII or NPTII-derived fragments were detected after exposure to pepsin-containing SGF or pancreatin-containing SIF as assessed by western immunoblot labelling following SDS-PAGE analysis.
- The NPTII protein is not acutely toxic in mice at dosages up to 5,000 mg/kg body weight, the highest dosage tested.

Based on the weight of the available evidence, the Board of the NBA concludes that the* Cry1Ab and NPTII *proteins produced in cowpea event 709A are unlikely to be toxic or allergenic to mammals.

Antibiotic resistance marker genes: Regarding the presence of the *nptII* gene in cowpea event 709A the probability that this gene would be successfully transferred to and expressed in microorganisms present in the human digestive tract is considered to be highly unlikely because of the number and complexity of the steps that would need to take place consecutively. Also, the potential impact on human health, in the unlikely event of successful transfer of a functional antibiotic resistance *nptII* gene in cowpea event 709A to microorganisms in the human digestive tract, is considered negligible.

The risks posed by the possibility of horizontal gene transfer from genetically modified plants containing the *nptII* gene to bacteria in the human digestive tract are negligible. The probability of such transfer is extremely remote, the relative impact if it were to occur is insignificant considering that the *nptII* gene is already widespread within the environment and microbial communities.

In the case of genetically modified plant events, such as 709A cowpea, where the *nptII* gene is interrupted with the CAT-1 intron, expression of this gene in bacteria is not possible thus removing any residual concerns related to the remote possibility of horizontal gene transfer.

Based on the above information on unlikely transfer of the nptII gene to gut microbiota, and from relevant scientific literature, the Board of the NBA does not identify any new hazard associated with the nptII gene transfer in cowpea event 709A.

Stable Integration into the Plant Genome: Based on the results of Southern hybridization analysis provided by the applicant, cowpea event 709A contained a single copy of the pMB4 T-DNA integrated at a single site within the cowpea genome. The introduced DNA in 709A cowpea did not contain any sequences derived from the pMB4 plasmid backbone region.

Results of the nucleotide sequence analysis of the entire T-DNA insert within 709A cowpea confirmed the organization of the inserted DNA. The inserted DNA comprised one complete copy of the plasmid pMB4 T-DNA, except for 10-bp and 29-bp truncations at the 5' and 3' termini, respectively, and a 735-bp inverted repeat derived from the 3' end of the T-DNA. The site of insertion of the T-DNA was mapped to a region on chromosome 2 of the cowpea genome. There were no new novel open reading frames created as a consequence of the DNA insertion that would have the potential to encode proteins with any significant amino acid sequence similarity to known or suspected toxins or allergens.

Also, based on the results of event-specific PCR analysis provided by the applicant, the inserted DNA derived from plasmid pMB4 T-DNA was stably inherited within progeny plants spanning ten generations of 709A cowpea in the direct line of descent from the original transformation event.

Additionally, analysis of two segregating generations ($F_2^{*1,*2,*3}$ and $BC_1F_1^{*1,*2,*3}$) that represented different crosses and back-crosses between cowpea event 709A (IT86D-1010) and non-genetically modified cowpea varieties confirmed that the introduced *Cry1Ab* encoding gene segregated as a single genetic locus according to Mendelian rules of inheritance.

Based on the findings above, the Board of the NBA concludes that there is a stable integration of a single copy of the inserted DNA in the plant genome for cowpea event 709A.

Environmental Risk Assessment

Potential of Cowpea Event 709A to become a Weed of Agriculture or be Invasive of Natural Habitats: The applicant provided data on phenotypic and agronomic traits to establish that cowpea event 709A is not weedier or more invasive than conventional cowpea hybrids.

Information provided by the applicant included studies that showed the establishment of feral populations of domesticated cowpea is theoretically possible, but this has rarely been observed in Africa. There was also information that a few small transient feral populations had been reported in coastal Kenya, which were not seen in consecutive years. However, cowpea cultivars are generally not capable of creating long-lived seed banks in the soil because their seeds are permeable to water and lack dormancy. The domestication of cowpea has resulted in loss of many primitive traits typically associated with weediness, such as perenniality, fecundity, hairiness, small size of seeds and pods, hard seeds, pod shattering, and significant out-crossing.

The applicant conducted field comparisons between 709A cowpea and its near-isogenic non-genetically modified counterpart over multiple locations and years, and did not identify any significant differences in plant growth and morphology, reproductive biology characteristics, seed set or shattering, that would indicate any unintended change in the weediness or invasiveness of conventional cowpea cultivars.

