



**REPORT OF THE NATIONAL BIOSAFETY COMMITTEE (NBC) ON THE
REVIEW MEETING FOR AUTHORIZATION OF GM MAIZE 3272,
MZIR098 AND SOYBEAN SYHT0H2 FOR FOOD, FEED AND FOR
PROCESSING, HELD AT DENIS HOTEL AND SUITES, ABUJA ON THE 9-
10TH DECEMBER, 2019**

In line with the National Biosafety Management Agency (NBMA) regulations, an ad-hoc National Biosafety Committee (NBC) was constituted by the DG/CEO, NBMA under the Chairmanship of Prof. Benjamin Ubi with the following under-listed members.

The Committee was mandated to review the submission of the National Biosafety Technical Subcommittee (NBTS) with the aim of advising the Agency on the merits and demerits of the application.

Applicant - SYNGENTA SOUTH AFRICA (PTY) LTD

Number of events reviewed - 3

S/N	Event	Observation	Comments
1	Soybean (SYHT0H2)	Herbicide tolerant	
	Source of Gene	The <i>avhppd-03</i> gene is sourced from seedlings of the common oat (<i>Avena sativa</i>) and the <i>pat</i> gene is the bacterial species <i>Streptomyces viridochromogenes</i> , strain Tü494. The AvHPPD protein confers tolerance to mesotrione while the PAT protein confers tolerance to glufosinate ammonium	
	Molecular Characterization	The <i>avhppd-03</i> coding region in the T-DNA is 1,320 bp in length and is driven by the constitutive promoter from <i>Cestrum yellow leaf curling virus</i> (CmYLCV), with enhancers from <i>Tobacco mosaic virus</i> (TMV), <i>Cauliflower mosaic virus</i> (CaMV) and <i>Figwort mosaic virus</i> (FMV). The coding region is terminated by a sequence from the 3' end of the <i>nopaline synthase (nos)</i> gene from <i>Agrobacterium</i>	

		<p>tumefaciens.</p> <p>The pat-03-01 gene is synthetic and was obtained from the company AgrEvo2. It is driven by the 35S constitutive promoter from CaMV and is terminated by the 3' end of the nos gene sequence. A two base pair difference was introduced into pat-03-01 to create pat-03-02. This change to pat-03-02 removed two restriction enzyme sites in order to facilitate the cloning process during construction of pSYN15954. The pat-03-02 gene is driven constitutively by a promoter region of CmYLCV with an enhancer from TMV. It is terminated by the 3' end of the nos gene sequence</p>	
	Food and Feed Safety Assessment	<p>Food and Feed product of SYHT0H2 are not known to be different from its conventional counterparts. The compositional analyses do not indicate any differences of biological significance between seed from soybean SYHT0H2 and the non-GM control 'Jack'.</p>	
	Toxicological and Nutritional Assessment	<p>The two (2) proteins (HPPD and PAT) are reported to have a history of safe use.</p> <p>The protein, p-hydroxyphenylpyruvate dioxygenase (AvHPPD-03) encoded by the <i>avhppd-03</i> gene from oat (<i>Avena sativa</i>) and PAT (phosphinothricin acetyltransferase) encoded by the <i>pat</i> gene have not been found to be associated with potential toxins based on bioinformatics analyses.</p> <p>The <i>PAT</i> enzymes are highly specific and do not possess the characteristics associated with food toxins or allergens, i.e. they have no sequence homology with any known allergens or toxins and they have no N-glycosylation sites. They are rapidly degraded in gastric and intestinal fluids.</p> <p>The HPPD proteins from oat or other species, have not been implicated in any food-related allergic reactions.</p> <p>SYHT0H2 is substantially equivalent to its conventional counterpart.</p>	<p>There is need for continuous assessment in case of presence of unintended novel proteins.</p>
	Contingency Plan	<p>The contingency plan as detailed in the dossier are adequate in line with the NBMA guidelines.</p>	
	Environmental Risk Assessment	<p><i>Streptomyces hygroscopicus</i> and <i>S. viridochromogenes</i> are common soil bacteria, therefore humans have a long history of exposure to the <i>PAT</i> protein through the consumption of roots and vegetables. Since 1995, humans have also been directly exposed to the <i>PAT</i> protein through the consumption of foods derived from GM glufosinate ammonium-tolerant canola, soybean, cotton and corn, without any evidence of toxicity.</p>	

		<p>The NBC was of the opinion that it is very unlikely that the <i>pat</i> and <i>AvHPPD</i> gene from SYHT0H2 (Soybean) would become transferred and established in the genome of micro-organisms in the environment of in the human and animal digestive tract.</p> <p>In the unlikely event of a horizontal gene transfer, no adverse effects on humans, animals and plants are expected as no new traits would be introduced into the environment.</p>	
	History of Safe Use	The event SYHT0H2 have been safely used in 15 countries including Japan, Taiwan, USA, China, Argentina, South Africa, Australia, Mexico, Columbia etc beginning from 2014 (from about 5 years ago) with no reported adverse effects.	

