National Biosafety Authority

DECISION DOCUMENT FOR CONFINED FIELD TRIAL OF GENETICALLY MODIFIED PLANT

Tracking No: 2024-138-SARI-007-C **Date: 3rd June 2024**

Decision on an Application from the Council for Scientific and Industrial Research, Savanna Agricultural Research Institute (CSIR-SARI) at Nyankpala, Tamale for Confined Field Trial of Event DPS 08501- Cowpea (*Vigna unguiculata L. Walp.*) Genetically Modified for Resistance to Cowpea Field Pest (*Maruca vitrata*).

Regulation

Pursuant to Sections 4, 11, 17, 19, 21, and 22 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 CSIR-SARI. This information addressed the safety of the Maruca resistant cowpea event DPS 08501. The Board of NBA has determined that the genetically modified plant does not present an altered environmental risk concern in Ghana. **The Board has therefore approved the confined field trial of event DPS 08501 - Cowpea (*Vigna unguiculata L. Walp.)* Genetically Modified for Resistance to Maruca Pod Borer (*Maruca vitrata*) for three (3) year period, renewable.**

1.0 Short Summary of the Genetically Modified Organism (GMO)

Identification of the Modified Plant	Cowpea event DPS 08501
Applicant	Council for Scientific and Industrial Research, Savanna Agricultural Research Institute (CSIR- SARI)
Plant Species	Cowpea. *Vigna unguiculata* L. Walp.
Modified Traits	Resistance to lepidopteran insect, *Maruca vitrata.*
Trait Introduction Method	*Agrobacterium tumefacians* mediated transformation.
Purpose (s) of the Modified Plant	To reduce loss of plant yield resulting from the Maruca Pod Borer infestation. Additionally, the event will be used in stacked combinations to develop durable cowpea varieties resistant to both field and storage pests, enhancing agricultural productivity and food security.

2.0 Application Summary

Cowpea (*Vigna unguiculata* L. Walp) is a significant grain legume consumed by approximately 120 million people globally. It is a rich source of protein, certain minerals, and vitamins. Cowpea is cleistogamous, meaning it reproduces entirely through self-pollination, with no mechanical dispersion of pollen since the anthers release pollen during the night when flowers are closed. Outcrossing is minimal, facilitated by honey and bumble bees, with rates between 0.5% – 0.85%

when cowpea is planted in alternate rows one metre apart, and between 0.01% – 0.13% when planted in concentric circles around a pollen source.

CSIR – SARI has acquired cowpea event DPS 08501 containing the gene *mCry1Ca* sourced from the Donald Danforth Plant Science Center (DDPSC), St. Louis, MO, USA. This transgenic line expressing *mCry1Ca*, was modified to resist damage by lepidopteran insect. (*Maruca vitrata*).

Cowpea event DPS 08501 was produced by *Agrobacterium*-mediated transformation and the selection method used in plant regeneration was antibiotic resistance. A derivative of the pCAMBIA2300 binary vector, p5000 (Beyene *et al.*, 2017), was modified by removing the *npt*II plant-selectable marker expression cassette and replacing it with the Cre recombinase gene driven by soybean heat-shock inducible promoter HSP17.3-B (Schoffl *et al.*, 1984), and the spectinomycin (SpcN) resistance selectable marker gene under the control of the soybean ubiquitin promoter (Che *et al.*, 2021). The gene encoding the red fluorescent protein (DsRed2) from *Discosoma sp.* under control of the soybean elongation factor 1A (EF1A) promoter was also included for visual identification of transformed plants (Wasson-Blader 2001). In addition, the base vector was designed to include restriction endonuclease sites and sequences to facilitate Golden Gate cloning (Engler et al., 2008) of the gene-of-interest expression cassette for production of mCry1Ca. The expression cassette contained the *mcry1Ca* gene under the control of the *Arabidopsis thaliana* actin 2 (ACT2) promoter and ACT2 3' untranslated region (UTR). Plasmid pDIICI-085 was introduced into *Agrobacterium tumefaciens* strain LBA4404 and used to transform cowpea embryonic axis explants using the method of Che *et al.* (2021).