Considering the above information on environmental risk assessment, the Board of the NBA concludes that cowpea event 709A has no increased weediness or invasiveness potential compared to conventional cowpea varieties.

Potential for Gene Flow from Cowpea Event 709A to Wild Relatives: The applicant provided information on the reproduction characteristics of cowpea, being cleistogamous, producing viable pollens and receptive stigma before anthesis, meaning that cowpea reproduction is entirely via self-pollination. However, out-crossing mediated by insects can occur naturally in the field, and while different insect species visit cowpea flowers, not all are responsible for pollen movement associated with out-crossing. Only honey bees and bumblebees are responsible for insect vectored pollen movement because only such heavy insects could depress the wings of cowpea flowers and expose their stamens and stigmas for pollination. Out-crossing rates between cultivated cowpea varieties are low, ranging from 0.5-0.85 percent when cowpea was planted in alternate rows of 1 meter apart, and between 0.01-0.13 percent when planted in concentric circles around a pollen source. There are no reports of natural hybridization between *V. unguiculata* and other *Vigna* species.

More so, there have been no changes in the reproductive biology of cowpea as a consequence of the genetic modification resulting in cowpea event 709A. Parameters such as percent germination, days to 50 percent flowering, pods per plant, healthy seed per plant, and seed weight are not significantly different between cowpea event 709A and control (unmodified plants) cowpea.

Expression of the introduced *cry1Ab* and *nptII* genes in 709A cowpea will not alter the frequency or efficiency of horizontal gene transfer (HGT). The potential for HGT and any possible adverse outcomes have been reviewed in the literature and the risk is negligible, due to the rarity of HGT events and also because the gene sequences (e.g., *cry1Ab* and *nptll*) are already present in the environment and available for transfer via demonstrated natural mechanisms.

The Board of the NBA concludes that the potential risk of gene flow from cowpea event 709A to wild relatives is negligible.

Altered Plant Pest Potential of Cowpea Event 709A: The intended effects of the introduced trait in cowpea event 709A are unrelated to plant pest potential, and cowpea is not considered to be a plant pest. Field observations of cowpea event 709A by the applicant did not reveal any modifications to disease and pest potential, other than to *Maruca* pod borer. Based on the available information, it can be concluded that 709A cowpea does not display altered plant pest potential.

The Board of the NBA in light of the foregoing, concludes that cowpea event 709A does not display altered pest potential compared to conventional cowpea varieties, except for the intended resistance to Maruca pod borer.

Potential Impact of Cowpea Event 709A on Non-Target Organisms: The applicant provided information and findings from several studies on the environmental safety of Cry1Ab to non-target organisms, which were reviewed as appropriate. There are existing data on the environmental safety of Cry1Ab to non-target organisms, which are entirely sufficient to complete the environmental risk assessment of 709A cowpea. The applicant's assessment on a range of non-target organisms revealed that environmental release and placing on the market would not result in altered impacts on interacting organisms, with the exception of target lepidopteran insect species (e.g., *Maruca vitrata*).

Furthermore, reviews of the environmental safety of Cry1Ab have concluded that based on toxicity testing with a range of representative non-target organisms, cultivation of genetically modified plants expressing *Cry1Ab* would not significantly affect the population of non-target arthropods in comparison with alternative insect management practices.

The Board of the NBA therefore concludes that, compared to conventional cowpea varieties, the environmental release and placing on the market of cowpea event 709A will not result in altered impacts on non-target organisms, including humans.

Potential Impact of Cowpea Event 709A on Biodiversity. Cowpea event 709A has no new phenotypic characteristics that would extend its range beyond the current geographic range of cowpea cultivation in Ghana. The applicant has also provided information to demonstrate that the insect resistance trait in cowpea event 709A will not spread into or persist in unmanaged environments. Cowpea event 709A does not pose an increased risk to interacting non-target organisms.

The Board of the NBA concludes that the potential impact on biodiversity by cowpea event 709A is equivalent to that of conventional cowpea varieties.

Potential for development of resistant *Maruca* population: The rate at which resistant insect populations develop is generally dependent on factors such as the biology and ecology of the insect species; the genetics of resistance; the insecticidal properties of the crop; and the characteristics of the agricultural production system.

