NATIONAL BIOSAFETY AUTHORITY

SUMMARY OF RISK ASSESSMENT REPORT ON THE APPLICATION FOR THE EVALUATION OF TRANSGENIC GYPSOPHILA PANICULATA (BABY'S BREATH) CONTAINING PAP-1 GENE FOR PINK FLOWER COLOUR STABILITY AT A CFT FACILITY AT BEAUTY LINE FARM, NAIVASHA, KENYA.

Background information

Introduction of the project, problem being solved by the genetic modification, objective (overall and specific), approach being employed to address the problem

The National Biosafety Authority received an application on 26th April 2013 from Kenya Agricultural Research Institute (KARI) to conduct a confined field trial on *Gypsophila paniculata* (Baby's breath) cut flower with PAP 1 gene event. The objective of the proposed CFT was to evaluate transgenic *Gypsophila paniculata* varieties for pink colour stability. The aim of the proposed work was to generate field biosafety data for the PAP 1 gene and evaluate the efficacy and stability of the inserted gene in terms of flower colour stability of transgenic Gypsophila varieties. The primary attribute that attract customers to buy flowers is colour. Flower crops with different colors are likely to draw more customers compared with those with one colour.

The most common commercial variety *G. paniculata* has predominantly white flowers and in rare cases there are varieties with light pink flowers whose colour stability depend on environmental conditions. In an effort to increase the range of flower colours in *Gypsophila*, Danziger, a Company incorporated in Israel, has developed new transgenic varieties with colours ranging from dark purple and red to light pink through introduction of Pap I gene, which regulates the production of phenylpropanoids, including anthocyanin pigments. The Pap I gene was derived from *Arapidopsis thaliana*.

The National Biosafety Authority (NBA) requires the generation of biosafety data to demonstrate their safety as a legal prerequisite for the introduction of these new transgenic Gypsophila cultivars for commercialization in Kenya. A confined field trial was conducted at Beauty Line Farm, Naivasha, where most cut-flowers are produced in Kenya, to satisfy this legal requirement.

This application was reviewed by three independent expert reviewers and another reviewed by

KEPHIS as the relevant regulatory agency as mandated by the Biosafety Act. Below is a summ ary of the risk assessment report.

Summary details of the application

Title of application: Evaluation of transgenic *gypsophila paniculata* (baby's breath) containing pap-1 gene for pink flower colour stability

Applicant: Kenya Agricultural Research Institute (KARI)

Collaborating Institutions: Danziger Ltd, Israel

Type of Application: Confined field trial

Location of Research: Beauty line farm Naivasha, Nakuru County, **(**1° 17'59.64"S, 36° 40' 51.78" E)

Parental Organism: *Gypsophila paniculata* (Baby's breath)

Trait being modified: Modified flower colour

Genetic modification method used: Agrobacterium mediated transformation

Risk Assessment Summary Table

No	Issues of concern	Potential adverse effects (Hazards)	Estimation of likelihood	Evaluation of identified risk/consequences	Risk management measures	Acceptable/ Manageable
1	Gene flow	Vertical gene transfer	Low	Crossing with neighbouring sexually compatible plants	• There are no known wild relatives of Gypsophila of the proposed CFT and its environs. It is native from Turkey, Ukraine and Iran. In areas with large scale production of Gypsophila including Kenya, Gypsophila has not been found growing wild, even in the immediate vicinity of Gypsophila growing areas where waste material has been discarded or has been left for composting. • Commercially grown Gypsophila is normally harvested at flower bud stage thus possibility of cross pollination with transgenic is minimal. • The applicant proposes an isolation distance of 350M (Section 4.4). During inspection visit of the facility, the company has undertaken to extend the isolation distance to 1.5KM. This mitigation is adequate to prevent out-crossing with other Gypsophila varieties. • 12 guard rows of non-transgenic gypsophila surrounding entire experimental plots will act as buffer zone.	Acceptable
		Horizontal gene transfer	Low	Transfer of genes to soil as micro-organisms	• There are no known reported instances of horizontal gene transfer from plants to bacteria in the soil in natural ecosystems (Nielson *et al.*, 1998)	Acceptable
				Antibiotic resistance	• The possibility of horizontal gene transfer between GM Gypsophila and bacteria in the mammalian gut is also considered as a rare event under natural conditions. In the current circumstance, Gypsophila is not used for consumption rather as an ornamental plant and therefore the risk is nil	Acceptable
2	Dispersal mechanisms	Escape or loss during import and transit	Low	Release into the environment	• The experimental material to be escorted from the port of entry to the trial site by NBA/ and KEPHIS inspectors	Acceptable
		Inadvertent loss of trial plant material from the trial site	Low	Unintended dispersal or movement of vegetative material	• Material is under confinement and chances of escape are low. Security will be provided 24/7 • Staff involved in the trial including security personnel will be trained on the rationale for biosafety containment of experimental materials. • Destruction and disposal of plant debris to be done on site except for experimental seeds which shall be monitored by NBA.	Acceptable
3	Persistence and weediness	Persistence	Low	Wild uncontrolled growth	• The applicant proposes to irrigate the field after harvest for two weeks and all volunteer plants will be monitored and destroyed before flowering for two months.	Acceptable
		Weediness/invasiveness	Low	Enhanced ecological fitness	• Though wild type Gypsophila have been reported to be invasive, cultivated gypsophila for cut flower production have not been reported as a weed. The introduced trait is unlikely to alter the weediness characteristics of the Gypsophila plant.	
4	Human/animal health	Adverse effects on human and animal health	Low	Toxicity	• Transgenic Gypsophila is designated for ornamental use only and is not intended for human or animal consumption as food or feed. ***If accidental consumption by animals occurs;***	Acceptable