S/N	Event	Observation	Comments
2	Maize 3272		The Applicant is required to clarify whether it is maize 3272 or maize 3273.
	Source of Gene	<p>Maize 3272 expresses a thermotolerant alpha-amylase encoded by the <i>amy797E</i> gene, which is composed of DNA sequences from three (3) parental alpha-amylase genes (BD5031, BD5064 and BD5063) derived from thermophilic microorganisms of the order Thermococcales (class Thermococci; phylum Euryarchaeota; domain Archaea). BD5031 and BD5064 were derived from <i>Thermococcus</i> strains, while BD5063 is said to have been derived from either a <i>Pyrococcus</i> or <i>Thermococcus</i> species.</p> <p>The source of the selectable marker gene <i>pmi</i> which encodes a phosphomannose isomerase (PMI enzyme) is derived from <i>E. coli</i>.</p>	
	Molecular Characterization	<p>The chimeric <i>amy797E</i> gene was assembled from the parental sequences and its sequence has been codon-adapted to achieve a high level of expression in maize. The final AMY797E protein intended to be expressed in event 3272 maize is 460 amino acids long and carries the maize gamma-zein signal sequence as an N-terminal fusion and an endoplasmic reticulum (ER) retention signal as a C-terminal fusion</p> <p>The molecular characterisation data established that</p>	

		the GM maize 3272 contains a single insert consisting of the amy797E and the <i>pmi</i> cassettes.	
	Food and Feed Safety Assessment	In relation to the allergenic potentials of AMY797E protein, the GMO panel concluded that the information provided does not completely address its previous concern(EFSA GMOpanel,2013)in the context of a full scope application. Owing to the nature and the knowledge available on this protein family (or functional class of enzymes). It is still unclear whether under specific circumstances the alpha amylase AMY797E has the capacity to sensitise certain individuals and to cause adverse effects. However, bioinformatic analyses and genetic stability studies of the expressed proteins (amy797E and the selectable marker gene PMI) did not raise safety issues.	It is required that the Applicant specifies the intended purpose of use in order to allow the NBMA to determine the safety for food, feed and processing.
	Toxicological and Nutritional Assessment	The two (2) proteins (AMY797E and PMI) encoded by the inserted genes in this event are reported to have a history of safe use. The encoded proteins have not been found to be associated with potential toxins based on bioinformatics analyses. The maize event 3272 is substantially equivalent in nutritional composition to its conventional counterpart.	
	Contingency Plan	The contingency plan as detailed in the dossier are adequate in line with the NBMA guidelines	
	Environmental Risk Assessment	In relation with plant to plant gene transfer, maize 3272, has no altered survival, multiplication or dissemination characteristics. Risks associated with a theoretically possible horizontal gene transfer from maize 3272 to prokaryotes (i.e. bacteria, Archaea) have been analysed and did not raise safety concerns. The likelihood of unintended environmental effects due to its establishment and spread will not be different from that of conventional maize varieties. Based on the report of EFSA GMO Panel, there is little likelihood of any adverse environmental impacts occasioned by the accidental release into the environment of viable grains from maize 3272. Considering its intended uses as food and feed, interactions with the biotic and abiotic environment were not considered to be an issue. The potential exposure to the environment including humans and animals of maize 3272 (in case of its use as feed) would be mainly through ingestion by animals, and their manure and faeces leading to exposure of gastrointestinal tract and soil	

		microorganisms, and with the accidental release into the environment of viable maize 3272 grains during transport and/or processing.	
	History of Safe Use	The event maize 3272 has been safely used for food, feed and processing (and even cultivation) in about 16 countries including the USA, Japan, Canada, Brazil, Singapore, etc. beginning from 2007 with no reported adverse effects	