Though there is no recommended standard refuge size due to lack of information on the frequency of *M. vitrata* resistance alleles and the susceptibility of *RS* heterozygotes, small, diversified cropping systems and expected low rate of release of new cowpea varieties containing event 709A will help delay the onset of resistant populations. However, resistance build up may occur over time.

In order to control the occurrence of this potential effect, the applicant submitted an insect resistance management (IRM) plan and farmers' communication and response plan to be implemented during the environmental release and placing on the market of the cowpea event 709A. Further, responsible product stewardship principles would be applied for cowpea event 709A. Additionally, the African Agricultural Technology Foundation (AATF) and CSIR have committed to ensuring that appropriate documented procedures are established and implemented.

The Board of the NBA concludes that the potential risk for development of resistant Maruca population is low, and recommends that the applicant should manage the risk through the implementation of the IRM plan and farmers' communication and response plan provided, as well as the adherence to responsible stewardship principles for cowpea event 709A.

Food and Feed Safety Assessments-Potential Impact of Cowpea Event 709A on Food and Feed Nutrition

Nutritional Composition: Applicant's submission indicated that compositional analyses were performed to compare the concentrations of major nutrient components in samples of whole grain, leaves and fodder, collected from cowpea event 709A and control cowpea grown at four different locations representing typical cowpea growing conditions in Ghana and Nigeria. Additionally, concentrations of key minerals were determined in samples of whole grain.

The applicant demonstrated that from the combined-sites analyses across the four locations, there were no significant differences in concentrations of proximates (crude protein, crude fat, carbohydrate, ash, moisture), calories, or minerals, between grain samples collected from cowpea event 709A and control cowpea. Similarly, there were no significant differences in concentrations of proximates, and calories between cowpea event 709A and control cowpea leaf and fodder samples when analysed using the combined-sites model.

Overall, no consistent patterns emerged to suggest that biologically meaningful changes in composition or nutritive value of the grain, leaves, or fodder had occurred as a consequence of the genetic modification or production of the Cry1Ab and NPTII proteins in cowpea event 709A. Thus, food products derived from cowpea event 709A are compositionally equivalent to their conventional counterparts. All mean values were within the commercial ranges and literature values as well as within the normal variation for conventional cowpea.

Anti-Nutrients and Secondary Metabolites: Concentrations of phytic acid were determined in samples of whole grain collected from cowpea event 709A and control cowpea grown at four different locations representing typical cowpea growing conditions in Ghana and Nigeria.

The applicant provided evidence to show that from the combined-sites analyses across the four locations, there were no significant differences in concentrations of phytic acid, between grain samples collected from cowpea event 709A and control cowpea, and no consistent patterns emerged to suggest any biologically meaningful changes. All mean values from the analyses were within the commercial ranges and literature values as well as within the normal variation for conventional cowpea.

The Board of the NBA concludes that the evidence provided by the applicant supports the conclusion that the nutritional composition of cowpea event 709A is substantially equivalent to that of conventional cowpea varieties.

Potential Impact of Cowpea Event 709A on Workers and Processors

The Cry1Ab and the NPTII proteins are commonly found in bacterial populations and have a history of safe use in approved genetically modified crops like maize in some jurisdictions (e.g. USA, European Union, South Africa).

The known function and specificity of Cry1Ab protein in binding to receptors on the brush border membrane of midgut epithelial cells in target lepidopteran insect species results in cell lysis and septicemia, causing insect deaths. This does not occur in other insect orders, mammals and other vertebrates. The Cry1Ab protein does not display significant amino acid sequence similarity to known or putative protein mammalian toxins or allergens and it is rapidly degraded in Simulated Gastric Fluid (SGF) containing pepsin, with more than 90 percent degradation within two minutes as assessed by SDS-PAGE and Western immunoblot analyses. Furthermore, the Cry1Ab protein is not acutely toxic in mice at dosages up to 4,000 mg/kg body weight, the highest dosage tested. These findings indicate that the Cry1Ab protein is unlikely to be a toxin or an allergen.

The known function of NPTII protein in catalyzing the ATP-dependent phosphorylation of the 3'-hydroxyl group of the amino-hexose portion of certain aminoglycosides is not similar to the activities of known protein toxins. Bioinformatic analyses showed that the NPTII protein does not display significant amino acid sequence similarity to known or putative protein toxins or allergens, and it is rapidly degraded in SGF containing pepsin and Simulated Intestinal Fluid (SIF) containing pancreatin. No intact NPTII or NPTII-derived fragments were detected after exposure to pepsin-containing SGF or pancreatin-containing SIF, as assessed by Western immunoblot labelling following SDS-PAGE analysis. The NPTII protein is not acutely toxic in mice at dosages up to 5,000 mg/kg body weight, the highest dosage tested. These results indicate that the NPTII protein is unlikely to be a toxin or an allergen.