				Allergenicity	• The vector is disarmed • Source of protein ie *Arapidopsis thaliana* is not toxic. The selectable marker gene *nptII* used for the constructs are safe and have been used successfully in other transformation work without any reported risks • Conventional single flower Gypsophila has been reported to possess saponin that causes allergens to some florists. Double flower Gypsophila has not been reported to possess any allergenicity properties. The introduced trait is unlikely to alter the allergenicity potential of Gypsophila.	
5	Stability of inserted gene	Gene instability	Unknown	Possibility of the colour pigmentation gene (PAP – gene) disintegration in subsequent generations	• This will be evaluated in the study as this is one of the objectives of this project.	Acceptable
6	Non target organisms	Effect on other organisms	Unknown	Mortality and/or effect growth characteristics	• This will be evaluated in the study. **NB:** The study should collect biosafety data on honey bees and flies which are the major pollinating agents.	Manageable

Overall conclusion on risk and risk management

It is noted that this application was for a confined field trial (CFT) and the research involves a non-food crop which minimizes the risk associated with food / feed pathways. The purpose of CFT is to collect data on biosafety and efficacy for use in the pursuit for future NBA approvals. This is considered to be a crucial research stage whose aim is to generate scientific findings whose data will inform the rationale for future commercial release of Gypsophila as a cut flower.

Based on the information submitted by the applicant in the application dossier, the review by the regulatory agency and the scientific opinions of the expert reviewers, along with the results of the NBA's internal technical review exercise, the application complies with the biosafety requirements laid down in the Kenyan Biosafety Act for the approval of the CFT research activity. The CFT facility has been inspected and meets the basic requirements for the CFT facility.

Decision

The application was approved with the following conditions.

Approval conditions

1. Applicant to obtain a plant import permit from KEPHIS and since the transgenic Gypsophila are to be imported from Israel, a schedule of importation should be prepared and availed to NBA and KEPHIS for monitoring purposes;

2. All cadres of staff to be involved in the trial need to be trained on handling transgenic plants and overall biosafety matters to ensure they understand biosafety requirements and their role in ensuring the achievement of biosafety;

3. A schedule of activities/detailed work plan to be provided to NBA and KEPHIS before commencement of the trial;

4. Put and implement measures to ensure that no plant material from the confined field trials may enter the human food or animal feed chain. All plant material except those taken out with NBA's Authority must be destroyed on site and records maintained;

5. Provide quarterly and annual progress reports to NBA;

6. Incorporate and collect biosafety data on pollinators of Gypsophila namely; bees and flies;

7. Notify the NBA and other relevant regulatory agencies of any changes to the experiment that might affect the risk status of the introduced material or those generated;

8. If the project proceeds to environmental release, appropriate Environmental Impact Assessment (EIA) approval certificate or exemptions must be obtained from National Environmental Management Authority (NEMA) prior to such release.

Approval details

Approval number: NBA/GMO/CO9/18/9

Approval Date: 9th December 2013

Duration of approval: 5 years (Renewable)

Approved by,

Prof. Dorington O. Ogoyi **Date: 18th April 2020**
Chief Executive Officer
National Biosafety Authority - Kenya