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# Background Information

1. AGBOOLA FARMS LIMITED’s application consisting of professional opinions on risk assessments of the following events of GM Soybean: MON 89788, MON 87701, Soybean 356043, A5547-127, MON 87708.

**2.1 Policy Framework**

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

* 1. **Assumptions and Monitoring plan for all products**

1. 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.
2. 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 manual or mechanical removal or herbicides application. Monitoring should be throughout the application period.

The panel has leaned heavily on the fact that these GM maize and

Soybean events have had a long history of safe use in many countries.

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| **Brief description of the molecular characterization, compositional analysis, toxicity and allergenicity, horizontal gene transfer and conclusion of examined soybean events.**  **Mon 89788 Herbicide Tolerant Soy**  **General Summary**  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.  Soybean MON89788 was transformed by *Agrobacterium tumefaciens*-mediated gene transfer technology. Soybean MON89788 expresses the codon-optimized *epsps* from *Agrobacterium sp.* strain CP4 encoding CP4 EPSPS that confers glyphosate tolerance to the plant.  **Molecular Characterization**  The molecular characterisation data established that a single insert with one copy of the intact *cp4 epsps* expression cassette is integrated in the soybean genomic DNA. Appropriate analyses of the integration site including sequence determination of the inserted DNA and flanking regions and bioinformatics analysis have been performed. Bioinformatics analysis of junction regions demonstrated the absence of any potential new ORFs coding for known toxins or allergens.  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 molecular characterisation of the DNA insert and flanking regions of soybean MON89788 does not raise any safety concern, and that sufficient evidence for the stability of the genetic modification was provided.  **Compositional Analysis**  The NBC compared the composition and agronomic characteristics of soybean MON89788 and its non-GM counterpart, assessed all statistical differences identified, and came to the conclusion that soybean MON89788 is compositionally equivalent to conventional soybean lines, except for the introduced transgenic trait.  The risk assessment included an analysis of data from analytical studies, bioinformatics, and *in vitro* and *in vivo* studies. The NBC concluded that the soybean MON89788 is as safe as its non-GM counterpart and that the overall allergenicity of the whole plant is not changed.  **Environmental Effects; Post Market Monitoring**  The application for soybean MON89788 concerns food and feed uses, import and processing of soybean MON89788 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 MON89788.  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 MON89788 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 MON89788. 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 MON89788 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 MON89788 is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses.  **4.2 MON 87701 Insect Resistant Soy**  **Molecular Characteristics**  This is an evaluation of a risk assessment of the genetically modified, insect resistant, soybean MON 87701 for food and feed uses, import and processing. Soybean MON 87701 was developed through *Agrobacterium*-mediated transformation.  It contains a single insert consisting of a *cry1Ac* expression cassette, encoding the Cry1Ac protein that confers resistance against specific lepidopteran insects. Bioinformatic analyses of the insert and its flanking regions, and levels of newly expressed protein did not raise safety concerns.  **Compositional Analysis; Toxicity and Allergenicity**  Comparative analyses of compositional, phenotypic and agronomic characteristics indicated that soybean MON 87701 is not different from its conventional counterpart (A5547) and equivalent to commercial soybean varieties, except for having increased vitamin E content (still within normal ranges) and expressing the Cry1Ac protein. The safety assessment of the Cry1Ac protein and soybean MON 87701 identified no concerns regarding potential toxicity and allergenicity.  **Feeding Studies; Horizontal Gene Transfer**  A feeding study on broiler chickens confirmed that defatted soybean MON 87701 meals is as nutritious as conventional defatted soybean meal. Considering its intended use as food and feed, environmental risks associated of an unlikely but theoretically possible horizontal gene transfer from soybean MON 87701 to bacteria have not been identified.  Potential interactions of soybean MON 87701 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 87701.  The NBC considers that the soybean MON 87701, 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.  **4.3 Soy 356043 Herbicide Tolerant Soy**  **Molecular Characterization**  This is an evaluation of a risk assessment for the genetically modified herbicide tolerant soybean 356043 for food and feed uses, import and processing.  This Soybean 356043 contains a single copy of intact *gat4601* and *Glycine max-hra* cassettes at a single insertion locus. The results of the bioinformatic analyses of the insert and the flanking regions, and the levels of newly expressed proteins did not raise a safety concern.  **Compositional Analysis; Toxicity and Allergenicity**  The comparative analysis of phenotypic and agronomic characteristics indicated that soybean 356043 is not different from its conventional counterpart.  