The Board of the NBA concludes that there is no potential impact of cowpea event 709A on workers and processors when compared to conventional cowpea varieties with respect to toxicity and allergenicity.

Socio-economic Impact Assessment

Global GMO regulatory approvals and adoption statistics: Available statistics indicate that as of 2019, Africa leads the progress among the regions of the world in adopting biotech crops by doubling the number of adopting countries. A total of 190.4 million hectares of GM crops had been planted worldwide. High biotech adoption rates in the top 5 biotech countries impacted 1.95 billion people globally. Since 1992, seventy-two (72) countries have issued 4,485 regulatory approvals for 29 different GM crops for consumption as food, or feed, or for commercial cultivation. Approvals were based on safety and nutritional assessments that GMOs are as safe as their conventional counterparts (*verifiable from OECD biotrack database and the international BCH*). Approvals made were in Argentina, Australia, Brazil, Canada, China, Colombia, Costa Rica, the European Community, Indonesia, Japan, Kenya, Malaysia, Mexico, New Zealand, Paraguay, Philippines, Republic of Korea, Russia, South Africa, Switzerland, Taiwan, Togo, Turkey, Uganda, United States of America, Uruguay, Vietnam, etc.

In Africa, GM maize, soybean, and cotton are being cultivated in South Africa while Sudan, Malawi, Nigeria, eSwatini, and Ethiopia all grow cotton. In addition, GM cowpea and GM cotton are cultivated in Nigeria and Kenya, respectively. Adoption of GM crops in Africa and elsewhere has been attributed to their contributions to food security (poverty alleviation/elimination of hunger), sustainable environmental practices, and climate change mitigation.

Socio-economic benefits and trade implications of adopting GM cowpea: Ghana's annual estimated demand for cowpea is 169,000 tons. Meanwhile, the country produces only 57,000 tons each year. The deficit is catered for by imports from neighbouring West African countries, notably Burkina Faso, Niger and Nigeria. Nigeria is the largest producer of cowpea globally (i.e., 45% of world production) followed by Niger (15%) and Burkina Faso (6%). Ironically, Nigeria has approved cultivation of GM cowpea with Burkina Faso expected to do same on completion of regulatory studies to further increase their market share in the subregion as the market preference is for quality produce.

Ghana has a huge potential to become a net exporter of cowpea considering the deficit in supply of this commodity across the continent. Thus, adopting GM cowpea that is more benign to the environment and gives higher yields than the current practice of insecticide control will have far reaching socio-economic benefits in terms of food security, improved livelihoods and trade. Other benefits include: savings on insecticide use, as frequency of spraying is reduced; health benefits arising from reduced farmer exposure to insecticides; and safety of non-target organisms thus contributing to conservation of biodiversity.

The applicant provided information from an ex-ante assessment of the potential impacts of releasing and adopting cowpea event 709A varieties in Ghana using an economic surplus partial equilibrium model, which was recently published by the International Food Policy Research Institute (IFPRI). The assessment revealed that the total estimated net present value (NPV) of adopting 709A cowpea varieties in Ghana ranged from USD 5.6 million under the "pessimistic" scenario to USD 125.4 million under the "optimistic" scenario. The magnitude of the benefits from 709A cowpea adoption are very sensitive to assumptions around yield advantage, cost change, and rate of adoption. In reality, the most likely scenario lies between the two extremes of "pessimistic" and "optimistic", which according to the authors' "business as usual" scenario resulted in a total NPV of USD 18.6 million. Based on this analysis, consumers actually receive the largest share of the benefits (ca. 57 percent). Ghana could thus produce more cowpea to feed its people and leave surplus for export to earn foreign exchange to develop the country.

Concerns on monopoly of seeds by multinationals: The gene used to develop the GM cowpea was obtained royalty-free from Monsanto (now Bayer) through the African Agricultural Technology Foundation. This therefore means that, varieties developed from this technology are developed as a public good and will be owned by the Ghanaian institution, CSIR (i.e., CSIR-SARI).