The modified Cry1Ca protein (mCry1Ca) present in event DPS 08501, is a chimeric insecticidal protein of 1164 amino acids wherein the N-terminal 619 amino acids comprise the core toxin from *Cry1Ca* fused to the protoxin segment derived from *Cry1Ab* (amino acids 620–1164) (Meade et al., 2016). The amino acid sequence of mCry1Ca is 95 percent identical to the sequence of Cry1Ca from *Bacillus thuringiensis* subsp. *aizawai* (MacKenzie, 2024b), which is present in the Bt-derived commercial biological insecticide XenTari® GD (ABTS-1857) where it comprises 7–11% of the total insecticidal protein together with Cry1Aa (26–33%), Cry1Ab (57–60%), and Cry1Da (3–4%) (Caballero et al., 2020). Microbial formulations of Bt, like XenTari, have a long history of safe use, being first used in France in 1938 (CERA, 2011), and commercial formulations containing combinations of several Cry proteins have been registered in the United States since 1961 (Betz et al., 2000; Schnepf et al., 1998). In their history of widespread and continuous use over more than 50 years, Bt microbial pesticides have caused no known adverse human or environmental effects (EPA, 1998). The World Health Organization (WHO) International Program on Chemical Safety report on environmental health criteria for Bt concluded that: "Owing to their specific mode of action, Bt products are unlikely to pose any hazard to humans or other vertebrates..." and "Bt has not been documented to cause any adverse effects on human health when present in drinking water or food" (IPCS, 1999). Bioinformatics analyses of the mCry1Ca amino acid sequence have shown no significant similarity to known allergens (MacKenzie, 2024a) or toxins (MacKenzie, 2024b) and there is therefore no expectation that transgenic events expressing this protein will pose a risk to health or environmental safety.

CSIR-SARI provided comprehensive data on cowpea event DPS 08501, detailing the transformation method, gene insertion site, gene copy number, and expression levels, along with characterisation of the produced proteins. The confined field trial (CFT) aims to evaluate the efficacy of this genetically modified cowpea, assess its growth and agronomic performance, and

ensure no unintended negative effects compared to the unmodified parental control. Additionally, this event will be used in stacked combinations to develop durable cowpea varieties resistant to both field and storage pests, enhancing agricultural productivity and food security. There were also no indications that the cowpea event DPS 08501 would be more invasive or persistent in the environment or have altered susceptibility to pests and diseases.

3.0 Risk Assessment

3.1 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 evaluating plant growth and agronomic performance, including yield, to demonstrate that the genetic modification did not result in unexpected, unintended, negative effects relative to the unmodified parental control cowpea. The risk assessment review considered the potential of:

- Pollination leading to establishment of an unapproved gene in wild populations.
- Seed dispersal from the CFT site
- Seed dispersal during transport
- Pilfering of seed from CFT site
- Harvest of CFT materials for food and feed use
- Impact on non-target organisms

3.2 Potential of Pollination Leading to Establishment of an Unapproved Gene in Wild Populations

The applicant provided data on the biology and mechanism of pollen dispersal of the cowpea to establish that the cowpea event DPS 08501 does not lead to unapproved gene in wild populations.

Cowpea is cleistogamous, producing viable pollens and receptive stigma before anthesis, meaning that cowpea reproduction is entirely via self-pollination. With the cultivated cowpea, there is no reported method of pollen dispersal for out-crossing because the anthers release pollen during the first half of the night when the flowers are still closed, and the pollen is sticky and heavy. Some out-crossing mediated by insects can occur naturally in the field, however, when different insect species visit cowpea flowers, not all are responsible for pollen movement associated with out-crossing. Only honeybees (*Apis mellifera*) and bumblebees (*Bombus* spp.) 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 between 0.5--0.85 percent when cowpea was planted in alternate rows one meter apart, and between 0.01--0.13 percent when planted in concentric circles around a pollen source. There are no reports of hybridization between *V. unguiculata* and other *Vigna* species.

Considering the above information, the Board of the NBA concludes that the establishment of an unapproved gene in wild population is very low (less than 1% cross pollination). There are also no sexually compatible wild relatives.

3.3 Potential of Seed Dispersal from the CFT Site

The applicant provided information that, domesticates usually have no effective seed dispersal mechanism, and thus differ from most wild plants. The modification of seed dispersal is one of the first steps in domestication, which is the case in cowpeas no less than in other crops. Certain changes have characterized the evolution of most seed crops, namely, loss of seed dispersal mechanisms, increase in seed and leaf sizes, development of determinate or compact growth habits, shifts in life cycle to annuality and shorter duration, changes from outbreeding to inbreeding and a general loss of sensitivity to the environmental signals that previously regulated development. Many of these changes have occurred in cowpeas. Cowpea seeds ingested by animals are easily digested because of their soft seed coats and therefore the dispersal of viable seeds via animal excrement is unlikely.