In the composition, differences were identified between 356043 soybean and its conventional counterpart in the newly expressed proteins *Glycine max*-HRA and GAT4601, and the levels of the fatty acids heptadecanoic, heptadecenoic and heptadecadienoic acid and the acetylated amino acids N-acetylaspartate (NAA) and N-acetylglutamate (NAG).  The safety assessment of the newly expressed proteins *Glycine max*-HRA and GAT4601 identified no concerns regarding potential toxicity and allergenicity.  **Allergenicity and Health, Nutritional Analysis**  Heptadecanoic, heptadecenoic and heptadecadienoic acid are present in the diet and the intake of small amounts of these fatty acids via food or feed is not expected to produce adverse effects.  NAA and NAG are normal constituents in the mammalian metabolism and the estimated increases in their intake are considered low when related to the normal intake of L-aspartic acid and L-glutamic acid. Further toxicological, allerginicity and nutritional analysis provided no indications of adverse effects.  There is no risk caused by a possible transfer of the recombinant gene from soybean 356043 to environmental microorganisms.  The NBC considers that soybean 356043 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.  **4.4 Soy A5547-127 Herbicide Tolerance**  **Molecular Characterization**  This is an evaluation of a risk assessment for the genetically modified herbicide tolerant soybean A5547-127 for food and feed uses, import and processing. Soybean A5547-127 was developed through particle bombardment.  It contains a single insertion site consisting of a copy of the intact pat expression cassette, encoding the PAT protein that confers tolerance to glufosinateammonium containing herbicides. Other inserted sequences include two truncated parts of the betalactamase (bla) gene from the transformation vector on each side of the pat expression cassette.  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 Allergenicity; Non-target organisms**  The comparative analysis of compositional, phenotypic and agronomic characteristics indicated that soybean A5547-127 is not different from its conventional counterpart (A5547), except for the newly expressed protein (PAT). The safety assessment of the PAT protein and the soybean A5547-127 identified no concerns regarding potential toxicity and allergenicity. A feeding study on broiler chickens confirmed that seeds of soybean A5547-127 are as nutritional as seeds of the conventional counterpart.  The risk caused by a possible transfer of the recombinant gene from soybean A5547-127 to environmental micro-organisms is regarded to be negligible due to the lack of any advantage that would be conferred in the context of its intended uses.  **Conclusion**  The monitoring plan and reporting intervals are in line with the intended uses of soybean A5547-127. The NBC considers that the soybean A5547-127, 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.  **4.5 MON 87708 Herbicide Tolerant Soy**  **Molecular Characterization**  Soybean event MON 87708 was developed by Monsanto Canada Inc. using recombinant DNA technology, resulting in the introduction of the dicamba mono-oxygenase (dmo) gene derived from the Gram-negative bacteria *Stenotrophomonas maltophilia.*  Soybean MON 87708 contains a single insert consisting of the dmo expression cassette. The DMO (dicamba mono-oxygenase) proteins confer tolerance to dicamba-based herbicides. Bioinformatic analyses of the inserted DNA and flanking regions do not raise safety issues.  **Toxicity and Allergenicity; Compositional Analysis**  The levels of DMO proteins in soybean MON 87708 have been sufficiently analysed. The stability of the genetic modification has been demonstrated. No differences were identified in the compositional data of forage and seeds obtained from soybean MON 87708 or in its agronomic and phenotypic characteristics that would require further assessment with regard to safety by the NBC.  The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the DMO proteins, or of soybean MON 87708. The compositional data indicating that soybean MON 87708 is as nutritious as non-GM soybean varieties were supported by the outcome of a chicken study.  **Horizontal Gene Transfer and Monitoring Plan**  Considering the scope of this application, potential interactions of soybean MON 87708 with the biotic and abiotic environment were not considered to be an issue. Environmental risks associated with an unlikely but theoretically possible horizontal gene transfer from soybean MON 87708 to bacteria have not been identified.  The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of soybean MON 87708.  **Conclusion**   * In conclusion, the NBC considers that the soybean MON 87708, as described in this application, is as safe as its conventional counterpart and non-GM soybean reference varieties with respect to potential effects on human and animal health or the environment, in the context of its intended uses. |

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| Ethical ConsiderationsThe livestock industry in Nigeria is dependent on the availability of sufficient soybean for feed production.Until Nigerian farmers can produce enough soybean to feed the livestock feed industry, importation of soybean is imperative for the survival of livestock industry and thereby for foods security in Nigeria. |

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| 6.0 Recommendations |
| The NBC recommends the use of MON 89788, MON 87701, Soybean 356043, A5547-127, MON 87708 for import as food and feed. |