Concerns on reusability of seeds: The PBR cowpea under development are not hybrids. Thus, just like other open pollinated varieties, farmers can save the GM cowpea seeds for planting the following season. It is recommended, however, as part of good agronomic practices for all crops (not just GMOs) that farmers buy certified seeds at least every 3 years to guarantee seed purity and maximize yields. CSIR-SARI has also been engaging in public education efforts with various stakeholders, including farmers and the media, to ensure informed decisions on technology adoption and husbandry practices.

Additionally, the applicant has committed to ensuring that the deployment of new Maruca pod borer resistant cowpea varieties containing event 709A will follow responsible product stewardship principles. Significant components of the stewardship plan include farmer education and outreach, implementing a quality management system to ensure seed quality and trait purity, following Insect Resistance Management (lRM) best-practices, and having procedures in place to respond quickly to farmer complaints or reports of unexpected damage, including the implementation of appropriate risk mitigation measures if necessary.

Public comment

Public involvement: On February 18, 2022, the NBA published a notice in the Government Gazette No. 24 of 2022 concerning the application for environmental release and placing on the market of the pod borer resistant cowpea in Ghana submitted by CSIR-SARI. The Authority subsequently published same in the Daily Graphic, the Ghanaian Times and the NBA website for the general information of the public. A 60-day period was allowed from the date of the first publication for the public to submit comments. From the submissions received, there were 19 letters with a total of 1,567 signatures; 474 individual responses and 2 responses from 2 separate organisations. From computation, a total of 2,043 signatures were thus received from various groups and individuals with 2,041 being in favour of the adoption of the technology, and with two (2) organisations against the release of the Cowpea event 709A.

All comments were carefully analysed to identify safety and non-safety concerns. Responses to the relevant comments on the application are available on the NBA website.

New Information Requirements

If at any time, the applicant becomes aware of any information regarding risk to the environment, including risk to human or animal health, which could result from release of cowpea event 709A in this country or elsewhere, the applicant shall immediately provide such information to the NBA. On the basis of any such new information, the NBA shall assess the potential impact of the cowpea event 709A on the environment, livestock and human health, and shall act appropriately.

Risk management requirements

Insect resistance management plan: The applicant shall ensure the implementation of the Insect Resistance Management (IRM) plan as provided in the dossier submitted to the NBA. Additionally, CSIR-SARI shall ensure that appropriate documented procedures are established and implemented.

Farmers' communication and response plan: The applicant shall ensure the implementation of farmers' communication and response plan as provided in the dossier submitted to the NBA.

Upon request by the NBA, CSIR-SARI shall provide verified positive and negative control tissue samples, PCR primers, and training as required to facilitate diagnostic identification of cowpea event 709A.

Conclusion: From the review of the Technical Advisory Committee (TAC) risk assessment report; information submitted by the applicant; comments submitted by the public; and the attendant socio-economic considerations, the adoption of the technology will be beneficial to Ghana. Further, findings from the comparisons of cowpea event 709A with its conventional counterpart confirmed that the insect resistance trait does not confer to cowpea event 709A any characteristic that would result in unintended environmental effects, following environmental release and placing on the market. The review also concludes that the modified event, and food and feed products derived from it are as safe and nutritious for human and livestock consumption as the conventional cowpea.

Decision: The Board of the National Biosafety Authority (NBA) in light of the foregoing, finds the proposed environmental release and placing on the market of the cowpea event 709A as of significant benefit to Ghana and has no increase in risk compared to conventional cowpea varieties. The Board therefore grants the approval for its environmental release and placing on the market in Ghana for a ten (10) year validity period, with subsequent renewals being administrative-based.

The Board further directs that any *Vigna unguiculata* progeny lines derived from cowpea event 709A may also be grown and used for food and feed, provided that: no cowpea products resulting from intra / inter-specific crosses of event 709A with other genetically modified (GM) events are commercialised without prior approval of the individual GM cowpea events; the intended uses are in line with the existing approval; it is known that these plants do not display any additional unapproved GM traits and, as a consequence, compared to conventional cowpea varieties, they are similar in terms of potential environmental impact, and substantially equivalent in terms of food and feed safety.

This approval is granted with effect from 30th June 2022 to 29th June 2032

Signature and Date:

....

Chief Executive Officer of the National Biosafety Authority **30th JUNE 2022**
Date

....

30TH JUNE 2022

Chairman, Board of the National Biosafety Authority **Date**