The Board of the NBA therefore concludes that, seed dispersal of the cowpea event DPS 08501 from CFT site is negligible.

3.4 Potential of Seed Dispersal During Transport

The applicant provided information that seeds of the regulated genetically modified cowpea event DPS 08501 will be packaged in a sealed plastic bag at least 500- gauge (0.125 mm) thickness (primary container), inside a sealed metal or plastic secondary container. The metal or plastic container shall be capable of protecting the seeds and preventing spillage or escape. The metal or plastic container will then be placed in an enclosed sturdy outer shipping container made of corrugated fiberboard, corrugated cardboard, or other material of equivalent strength. The primary packaging materials (plastic bag) will be destroyed by incineration on the trial site. Secondary containers (metal or plastic containers) will be cleaned by hand on the trial site and verified to be free of any residual plant material prior to removal from the trial site and return to CSIR-SARI Nyankpala research station.

The Board of the NBA considering the foregoing, concludes that seed dispersal of cowpea event DPS 08501 during transport is unlikely.

3.5 Potential of Pilfering of Seed from CFT Site

The applicant provided information that the trial site will be fenced to prevent the removal of plant material from the trial site. The trial site will have a continuous twenty-four-hour (24/7) security guarding regime to prevent unauthorized entry and to monitor for any breaches in the integrity of the security fencing. Additionally, staff will be trained to understand the need to confine the seed.

Considering the information provided by the applicant above, the Board of the NBA concludes that the potential of pilfering of seeds from CFT site is unlikely.

3.6 Potential of Harvest of CFT Materials for Food and Feed Use

The applicant stated that staff will be trained to understand the need to confine the seed. They also provided information that the trial site will be fenced and have a 24/7 security guarding regime to

prevent the removal of plant material or unauthorized entry, and to monitor for any breaches from the trial site. In addition, the Trial-in-Charge will be responsible for ensuring any required monitoring and for the disposition and/or storage of harvested material. All activity will be supervised and recorded in the Compliance Document Binder by the Trial Manager.

The Board of the NBA concludes that the potential of harvest of CFT materials for food and feed use is unlikely.

3.7 Potential of Impact on Non-Target Organisms

The applicant indicated that the protein mCry1Ca is not toxic to humans or non-target organisms. The expression of the mCry1Ca protein is constitutive. The amino acid sequence of mCry1Ca is 95 percent identical to the sequence of Cry1Ca from *Bacillus thuringiensis* subsp. *aizawai* (MacKenzie, 2024b), which is present in the Bt-derived commercial biological insecticide XenTari® GD (ABTS-1857) where it comprises 7–11% of the total insecticidal protein together with Cry1Aa (26–33%), Cry1Ab (57–60%), and Cry1Da (3–4%) (Caballero *et al.,* 2020).

Why Cry1 Protein targets only Lepidoptera Insect Species and not non-target organisms (NTOs)

Specificity of Cry1 Protein Action

Molecular Mechanism of Cry1 Protein:
The Cry1 protein, produced by Bacillus thuringiensis (Bt) and used in genetically modified (GM) crops, has a highly specific mode of action. This specificity is due to several key factors:

a. Receptor Binding:
Cry1 proteins bind to specific receptors found in the gut cells of susceptible insects. These receptors are unique to certain species within the Lepidoptera order (such as caterpillars and moths). When Cry1 proteins bind to these receptors, they form pores in the gut cell membranes, leading to cell lysis and the insect's death (Bravo *et al.,* 2007).

b. Alkaline Gut Environment:
The Cry1 protein is activated in the alkaline environment of the Lepidoptera insect gut. This alkaline environment is necessary for the Cry1 protein to change its conformation, allowing it to bind to the gut receptors. Most other organisms, including humans, have an acidic gut environment, which prevents this activation and binding process from occurring (Schnepf *et al.,* 1998).

c. Enzymatic Activation:
In the Lepidoptera gut, specific proteases cleave the Cry1 protoxin to produce the active toxin. These proteases are not present or are different in non-target organisms, including beneficial insects, mammals, birds, and aquatic organisms, which further limits the activity of Cry1 proteins to specific insect pests (Crickmore *et al.,* 1998).

