

MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER THE GMO ACT, 1997 HELD ON 02 MARCH 2021, MICROSOFT TEAMS

PRESENT

Dr J Jaffha (Chairperson)
 Mr B Durham
 Ms N Tshidada
 Prof G Bouwer
 Dr M Jugmohan-Naidu
 Dr N Netnou-Nkoana
 Ms T Ndukwana
 Dr M Matlala
 Ms T Masilela
 Ms P Campbell
 Dr A Sigobodhla
APOLOGIES
 Ms J Mhlophe

Department of Agriculture, Land Reform and Rural Development (DALRRD)
 Department of Science and Innovation (DSI)
 Department of Environment, Forestry and Fisheries (DEFF)
 Chairperson of the Advisory Committee (AC) under the GMO Act, 1997
 Department of Science and Innovation (DSI)
 Department of Agriculture, Land Reform and Rural Development (DALRRD)
 Department of Trade, Industry and Competition (**the dtic**)
 Department of Water & Sanitation (DWS)
 Department of Water & Sanitation (DWS)
 Department of Health (DoH)
 Department of Health (DoH)

Department of Employment and Labour (DEL)

IN ATTENDANCE

Ms A Madzivhandila
 Ms T Mogapi
 Ms M Hialele
 Ms R Ngoepe
 Mr S Mokhothu
 Ms B Mahlangu
 Ms N.L. Mkhonza

Department of Health (DoH)
 Department of Environment, Forestry and Fisheries (DEFF)
 Department of Environment, Forestry and Fisheries (DEFF)
 Department of Agriculture, Land Reform and Rural Development (DALRRD)
 Department of Agriculture, Land Reform and Rural Development (DALRRD)
 Department of Agriculture, Land Reform and Rural Development (DALRRD)
 Department of Agriculture, Land Reform and Rural Development (DALRRD)

NO.	SUBJECT	FOR ATTENTION
1.	OPENING AND WELCOME The Chairperson welcomed those present at the EC meeting.	EC Chairperson
2.	ATTENDANCE REGISTER AND APOLOGIES The OoR noted the attendance since this was a virtual meeting.	EC Chairperson
3.	ADDITIONS TO AND ADOPTION OF THE AGENDA The agenda was adopted with no additions.	All
4.	APPROVAL OF THE RECORD OF PROCEEDINGS OF 10 NOVEMBER 2020 The record of proceedings of 10 November 2020 was approved with amendments.	All
5.	MATTERS ARISING FROM	

MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER THE GMO ACT, 1997 HELD ON 02 MARCH 2021, MICROSOFT TEAMS

	THE PROCEEDINGS	EC
5.1	Feedback Interview: vacancy in the Advisory Committee (EC Chairperson)	<p>(i) The EC Chairperson reminded the EC that on 02 December 2020, four candidates were interviewed for the two Advisory Committee vacancies. The interview panel members were the DWS, DSI as well as the EC and AC Chairpersons.</p> <p>(ii) The EC Chairperson informed the EC that two candidates were recommended for appointment to the AC and the other candidates were recommended for inclusion in the AC subcommittee</p> <p>(iii) The EC noted and deliberated on the recommendation by the interview panel.</p> <p>(iv) In conclusion:</p> <ul style="list-style-type: none"> • The EC supported the recommendation for appointment of the two candidates to the AC, as well as the appointment of the other candidates to the AC subcommittee. • The OoR will draft a submission for the appointment of AC members by the Minister. • The OoR will communicate EC's recommendation to the candidates that have been recommended for appointment to the AC subcommittee and also request confirmation of their availability in this regard.
5.2	Legal opinion for gene therapy (OoR)	<p>(i) The EC Chairperson reminded the EC that at the November 2020 meeting the EC considered a notification for an early termination of a trial release for a gene therapy event FLT180a that was approved by EC in 2019. During deliberations the DoH was of the view that gene therapy falls outside the scope of the GMO Act. It was then concluded that a legal opinion should be requested to clarify whether gene therapy applications should be considered under the GMO Act even if the source material/vector is a GMO.</p> <p>(ii) The OoR informed the EC that section 2(1)(c) of the GMO Act states that the Act shall apply to the use of gene therapy and section 2(2)(a) states that the Act shall not apply to techniques involving human gene therapy.</p>

MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER THE GMO ACT, 1997 HELD ON 02 MARCH 2021, MICROSOFT TEAMS

5.3	Draft concept note: Insect Resistance Management	<p>(iii) The OoR informed the EC that based on section 2 of the Act; it is not quite clear what the legal question should be and requested the DoH to assist in formulating a legal question for this matter.</p> <p>(iv) The EC deliberated and it was concluded that the EC Chairperson will draft a legal question and circulate to the DoH for further inputs.</p> <p>(i) The EC Chairperson reminded the EC that at the November 2020 meeting the EC had deliberated on Insect Resistance Management (IRM) and concluded that the AC Chairperson should draft a concept note clarifying the IRM problem.</p> <p>(ii) The concept note on IRM was circulated to the EC for discussion at this March 2021 meeting. The AC Chairperson provided an overview of the concept note.</p> <p>(iii) The EC deliberated and concluded that they will provide further inputs/comments on the IRM concept note by 10 March 2021.</p>	EC Chairperson/DoH
5.4	Update: AC NBT workshop	<p>(i) The EC Chairperson reminded the EC that at the November 2020 meeting there was an indication that the AC will conclude the NBT work by the end of 2020 or early 2021.</p> <p>(ii) The AC Chairperson informed the EC that the AC concluded the NBT work at a third workshop held in February 2021. The AC Chairperson gave an overview on the approach followed by the AC.</p> <p>(iii) The EC deliberated and concluded that:</p> <ul style="list-style-type: none"> • The EC will provide further inputs/comments by 19 March 2021. • The OoR will consolidate the comments from the EC and circulate to EC and the EC will determine: <ul style="list-style-type: none"> (a) If there's a need to further engage the AC on this matter. (b) A way forward regarding stakeholder engagement. • There would be an EC report upon conclusion of the NBT work by the EC. 	EC Chairperson AC Chairperson
5.5	Feedback: Socio-economic workshop (DSI)	The DSI informed the EC that on 11 November 2020 the DSI hosted a virtual workshop on national testing of the socio-economics guidance focusing on the principles behind the socio economics assessment. The DSI will provide a workshop report in the next EC meeting.	EC Chairperson DSI

MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER THE GMO ACT, 1997 HELD ON 02 MARCH 2021, MICROSOFT TEAMS

<p>6.</p>	<p>Compliance/Non-compliance</p>	<p>a. <u>Inspections</u> The OoR informed the EC that 16 post-plant and 03 pre-flowering inspections were conducted in January 2021. A summary of the annual report assessment was circulated to EC.</p> <p>b. <u>Annual Reports</u> The OoR informed the EC that no annual reports were received in February 2021.</p> <p>c. <u>AMGEN notification: Termination of trial for T-VEC (Talimogene laherparepvec)</u> The OoR informed the EC that a notification for an early termination of a trial release for T-VEC was submitted by AMGEN. AMGEN indicated that the early termination was based on the review conducted by an external Data Monitoring Committee (DMC), which showed that the efficacy of T-VEC was not statistically significant.</p> <p>d. <u>Request by BASF to transfer permit to Syngenta</u> (i) The OoR informed the EC that a request to transfer the commodity clearance permit for FG72 soybean under BASF (Pty) Ltd into the name of Syngenta was submitted by BASF in December 2020. The OoR had then requested a written proof, e.g. board resolution, showing that the regulatory affairs manager was authorized to bind the company in this type of matter. BASF subsequently submitted an agreement signed by BASF's Vice President: Regulatory and Stewardships Seeds and Traits and MS Tech/Syngenta's President confirming a transfer of FG72 soybean from BASF to Syngenta.</p> <p>(ii) The EC noted the signed transfer agreement, and based on the confirmation received from BASF, the EC approved that the BASF permit can be reissued under Syngenta's name. The OoR will reissue the permit.</p>	<p>OoR</p> <p>EC</p> <p>EC/OoR</p>
-----------	----------------------------------	--	------------------------------------

MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER THE GMO ACT, 1997 HELD ON 02 MARCH 2021, MICROSOFT TEAMS

		e. <u>Request by Sensako to use imported Soybean seeds in a contained use</u>	
		(i) The OoR informed the EC that a request to use imported soybeans seeds in a contained use was submitted by Sensako on 09 November 2020. Sensako obtained an import and trial release for HB4 soybean in October 2020; however the trial release was not planted due to a late arrival of imported seeds. Sensako is in a process of submitting the contained use and trial extension applications	OoR
		(ii) The EC deliberated and approved Sensako's request subject to submission of an application for contained use.	EC
7.	APPLICATIONS TO BE CONSIDERED BY EC (REGISTRAR)		Registrar
	Time extensions, amendments to (existing) permits, import and exports	None	
	New applications		
	Commodity clearance		
7.1	BASF - 20/005: Commodity clearance for GHB811 cotton	The EC approved the BASF - 20/005: Commodity clearance application for GHB811 cotton.	EC
7.2	BASF - 20/006: Commodity clearance for GMB151 soybean	The EC approved the BASF - 20/006: Commodity clearance application for GMB151 soybean.	EC
	General Release		
7.3	Bayer - 20/127: General release for MON87701 x MON89788 soybean	The EC's decision on the Bayer - 20/127: General release application for MON87701 x MON89788 soybean is pending submission of additional information by the applicant.	EC
7.4	Syngenta - 20/171: General release for Bt11xMIR162xMON89034xG A21 maize	The EC's decision on the Syngenta - 20/171: General release application for Bt11xMIR162xMON89034xGA21 maize is pending submission of additional information by the applicant.	EC

MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER THE GMO ACT, 1997 HELD ON 02 MARCH 2021, MICROSOFT TEAMS

7.5	Intervet – 20/004: General release for Innovax ND-ILT vaccine Trial release and import and/or export	The EC approved the Intervet – 20/004: General release application for Innovax ND-ILT vaccine subject to submission of additional information by the applicant and Act 36 approval.	EC
7.6	Pioneer - 20/1370: Import and trial release of maize MON89034xDAS-40278-9 (applicant's responses to EC's questions)	The EC's decision on the Pioneer - 20/1370: Import and trial release application for maize MON89034xDAS-40278-9 is pending submission of additional information by the applicant.	EC
7.7	Pioneer - 20/1371: Import and trial release for maize TC1507xNK603 (applicant's responses to EC's questions)	The EC's decision on the Pioneer - 20/1371: Import and trial release application for maize TC1507xNK603 is pending submission of additional information by the applicant.	EC
	Contained use and import and/or export	None	
8.	Applications considered by EC in December 2020 and January 2021 (intersessional)		
	<u>Contained use</u> 8.1 ASPEN - 20/001 import and contained use of application of AD26.COVS.2 vaccine	The EC noted that EC's decision for the four applications reviewed during the intersessional period (December 2020 and January 2021) was as follows: <ul style="list-style-type: none"> • Aspen-20/001 import and contained use application of AD26.COVS.2 vaccine was approved. • Decision on Bayer-20/118 import and trial release for maize MON87427 x MON89034 x MIR162 is pending submission of additional information. • Biovac-20/002 import and trial release of hAd5-S-Fusion + N-ETSD vaccine was approved subject to submission of SAHPRA's approval. 	EC
	<u>Trial release and import and/or</u>		

MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER THE GMO ACT, 1997 HELD ON 02 MARCH 2021, MICROSOFT TEAMS

	<p><u>export</u> 8.2 Bayer - 20/118: Import and trial release for maize MON87427 x MON89034 x MIR162 8.3 Biovac - 20/002: Import and trial release of hAd5-S-Fusion + N-ETSD vaccine General release 8.4 Biovac-21/003: General release for ChAdOx1 nCoV-19 vaccine</p>	<ul style="list-style-type: none"> Biovac-21/003 general release for ChAdOx1 nCoV-19 vaccine was approved subject to submission of SAHPRA's approval. 	
9	Standing matters		
9.1	Regulatory and policy developments (All)	None	
9.2	Cartagena Protocol (All)	The DEFF informed the EC that the CBD Secretariat convened an informal session of SBS TTA -24 and SBI-3 from 17 to 25 February 2021.	DEFF
10.	General		
11.	Date of the next meeting	The EC noted that the date of the next EC meeting is scheduled for 04 May 2021. The EC meeting is likely to be a virtual meeting via MS teams.	All
12.	Closure	The meeting was concluded at 12:25.	All

Approved by Chairperson
Dr. J Jaffha


.....
Signature

Approved by Registrar
Ms NL Mkhonza


.....
Signature