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**NATIONAL BIOSAFETY COMMITTEE OPINION ON AN APPLICATION BY CHI FARMS LTD FOR THE PLACING ON THE MARKET OF GENETICALLY MODIFIED SOYBEAN FOR FEED USES, IMPORT AND PROCESSING OF GM SOYBEANS CONTAINING EVENTS, MON 87705 (HERBICIDE-TOLERANT INCREASED OLEIC ACID) MON 87769-7 (TO CONTAIN STEARIDONIC ACID), BPS-CV127-9 (HERBICIDE-TOLERANT), DAS-44406-6 (HERBICIDE-TOLERANT)**

**Policy Framework**

* To ensure safety to human health and the environment taking into consideration food security

**General Assumptions and Monitoring plans for all products**

* The NBC in expressing these opinions has relied heavily on previous positive reviews of risk assessment for these products in the USA and Canada and especially from European Food Safety Authority (EFSA) as well as on the long history (more than 20 years) of safe use in the USA, Canada, South America, China, India, Europe and South Africa.
* The scientific assessment of this product included molecular characterization of the inserted DNA and expression of the new protein. A comparative analysis of agronomic traits and composition was undertaken and the safety of the newly expressed protein and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and the post-market environmental monitoring plan were undertaken.
* The monitoring plan and reporting intervals were in line with the intended uses. spillage during loading and offloading should be avoided and where spills accidentally occur, clean up measures should be instituted and such seeds destroyed in line with biosafety guidelines. adventitious sprouts should be removed by methods such as mechanical removal or herbicides application. Monitoring should be throughout the application period.

**MON 87705 (herbicide-tolerant increased oleic acid) Soybean**

Molecular Characterization

* Soybean MON 87705 was transformed using *Agrobacterium tumefaciens* (renamed as *Rhizobium radiobacter*) and expresses the CP4 *epsps* gene from *Agrobacterium* sp. CP4 coding for 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS), which renders MON 87705 tolerant to glyphosate-containing herbicides. Soybean MON 87705 also expresses fragments of the endogenous *FAD2-1A* and *FATB1-A* genes resulting, through RNA interference, in the decreased levels of fatty acid Δ12-desaturase (FAD2) and palmitoyl acyl carrier protein thioesterase (FATB) enzymes, and in turn an increased oleic acid phenotype.
* The molecular characterisation data establish that genetically modified soybean MON 87705 contains a single insert, consisting of the intact copies of the *FAD2-1A/FATB1-A* and CP4 *epsps* expression cassettes. No other parts of the plasmid used for transformation are present in the transformed plant.
* Results of the bioinformatic analysis of the 5′ and 3′ flanking sequences and ORFs within the insert and spanning the junction sites did not indicate a safety issue. The stability of the inserted DNA was confirmed over several generations and a Mendelian inheritance pattern was demonstrated. The expression of the genes introduced by genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated .
* The NBC is of the opinion that the observed compositional differences between soybean MON 87705 and its conventional counterpart in the light of the measured biological variation and the level of the studied compounds in soybean reference varieties, and concludes that soybean MON 87705 differs from the conventional counterpart and other non-GM soybean reference varieties only in the fatty acid profile and the newly expressed protein CP4 EPSPS, as intended.

**Compositional Analysis**

* Evidence from bioinformatics studies of the protein showed no homology to known toxic proteins and allergens. A subchronic 90- day feeding study in rats using diets including defatted meal derived from soybean MON 87705 provided no indications of adverse effects. Testing of extracts from soybean MON 87705 and the conventional counterpart A3525 with sera from patients allergic to soybeans showed that the allergenicity of the whole plant had not been changed due to the genetic modification. A feeding study in broiler chickens demonstrated that diets formulated with defatted meal from soybean MON 87705 are as nutritious as diets with defatted meal from the conventional counterpart and non-GM soybean reference varieties.
* The NBC is of the opinion that soybean MON 87705 is as safe as its conventional counterpart and non-GM soybean reference varieties in the context of the intended uses as proposed by the applicant. The altered fatty acid profile did not raise concerns regarding toxicity.

**Environmental effects: Post Market Monitoring**

* The application for soybean MON 87705 concerns food and feed uses, import and processing of soybean MON 87705 and all derived products, but excluding cultivation in Nigeria. There is therefore no requirement for scientific assessment of possible environmental effects associated with the cultivation of soybean MON 87705.
* Considering the scope of the application, not for cultivation, the NBC is of the opinion that the likelihood of the spread and establishment of soybean MON 87705 is very low and that unintended environmental effects due to this soybean will be no different from that of conventional soybean varieties.
* The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of soybean MON 87705. The monitoring plan provided by the applicant is in line with NBC guidance document and the Opinion of the NBC on post-market environmental monitoring.