S/N	Event	Observation	Comments
3	Maize MZIR098	For Insect-Resistant and Herbicide-Tolerant	
	Source of Gene	Codon-optimized genes <i>ecry3.1Ab</i> and <i>mcry3A</i> from <i>Bacillus thuringiensis</i> and <i>pat-08</i> from <i>Streptomyces viridochromogenes</i>	
	Molecular Characterization	Genetic characterization studies demonstrated that MZIR098 corn contains, at a single locus within the corn genome, a single copy of each of the following functional elements: <i>ecry3.1Ab</i> , <i>mcry3A</i> , <i>pat-08</i> , NOS-02 enhancer, CMP-04 promoter, <i>Ubi1-18</i> promoter, NOS-20 terminator, and 35S-04 promoter and two copies of the NOS-05-01 terminator, as expected. It does not contain any extraneous DNA fragments of these functional elements elsewhere in the MZIR098 corn genome, and it does not contain backbone sequence from transformation plasmid pSYN17629.	
	Food and Feed Safety Assessment	<p>The safety of <i>eCry3.1Ab</i> in existing commercial transgenic crop products is supported by a permanent exemption from food and feed tolerances in corn in the U.S. Insecticidal Cry proteins from <i>B. thuringiensis</i> have a long history of safe use in food crops. There are no scientific reports of concern about <i>eCry3.1Ab</i> as it exists in commercially available transgenic food crops. It is concluded that <i>eCry3.1Ab</i> does not pose a risk to the health of humans or livestock through consumption of MZIR098 corn</p> <p>The <i>mCry3A</i> protein produced in MZIR098 corn has been well characterized and no safety concerns have been identified. There are no scientific reports of concern about <i>mCry3A</i> as it exists in commercially available MIR604 corn and breeding stacks thereof. It has been concluded based on several molecular studies and bioinformatics analyses that <i>mCry3A</i> does not pose a risk to the health of humans or livestock through consumption of MZIR098 corn.</p> <p>The PAT protein produced in MZIR098 corn has</p>	

		been well characterized and no safety concerns have been identified. PAT has a very specific and well characterized mode of action; it is not acutely toxic, and it has no characteristics consistent with potential allergenicity. It was therefore concluded from several molecular studies and bioinformatics analyses that PAT does not pose a risk to the health of humans or livestock through consumption of MZIR098 corn.	
	Toxicological and Nutritional Assessment	The three (3) proteins (eCry3-1Ab, mCry3A and PAT) encoded by the inserted genes in this event are reported to have a history of safe use. The encoded proteins have not been found to be associated with potential toxins based on bioinformatics analyses. The 2 modified cry genes which are derived from the native gene of <i>Bacillus thuringensis</i> are known to pose no safety concerns. The PAT enzymes are highly specific and do not possess the characteristics associated with food toxins or allergens, i.e. they have no sequence homology with any known allergens or toxins and they have no N-glycosylation sites. They are rapidly degraded in gastric and intestinal fluids. The maize event MZIR098 is substantially equivalent in nutritional composition to its conventional counterpart.	
	Contingency Plan	The contingency plan as detailed in the dossier are adequate in line with the NBMA guidelines.	
	Environmental Risk Assessment	In relation with plant to plant gene transfer, MZIR098, has no altered survival, multiplication or dissemination characteristics. The likelihood of unintended environmental effects due to its establishment and spread will not be different from that of conventional maize varieties.	
	History of Safe Use	The event MZIR098 has been safely used for food, feed and processing in more than 20 countries including the European Union beginning from 2015 (from about 4 years ago) with no reported adverse effects	

OBSERVATION

1. There is need for continuous assessment in case of presence of unintended novel proteins
2. For GM maize 3272, It is required that the Applicant specifies the intended purpose of use in order to allow the NBMA to determine the safety for food, feed and processing

RECOMMENDATION

The NBC having critically looked through the dossiers submitted and relying on the recommendation of the National Biosafety Technical Sub-committee (NBTS) recommends to the National Biosafety Management Agency (NBMA) the approval of the authorization of Syngenta Soybean SYHT0H2, Maize 3273 and MZ1R098 for food, feed and processing under the NBMA terms and conditions

NBC Members

S/N	Name	Phone	e-mail
1	Prof. Benjamin Ubi	08064949470	Ubi.benjamin1@yahoo.com
2	Prof. P.C. Onyenekwe	08036347293	pconyenekwe@yahoo.com
3	Ukpoju, Sam Adam	08065701244	samukpoju@gmail.com
4	Prof. P.O. Anyaegbu	08033703511	anyaegbupoly@yahoo.com
5	Loko E. Veronica	07062178114	dverala@gmail.com
6	Fatimah O. Ojo	08065374321	Fatimah.ojo@cpc.gov.ng
7	Rasheed A.H.	08161132475	Amiimirasheed89@gmail.com
8	Raheem Rasheed A.	08065545220	raheemomolawole@gmail.com
9	Azosiri Chioma E.	07062444172	azosirichioma@yahoo.com
10	Anthony O. Abah Esq.	07038643848	gudtony@yahoo.com
11	Barr. Princess Frank-Chukwuam	08037035359	Princessfranchesca4@yahoo.com
12	Maymuna L. Idris	08033498698	maymunahidris@yahoo.com
13	Dr. Barth Ugwu	08037238499	ugwubato@yahoo.com