# Recommendation Document

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| Recommendation of National Biosafety Committee (NBC) on:Applications FOR IMPORT/EXPORT OF GENETICALLY MODIFIED ORGANISMS FOR FOOD, FEED AND FOR PROCESSING. | |
| General information | |

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| Background information |
| The National Biosafety Committee (NBC) has received and reviewed the information supplied in   1. GOLDEN AGRI INPUTS LIMITED’s application consisting of professional opinions on risk assessments of the following events of GM Maize: T25, TC 1507, DAS 59122-7, MON 87427, MON 87460, 5307.   **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 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 maize events. |
| * 1. **T25 Herbicide Tolerant Maize**   **Molecular Characterization**  Insertion: Maize T25 contains a single insertion locus containing a *pat* cassette conferring tolerance to glufosinate-based herbicides.  Bioinformatic analyses, protein expression data and genetic stability studies did not raise safety issues.  **Compositional Analysis, Toxicity and Allergenicity**  The compositional, agronomic and phenotypic characteristics of maize T25 grain and its conventional counterpart showed no differences that are of relevance for food/feed safety.  The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly introduced PAT protein.  The compositional data indicating the nutritional equivalence of maize T25 were supported by the results of the feeding studies  There was no evidence that the genetic modification might significantly change the overall allergenicity of maize T25.  **Horizontal Gene Transfer**  Considering its intended uses as food and feed, interactions with the biotic and abiotic environment were not considered an issue  Risks associated with an unlikely but theoretically possible horizontal gene transfer from maize T25 to bacteria have not been identified.  **Conclusions**  The panel concluded that Maize T25 as described in the aapplication is as safe as its conventional counterpart with respect to potential effct on human health or the environment in the contect of its intended use for food and feed import and processing.   * 1. **Genetically Modified Maize TC1507 Insect Resistant and Herbicide Tolerant**   **General Summary**  1507 maize was assessed with reference to its intended use employing the appropriate principle. The scientific assessment included examination of the DNA inserted into the 1507 maize and the nature and safety of the target proteins produced by the transgenic plants with respect to toxicology and allergenicity. Furthermore, a comparative analysis of agronomic traits and composition was undertaken and the safety of the whole feed was evaluated. A nutritional and an environmental assessment, including monitoring plan, were both undertaken.  **Molecular analysis**  Molecular analysis showed that 1507 maize contains one copy of the DNA fragment used for transformation and that this is present at a single locus in the nuclear genome of the GM plant.  The complete DNA sequence of the insert was provided. In addition to the intact genes, the insert in 1507 maize includes DNA sequences originating from the fragment used for transformation as well as maize chloroplast and nuclear genome sequences at both ends of the inserted sequence.  While these sequences may have resulted from the transformation process (insertional events), there were no indications that these additional fragments would result in the transcription of new RNA other than the mRNAs transcribed from the *cry*1F and *pat* genes.  In the unlikely event that this does occur, bioinformatics analysis showed that any resulting peptides or proteins would have no homology to known toxins or allergens.  Analysis of DNA sequences flanking both ends of the insert shows that they correspond to maize genomic DNA.  **Compositional Analysis**  Analysis of kernel chemical composition from field trials in South America and Europe showed that 1507 maize was substantially equivalent to its non-GM comparator. Furthermore, appropriate animal feeding trials indicated that 1507 maize is nutritionally equivalent to its non- GM comparator.  1507 maize is comparable with maize bred traditionally, except for the expression of tolerance to glufosinate herbicide and certain lepidopterans. Maize does not colonise and rarely survives outside the cultivated environment.  Therefore, no unintended environmental effects due to the establishment and spread are anticipated.  **Non target Organisms and Conclusions**  The likelihood of adverse effects on non-target organisms or on soil functions due to the expression of the *cry* gene or the *pat* gene is considered to be very low.  In conclusion, the Panel considers that the information available for 1507 maize suggests that it will not have an adverse effect on human and animal health or the environment in the context of the proposed use.  **3.3 DAS-59122-7 Herbicide tolerant and insect resistant Genetically Modified Maize**  **General Summary**  The scientific evaluation of the risk assessment for this product included molecular characterisation of the inserted DNA and expression of target proteins. An evaluation of the comparative analyses of the composition and agronomic and phenotypic characteristics was undertaken, and the safety of the new proteins, both individually and in combination, and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional quality. An evaluation of environmental impacts and the post-market environmental monitoring plan was undertaken.    **Molecular Characterization**  The molecular characterisation data establish that maize 59122 contains a single insert of the T-DNA. No vector backbone sequences are present in the transformed plant.  Bioinformatic analyses of the open reading frames spanning the junction sites within the insert or between the insert and genomic DNA did not raise safety issues.  The levels of the Cry34Ab1, Cry35Ab1 and PAT proteins in various plant parts collected from field trials performed in Europe have been sufficiently analysed.  **Compositional Analysis; Toxicity**  Based on the results of compositional analysis of samples, theNBC concludes that kernels of maize 59122 are compositionally equivalent to those of conventional maize, except for the presence of Cry34Ab1/Cry35Ab1 and PAT proteins.  The Cry34Ab1/Cry35Ab1 proteins induced no adverse effects in acute and repeated dose oral toxicity studies in rodents. In addition, these proteins are rapidly degraded in simulated gastric fluid and inactivated during heat treatments i.e. they are not toxic.  **Nutritional Value**  A 90-day feeding study of rats fed a diet including kernels from maize 59122 at a level of 35 % indicated no adverse effects. A feeding study of broilers did not indicate differences in the nutritional value of maize 59122 versus the conventional comparator.  These animal studies support the findings of the compositional analysis and indicate no effect beyond the intended introduction of the Cry34Ab1/Cry35Ab1 and PAT proteins.  