Safety for Non-Target Organisms

i. Human Safety:

Human stomachs have a highly acidic environment (pH 1.5-3.5), which denatures proteins like Cry1, preventing their activation. Additionally, humans lack the specific gut receptors that Cry1 proteins target. Thus, Cry1 proteins pass through the human digestive system without causing harm (Betz *et al.,* 2000).

ii. Environmental Safety:

Extensive studies have been conducted to assess the impact of Cry1 proteins on non-target organisms. These studies consistently show that Cry1 proteins are highly specific to their target pests and do not adversely affect beneficial insects, birds, fish, and mammals. Regulatory agencies, such as the US EPA and EFSA, have reviewed these data and confirmed the safety of Bt crops for the environment (Romeis *et al.,* 2006).

From the above, Cry1 protein used in genetically modified insect-resistant crops is highly specific to certain species of the Lepidoptera order due to the presence of unique gut receptors, the alkaline gut environment necessary for activation, and specific proteases required for its activation. These factors ensure that Cry1 proteins do not affect non-target organisms, including humans, other animals, and beneficial insects. This specificity and the rigorous safety assessments conducted by regulatory bodies ensure the safe use of Cry1 protein in agriculture.

In addition, information by the applicant indicated that microbial formulations of *Bacillus thuringiensis (*Bt), like the commercial biological insecticide XenTari, have a long history of safe use, being first used in France in 1938 (CERA, 2011), and commercial formulations containing combinations of several Cry proteins have been registered in the United States since 1961 (Betz *et al.,* 2000; Schnepf *et al.,* 1998). In their history of widespread and continuous use over more than 50 years, Bt microbial pesticides have caused no known adverse human or environmental effects (EPA, 1998). The World Health Organization (WHO) International Program on Chemical Safety report on environmental health criteria for Bt concluded that: "Owing to their specific mode of action, Bt products are unlikely to pose any hazard to humans or other vertebrates" and "Bt has not been documented to cause any adverse effects on human health when present in drinking water or food" (IPCS, 1999). Bioinformatics analyses of the mCry1Ca amino acid sequence have shown no significant similarity to known allergens (MacKenzie, 2024a) or toxins (MacKenzie, 2024b) and there is, therefore, no expectation that transgenic events expressing this protein will pose a risk to health, environmental safety or potentially impact on non-target organisms.

Based on the information provided by the applicant, and additional information from TAC on the mechanism of cry1 protein on lepidopteran and not other non-target insects, the Board of the NBA concludes that the potential impact on non–target organisms is negligible.

4.0 Conclusion

In accordance with Section 21 of the Biosafety Act, 2011 (Act 831) the Board of the NBA has reviewed the application from CSIR-SARI to conduct a confined field trial at Nyankpala, Tamale on event DPS 08501 - cowpea (*vigna unguiculata* L. Walp.) genetically modified for resistance to Maruca Pod Borer (*Maruca vitrata*).

This review included a risk assessment that was carried out by the TAC in accordance with Section 28 sub-section (1) of the Act.

Based on the recommendations from TAC, and the information provided by the applicant the Board concludes that the confined field trial on the event DPS 08501 (Tracking Number: 2024-138-SARI-007-C) can be carried out safely at the approved site. The Board requires that the applicant, in carrying out the confined field trial, adheres to the Terms and Conditions specified in the schedule attached to this approval. The applicant is required to keep on file all documentation and records related to the trial. These documents should be available for inspection for at least seven (7) years following trial completion.

5.0 Decision

In light of the foregoing the Board of NBA, finds the proposed conduct of confined field trial of event DPS 08501 - Cowpea (*Vigna unguiculata* L. Walp.) genetically modified for resistance to Maruca Pod Borer (*Maruca vitrata*) could be carried out at the research station at Nyankpala.

The Board therefore grants approval for the confined field trial of the cowpea (*Vigna unguiculata* L. Walp.) for a three (3) year validity period effective 3rd June 2024, with subsequent renewals being administrative-based. Further to that, and in line with paragraph 3.4 the Board grants clearance for the importation of the seeds for the purposes of the research activity during the permit duration, subject to final approval from the Plant Protection and Regulatory Services Directorate of MOFA (PPRSD) based on the Plant and Fertilizer Act 2010 (Act 803).

Kindly note that this permission is not transferable. Failure to adhere to the conditions specified in the attached schedule shall result in the withdrawal of the approval for the confined field trial.

