

**MINUTES OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER GMO ACT, 1997 HELD ON
12 MAY 2009, HARVEST HOUSE, ROOM 332, PRETORIA**

PRESENT

Dr J Jaffha (Chairperson)
Mr B Durham
Dr G Bouwer
Ms W P Mandivenyi
Mr A Pretorius
Ms E Koekemoer

Department of Agriculture (DoA)
Department of Science and Technology (DST)
Chairperson of the Advisory Committee (AC) under the GMO Act, 1997
Department of Environmental Affairs and Tourism (DEAT)
Department of Health (DoH)
Department of Trade and Industry (DTI)

VACANT

Representative

Department of Labour (DoL)

IN ATTENDANCE

Ms C Arendse
Ms G Christians
Ms E Jantjies
Ms R Ngoepe
Ms R Chanda
Mr S Mokhothu
Ms L Segooa
Ms P Kershaw

Department of Agriculture
Department of Agriculture
Department of Agriculture
Department of Agriculture (secretariat)
Department of Health
Department of Agriculture
Department of Science and Technology
Department of Environmental Affairs and Tourism

NO.	SUBJECT	RESOLUTION	FOR ATTENTION
1.	OPENING AND WELCOME	The Chairperson welcomed those present and suggested that the Council goes through the minutes of the EC meeting held on 03 March 2009 while waiting for one other member.	
2.	ATTENDANCE REGISTER AND APOLOGIES	The attendance register was circulated to everyone present for signature.	
3.	ADDITIONS TO AND	The agenda was adopted with the following additions:	

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	ADOPTION OF THE AGENDA	6.4 ARC: VOPI -08/039: General release potato, SpuntaG2	
4.	APPROVAL OF THE RECORD OF PROCEEDINGS OF 03 MARCH 2009	The record of proceedings of the meeting of 03 March 2009 were amended and approved with the following alterations:- 5.3 (i) the dti instead of DTI 5.4 (ii) at AC level not on AC level 6.2 DoH: Recommended subject to approval in terms of section 21 of the Medicines and Related substances Act 101, 1965. 7.6 (TIA) Technology Innovation Agency not TIER innovation centres	
5.	MATTERS ARISING FROM THE PROCEEDINGS		

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	Feedback from permit holders in terms of the risk management measures and plans	<p>(iv) The EC noted that all applicants (Monsanto, Bayer, Dow Agro Sciences, Pioneer and Syngenta) have submitted their responses to the request for risk management plans, which have been sent to the EC.</p> <p>(v) The EC noted that with regard to amendment of existing commodity clearance permits: the permit conditions may be amended at any given time if the need arises.</p> <p>(vi) The EC noted that the users should be limited to millers to facilitate that consignments are directly transported to the mill for processing.</p> <p>(vii) The EC indicated that the applicants must already have the buyers when the application is submitted.</p> <p>(viii) The EC suggested that the OoR facilitate a visit to the Durban and PE port in order to gauge the capacity of storage and milling facilities at these ports.</p>	OoR OoR OoR
5.4	Appointment of AC members	(i) The EC noted that additional interviews were conducted with nominated AC subcommittee members	OoR
5.5 5.6	<p>Syngenta – 08/096: Commodity clearance of maize MIR604xGA21 (Registrar) AND</p> <p>Syngenta – 08/097: Commodity clearance of triple stacked Maize Bt11xMIR604xGA21 (Registrar) AND</p>	(i) The EC noted that a report from an allergen expert regarding all four applications was received with additional questions and these have been forwarded to the applicant and that a response has not yet been received from the applicant.	OoR