**Conclusions**

* In conclusion, the NBC considers that GM soybean MON 87705 is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore, the NBC concludes that soybean MON 87705 is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses.

**MON 87769-7 (modified to contain stearidonic acid)**

**Molecular Characteristics**

* Soybean MON 87769 was developed using *Agrobacterium tumefaciens* transformation and was intended to modify the lipid profile of the extracted oil. Soybean MON 87769 contains a single insert consisting of the *Pj.D6D* gene encoding the Δ6 desaturase protein from *Primula juliae* and the *Nc.Fad3* gene encoding the Δ15 desaturase protein from *Neurospora crassa,* both involved in the desaturation of endogenous fatty acids into stearidonic acid.

**Compositional Analysis, Toxicity Allerginicity**

* A comparative analysis of soybean MON 87769 identified no phenotypic or agronomic differences with respect to its conventional counterpart (soybean A3525) and to non-GM soybean reference varieties. However, it confirmed that the composition of soybean MON 87769 differs from that of the conventional counterpart and non-GM soybean reference varieties. The newly expressed desaturases in soybean MON 87769 seeds resulted in an alteration of the fatty acid profile, leading to the appearance of four new fatty acids (stearidonic acid (SDA), -linolenic acid and two trans-fatty acids) and a reduction in linoleic acid (LA).
* The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly introduced desaturase proteins. There are no indications that the genetic modification might change the overall allergenicity of soybean MON 87769 when compared with that of its conventional counterpart.

**Feeding Studies; Horizontal Gene Transfer**

* The NBC is of the opinion that the estimated changes in fatty acid intake by consumers using oil from MON 87769 are unlikely to constitute a toxicological risk or to have negative nutritional consequences for humans.
* Based on the results of studies in rats, it is concluded that feeding stuffs derived from defatted soybean MON 87769 are as safe and nutritious as those derived from other non-GM soybean varieties.
* Potential interactions of soybean MON 87769 with the biotic and abiotic environment were not considered due to the low level of exposure. The monitoring plan and reporting intervals are in line with the intended uses of soybean MON 87769.
* The NBC considers that the soybean MON 87769, as described in this application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses.

**CV127 herbicide-tolerant soybean**

**Molecular Characterization**

* the transformation involved the use of embryonic axis tissue derived from the apical meristem of soybean seed of the commercial variety Conquista transformed by particle bombardment with a purified, linear DNA fragment derived from plasmid pAC3219 by digestion with *Pvu*II restriction endonuclease. The resulting *Pvu*II fragment contained the *ahasl* gene, which is a natural mutant allele (S653N) of the gene *ahasl* from *A. thaliana* that encodes acetohydroxyacid synthase (AHAS) large sub-unit. The AHAS enzyme catalyses the first step in the biosynthesis of branched-chain amino acids, and the enzyme encoded by the *ahasl* mutant allele retains the normal catalytic activity while preventing the binding of imidazolinone herbicides.
* The molecular characterisation data provided shows that the genetically modified soybean BPS-CV127 contains a single insertion. Rearrangements of the plant genome were shown at the insertion site; however, bioinformatic analysis of the insert and the 5′ and 3′ flanking regions did not reveal disruption of known genes or creation of ORFs that would raise a safety issue. The stability of the inserted DNA was confirmed over several generations and a Mendelian inheritance pattern was demonstrated. The NBC concludes that the molecular characterisation of soybean BPS-CV127 does not raise any safety issues.

**Compositional Analysis, Toxicity and Allergenicity**

* Bioinformatic analyses did not raise safety issues. No differences were identified in the seed composition that would require further assessment with regard to safety. Regarding agronomic and phenotypic characteristics, a difference in seed weight was identified; however, this difference does not affect the overall safety of this soybean. Although the NBC cannot conclude on its forage composition, soybean forage is not expected to be imported in significant amount for feed uses.
* Safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly expressed proteins or soybean CV127. Compositional data indicating that soybean CV127 is as nutritious as non-GM soybean varieties were supported by the outcome of a chicken feeding study.