Diets formulated with 59122 were shown to be as nutritious as those formulated with commercial non-GM maize varieties.  The Panel concluded that maize 59122 is unlikely to have any adverse effect on human and animal health in the context of its intended uses.  **Environmental effects; Horizontal gene transfer**  The likelihood of unintended environmental effects due to the establishment, survival and spread of maize 59122 is considered to be extremely low, and will be no different from that of conventional maize varieties.  It is highly unlikely that the recombinant DNA will transfer and establish in the genome of bacteria in the environment or human and animal digestive tracts. In the rare but theoretically possible case of transfer of the *cry34Ab1*, *cry35Ab1* and *pat* genes from maize 59122 to soil bacteria, no novel property would be introduced into the soil bacterial community and thus no positive selective advantage that would not have been conferred by natural gene transfer between bacteria would be provided.  **Conclusions**  The NBC considers that maize 59122 is unlikely to have any adverse effect on the environment, except for the possible resistance evolution to the Cry34Ab1/Cry35Ab1 proteins in coleopteran target pests.  The NBC considers that maize 59122-7, as described in this application is as safe as its conventional counterpart and commercial maize varieties with respect to potential adverse effects on human and animal health.  **3.4 MON 87427**  **Molecular Characterization**  Maize MON 87427 was developed by *Agrobacterium tumefaciens*-mediated transformation to express the CP4 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS) protein, in all tissues except for the male reproductive tissues, conferring tissue-selective tolerance to glyphosate.  The molecular characterisation of maize MON 87427 did not give rise to safety issues. Agronomic and phenotypic characteristics as well as compositional data of maize MON 87427 did not raise food/feed and environmental safety concerns.  **Compositional Analysis; Toxicity and Allergenicity**  No differences in the compositional data requiring further safety assessment were identified.  There were no concerns regarding the potential toxicity and allergenicity of the newly expressed CP4 EPSPS protein.  The nutritional value of maize MON 87427 is not expected to differ from that of non-genetically modified (GM) maize varieties.  **Conclusions**  Risks associated with an unlikely, but theoretically possible, horizontal gene transfer from maize MON 87427 to bacteria have not been identified.  The Monitoring plan and reporting intervals are in line with the scope of the application for maize MON 87427  In conclusion, the NBC considers that MON 87427 is as safe as its conventional counterpart and non-GM reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of the application.  **3.5 Genetically Modified Drought Tolerant Maize MON 87460**  Maize MON 87460 was developed through *Agrobacterium*-mediated transformation and expresses the cold shock protein B (CspB) from *Bacillus subtilis* and neomycin phosphotransferase II (NPTII) from *Escherichia coli* to reduce yield loss under water-limited conditions.  Maize MON 87460 contains a single copy of the *csp*B and *npt*II expression cassettes. Bioinformatic analysis of the flanking sequences and the open reading frames spanning the junctions created by the transformation did not raise safety issues.  **Compositional Analysis**  Comparative analyses established that, besides the expression of the CspB and NPTII proteins, some differences were observed in the composition of grain produced from maize MON 87460 compared with its conventional counterpart, when grown under well-watered conditions.  Given the magnitude of these changes and the characteristics of these endpoints, the NBC Panel concluded that the observed differences do not raise safety concerns for humans and animals.  **Toxicity and Allergenicity**  Under stressful conditions, maize MON 87460 can show enhanced agronomic performance characteristics and some differences in chemical composition in comparison with its conventional counterpart. Given the intended trait, the observed differences were not unexpected, and did indicate no safety concerns.  The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the CspB and NPTII proteins or of maize MON 87460. Maize MON 87460 is as nutritious as any other maize and can be used in the same way.  **Environmental Effects**  In cases of spillage, there are no indications of increased likelihood of the establishment or survival of feral maize plants MON 87460.  Risks associated with a theoretically possible horizontal gene transfer from maize MON 87460 to bacteria have been analysed in detail, including different scenarios of integration, and did not raise safety concerns for the intended uses of maize MON 87460.  The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of maize MON 87460   * 1. **5307 Insect resistant maize**   Maize 5307 was developed by Agrobacterium tumefaciens-mediated transformation to express two proteins: eCry3.1Ab, conferring resistance to certain coleopteran pests, and phosphomannose isomerase (PMI), used as selection marker.  The molecular characterisation showed relevant similarities between the amino acid sequence of PMI and a known allergen, and between the amino acid sequence of eCry3.1Ab and a potential toxin.  **Compositional Analysis**  No differences in the compositional data requiring further safety assessment were identified. There were no concerns regarding the potential toxicity and allergenicity of the PMI protein.  28 day toxicity study in mice on the eCry3.1AB protein (1000 mg/kg body weight (bw) per day) did not show adverse effect.  Risks associated with the unlikely but theoretically possible horizontal gene transfer of recombinant genes from maize 5307 to bacteria were not identified.  The post-market environmental monitoring plan and reporting intervals are in line with the scope of the application.  **Conclusions**  The NBC concludes that Maize 5307 as assessed is as safe and nutritious as its conventional counterparts in the scope of this application.  Agronomic and phenotypic differences between Maize 5307 and its conventional counterparts were observed (higher heat unit to 50% pollen shed, grain moisture, plant height, grain yield); However the panel considered that these do not give rise to food/feed or environmental safety concerns. |
| Ethical ConsiderationsThe livestock industry in Nigeria is dependent on the availability of sufficient maize and soybean for feed production.Until Nigerian farmers can produce enough maize to feed the livestock feed industry, importation of maize is imperative for the survival of livestock industry and thereby for foods security in Nigeria. | |

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| 6.0 Recommendations |
| 1. The NBC recommends the use of T25, TC 1507, DAS 59122-7, MON 87427, MON 87460, 5307 for import as food and feed. |