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ERIC AMANING OKOREE
CHIEF EXECUTIVE OFFICER

30th June, 2024
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Date

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PROF. YAO TETTEY
CHAIRMAN

3RD JUNE 2024
.....
Date

THE SCHEDULE TO THE APPROVAL FOR CONFINED FIELD TRIAL OF MARUCA RESISTANT COWPEA (EVENT DPS 08501) IN GHANA:

TRACKING NO: 2024-138-SARI-007-C

Terms and conditions for Confined Field Trial of Genetically Modified Cowpea in Ghana

Approval

Pursuant to Section 21 of the Biosafety Act, 2011 (Act 831), and on the basis of the information contained in the application 2024-138-SARI-007-C and the risk assessment report submitted by the TAC on the application, this approval is issued authorizing CSIR-SARI to undertake confined field trial of genetically cowpea resistant to Maruca pod borer *(maruca vitrata)* at the approved site at Nyankpala, near Tamale subject to the following terms and conditions.

1.0 Authorisation and Compliance

No genetically modified cowpea plant material can be removed from the trial site, transported, planted, or distributed without explicit authorization by NBA unless it is authorised under this permit. Failure to comply with the conditions of an authorized release is a contravention of Section 41 of the Biosafety Act, 2011 (Act 831), which attracts punitive action.

2.0 Packaging and Storage

2.1 All genetically modified cowpea plant material including seeds intended for transportation must be packaged in at least two secure containers to prevent spillage, dissemination, or infestation.

2.2 These packages must be clearly labelled with the inscription "GM material", dated and the name and contact details of the person responsible for the confined field trial and the confinement material.

2.3 GM cowpea plant material and seeds must be segregated and kept separately from non-GM cowpea to minimize mishandling or co-mingling.

3.0 Transportation

3.1 The transportation of genetically modified cowpea plant material must be done through the most direct and safe route including air transport if necessary.

3.2 Records of the dispatch and receipt of genetically modified cowpea plant material must be kept.

3.3 Records of seed quantities transported must be maintained and provided to NBA, when requested.

3.4 The CSIR-SARI is to liaise with the Ghana Revenue Authority, Customs Division (GRA-Customs), and Plant Protection and Regulatory Services Directorate (PPRSD) for advice on the importation and clearance of the seeds on arrival at the port of entry.

4.0 Reproductive Isolation

4.1 Reproductive isolation should be provided by border rows and an isolation distance. **One border row** should be planted with a mixture of conventional cowpea varieties (to ensure flowers are present while the test plants flower) and should be planted at the same or higher density than the test plants and treated with the same agronomic inputs to ensure healthy growth.

4.2 The border rows should be monitored weekly until the end of flowering to ensure sufficient growth and flowering to act as a pollen trap for foraging insects.

4.3 **An isolation distance of 10m outside** the border rows should be cleared of cowpea plants prior to planting.

4.4 The isolation distance should be monitored at least once every four weeks to identify and remove cowpea plants prior to flowering.

4.5 Should cowpea plants set seed in the isolation area before they are uprooted, the whole isolation area should be included in the post-harvest monitoring.

5.0 Preventing Dissemination of Plant Material

5.1 No plant material from these trials shall enter the human food or livestock feed chain. The trial site **should be secured to discourage foraging and pilfering**.

5.2 The site must be marked with signs indicating that the cowpea plants shall not be used for animal feed or food.

5.3 Seeding, planting, site maintenance, and harvesting equipment must be cleaned of all residual plant material at the trial site prior to being moved to other locations to prevent dispersal of genetically modified plant material.

5.4 All staff members must be trained to comply with the terms and conditions of this approval

and to understand why the materials cannot be used for food or feed at this stage in the research.

5.5 Personnel leaving the trial site must not carry any plant material with them unless it is authorized for transfer to a contained facility and is securely packaged and labelled and recorded appropriately in the log-book.

6.0 Trial Boundary Marking

6.1 In addition to physical barriers, markers should be placed at all corners of the trial site to identify the confined field trial boundaries. The markers (*e.g.*, flags, corner posts.) should be conspicuous, identifiable, and in place for both the trial seasons and the post-harvest restriction period.