**Horizontal gene transfer**

* There are no indications of an increased likelihood of spread and establishment of feral soybean BPS-CV127-9 plants, unless they are exposed to imidazolinone-containing herbicides.
* Risks associated with an unlikely, but theoretically possible, horizontal transfer of recombinant genes from soybean BPS-CV127-9 to bacteria have not been identified.
* Considering the scope of this application, interactions with the biotic and abiotic environment are not considered to be a relevant issue.
* The post-market environmental monitoring plan and reporting intervals are in line with the scope of this application.
* There is no risk caused by a possible transfer of the recombinant gene from soybean CV127 to environmental microorganisms.
* The NBC considers that soybean CV 127 is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses.

**DAS-44406-6 herbicide-tolerant soybean**

**Molecular Characterization**

* Soybean DAS-44406-6 was developed by Agrobacterium tumefaciens (also known as *Rhizobium radiobacter*)-mediated transformation of cotyledonary nodes derived from germinated soybean (G. max) cv. Maverick seeds. It expresses the AAD-12, 2mEPSPS and PAT proteins, which confer tolerance to 2,4-D, glyphosate-based and glufosinate ammonium-containing herbicides.
* The molecular characterisation data established that soybean DAS-44406-6 contains a single insert consisting of the 2mepsps, aad-12 and pat expression cassettes. No other parts of the plasmid used for transformation were detected in soybean DAS-44406-6.
* Bioinformatic analyses did not indicate significant similarities to toxins and allergens, and genetic stability was demonstrated. The levels of the newly expressed proteins present in soybean DAS-44406-6 were obtained and reported adequately.
* The results of the bioinformatic analyses of the insert and the flanking regions, and the levels of newly expressed protein did not raise a safety concern.

**Toxicity and Allergenicty: Non-target organisms**

* No differences in composition requiring further assessment for food/feed safety were found between soybean DAS-44406-6 and its conventional counterpart, except for a higher lectin activity (up to 31%) in soybean DAS-44406-6. The increase in lectin activity is unlikely to raise additional concerns for food/feed safety and nutrition for soybean DAS-44406-6 as compared to its conventional counterpart and the non-GM commercial varieties.
* The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly expressed 2mEPSPS, AAD-12 and PAT proteins in soybean DAS-44406-6 and found no evidence that the genetic modification might significantly change the overall allergenicity of soybean DAS-44406-6. The NBC concludes that soybean DAS-44406-6 is as safe and as nutritious as its conventional counterpart and the non-GM soybean reference varieties.
* In the case of accidental release into the environment of viable seeds of soybean DAS-44406-6, there are no indications of an increased likelihood of establishment and spread of occasional feral soybean DAS-44406-6 plants, unless these plants are exposed to the intended herbicides. The NBC is of the opinion that this will not result in different environmental impacts compared to conventional soybean. Considering the scope of this application, interactions with the biotic and abiotic environment are not considered to be relevant issues.

**Conclusion**

* The monitoring plan and reporting intervals are in line with the intended uses of soybean DAS-44406-6. The NBC considers that the soybean DAS-44406-6, as described in this application, is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of the intended uses.
* The potential interactions of the GM plant with target organisms, non-target organisms and the abiotic environment and biogeochemical cycles were not considered an issue by the NBC.

**OBSERVATIONS**

1. Importation of this GM-soybean can infringe on and discourage local production of soybeans;
2. This importation can impact negatively on the welfare of soybean farmers;
3. It will increase availability of soybean oil in the Nigerian market and make it more affordable for Nigerian citizens;
4. Nigeria may also become a hub for exporting soybean oil especially in the West African sub-region;
5. Appropriate preventive measures should be put in place to prevent accidental release of viable seeds into the environment;
6. In the implementation of the recommendations, strict compliance to NBMA’s regulatory framework on importation, transportation, handling and use should be adhered to;
7. The intended use of this application is for oil processing; it is not to be cultivated in Nigeria;
8. Further review of literature indicates that some abiotic factors such as temperature can affect the quality and nutritional value of these grains, hence it is pertinent that importers should have measures in place for testing the nutritional integrity of these grains if they are going to be on the shelf for a long time;
9. Future applicants should be required to indicate methods for testing pre-production raw material nutritional values; and
10. Terms and conditions set by NBMA should be strictly adhered to.

**Recommendations**

* The NBC having critically looked through the dossiers recommends to the National Biosafety Management Agency (NBMA), the approval of the application for importation of four (4) GM soybean events Soybean MON 87705, MON 87769, BPS-CV 127 and DAS 44406-6 **STRICTLY** for feeds production by CHI Farms LTD.