7.0 Fertilizer and Pesticide Application

7.1 If fertilizer and pesticide are used on the trial site that requires a temporary prohibition on entry into the site, a sign must be posted at the access to the trial indicating the date and time of spraying as well as the re-entry period. This condition is intended to protect the health and safety of the inspection staff. The use of fertilizer and pesticide must comply with existing regulations i.e., Section 44, sub-section (1), (2), (3), (4), (5), and (6) of the Environmental Protection Agency Act, 1994 (Act 490) and the Plants and Fertilizer Act, 2010 (Act 803).

8.0 Harvesting and Seed Set

8.1 The trial may be terminated before the onset of flower development. If not, all seed and propagation materials, including non-modified control materials, must be destroyed on the site, unless authorized and NBA permission has been obtained to keep plant materials for further testing or seed for subsequent study or use in subsequent authorized planting(s) under CFT guidelines.

9.0 Disposal

9.1 All primary packaging materials for imported seeds must be destroyed by controlled burning to ashes.

9.2 All plant material harvested from the confined field trial that is not retained, must be destroyed by controlled burning to ashes or buried at a depth of at least one metre below the surface.

9.3 All non-modified seed and plant material harvested from trial sites must be considered genetically modified and destroyed on site.

10.0 Storage

10.1 All genetically modified cowpea seeds and planting materials retained from planting or harvesting must be stored in clearly labelled and secure containers (designed to minimize the potential for spillage, mixing, or dissemination) and kept separate from conventional seeds and plant materials. Appropriate records must be retained.

10.2 Each container of genetically modified cowpea planting material must be labelled with the inscription "Genetically modified- Do not use without authorization" and dated.

10.3 The storage area for genetically modified cowpea planting material must be labelled, including the contact details of the Principal Investigator responsible for the research.

10.4 In the event of any accidental spill, mixing or dissemination of material, corrective action must be initiated and documented immediately. This must be done in consultation with the biosafety officer / IBC while the National Biosafety Authority is notified by telephone immediately and in writing within 24 hours.

11.0 Post-Harvest Period

11.1 The post-harvest period may be delayed if repeat cowpea trials with the same events are run on the same site for subsequent seasons.

11.2 Upon completion of the trial, the site must be put under irrigation to induce germination of all volunteer cowpeas.

11.3 Post-harvest monitoring must continue once a week for at least 5 weeks, or until no cowpea volunteers have been identified for two consecutive weeks. During this period all cowpea volunteers must be recorded, uprooted, and destroyed.

11.4 All volunteer cowpea plants should be treated as genetically modified and destroyed on site by desiccation and controlled burning to ashes. If volunteers set flowers or seed before being uprooted the post-harvest monitoring period must be extended for another 5 weeks.

12.0 Monitoring

12.1 During the trial growing seasons, the isolation distance must be monitored weekly to ensure that all cowpea plants are removed before the seed set. Records must be kept of this in-season monitoring of the isolation area.

12.2 During the post-trial growing season, the trial site and the additional 5-metre zone must be monitored weekly (refer to section 11 on "Post-harvest period"). Records must be kept of the post-harvest monitoring of the trial site.

13.0 Unintended Release

13.1 In the case of unintended release of viable planting materials into the environment, recoverable seeds or seedlings must be collected, destroyed, and documented immediately in consultation with the biosafety officer / IBC. The National Biosafety Authority and the Environmental Protection Authority (EPA) must be notified by telephone immediately and in writing within 24 hours.

13.2 All cowpea plants at the release site must be destroyed as described in section 9 above. The release site must be marked and monitored weekly.

14.0 Records

14.1 A detailed trial logbook and a file must be kept. This book and file must contain the permit(s) and records of transport; storage; staff compliance training; planting; in-season crop treatments; border row and isolation area monitoring; early termination or harvest; equipment cleaning; retained materials; crop and seed destruction; post-harvest site management and monitoring; and unintended release management.

14.2 These records must be maintained by the applicant and be available for inspection for at least seven years after the end of the post-harvest period.

15.0 Reporting

15.1 The National Biosafety Authority must be notified in writing or by e-mail at least 10 days before planting and at least 10 days before harvesting each trial on the site.

15.2 A short trial report summarizing the biosafety aspects of the completed trial(s), including any approved amendments to the original confinement conditions, must be sent to the NBA not more than three weeks after the end of the post-harvest period.

16.0 Transferability

This approval shall not be transferred to any other institute, event, or location. It covers only the Institutional Biosafety Committee of CSIR-SARI and its operations at Nyankpala.