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NO.	SUBJECT	RESOLUTION	FOR ATTENTION
5.7	Pioneer 08/336: Commodity clearance – Soybean 356043 (Registrar) AND Pioneer 08/340: Commodity clearance – Soybean 305423 (registrar)		
5.8	Monsanto 08/470: Trial Release of GM maize event MON89034 and stacked event MON89034 x NK603	(i) The EC recommended that Monsanto clarify their applications by giving a presentation to the EC with regard to the concerns raised. (ii) The EC indicated that the decision for the extension application is pending.	OoR
5.10	Monsanto 08/546: Fast Track of GM maize event MON89034	(i) The EC noted that the current permit expires at the end of May 2009 and that they have planted another cycle. It was agreed that Monsanto be permitted to conclude the current activities but that no new plantings be allowed until this matter has been concluded by the EC.	OoR
5.11	Stellenbosch 06/011 GM Grapevine	(i) The EC noted that the applicant has submitted the information that was outstanding and information was requested from the industry sectors with regards to the opinion and their support for this application. (ii) The EC indicated that visit to the site should be facilitated by the OoR.	OoR OoR
5.12	Feedback on Austrian Study	(i) The EC had referred this study to the AC to provide a recommendation with regard to results obtained in the study. This study was initiated by the Austrian authorities because of the reproductive effect on mice that was fed food containing GM maize. The report was circulated containing the major issues in terms of the methodology and analysis of data. On the basis of the study and the review conducted by the AC it is recommended that the position of the EC in relation to the MON810 and NK603 event should not	AC Chairperson

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6.	NEW APPLICATIONS TO BE CONSIDERED BY EC	change.	
6.1	Fort Dodge 08/001 Poultry vaccine	(i) The EC decided that the decision for this application is pending final recommendation from the AC.	OoR
6.2	Pioneer 09/395 Trial release of maize event 98140	(i) The EC decided that the application is pending and that the issues raised must be addressed.	OoR
6.3	Triclinium 08/021: Import and trial release measles vaccine (MVA-mBN85B)	(i) The EC noted that DoA will engage with the MCC in order for the EC to gain more insight into the MCC approval process for clinical trials. (ii) The EC recommended approval subject to the raised issues being addressed with regard to MCC and Ethics Committee approval and storage and security issues are addressed	OoR OoR
6.4	ARC:VOPI 08/039 General release of potato SpuntaG2	(i) The EC noted that the application will be referred back to the Advisory Committee for further deliberation and final recommendation. (ii) The EC noted that the decision on this application is pending the final recommendation from the AC.	OoR, AC
7	GENERAL		
7.1	Regulatory and policy development (All)	(i) The EC noted the promulgation of the Consumer Protection Act (Act No.68 of 2008) which will be followed by the development of the Regulations. A letter from the EC will be sent to the dti in order to clarify what product labelling and trade descriptions will be required in terms of the Consumer Protection Act. Clarification will also be requested in terms of which prescribed goods will need to be labelled; the format of the notice for packaging and the implementation of applicable regulations. (ii) The EC noted that DST will have a Board induction meeting for TIA by the	

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		<p>end of May 2009.</p> <p>(iii) The EC noted that the amendments to National Environmental Management Act 107 of 1998 (NEMA) have been passed and will be circulated to the EC. These amendments clarify SANBI's mandate which is to conduct biosafety research on commercially released GMOs in support of the regulatory process. The National Environmental Management: Biodiversity Act 10 of 2004 (NEMBA) has been amended to be more specific as to the role of SANBI.</p> <p>(iv) The EC noted that changes to the mandates of Government Departments will affect representation on the Council in terms of the GMO Amendment Act.</p>	DEAT
7.2	Registration of Facilities	(i) The EC noted that the guideline has been finalized by the AC and has been circulated to the EC for comments. EC members to submit comments/recommendations to the Office of the Registrar by 26 May 2009 for finalisation of the guideline document.	EC members
7.3	Time extension policy	(i) The EC recommended that further amendments be made to the document. Policy to be finalised at the next EC meeting in July 2009.	EC members/ OoR
7.4	Monsanto Crop Failure	(i) The EC noted that a report has been submitted by Monsanto with regard to the recent reported crop failures. According to initial investigations conducted by Monsanto, it appears that this may have resulted from incorrect spraying regimes being implemented. Plant material has been collected by Monsanto and will be subjected to further scientific analysis. (ii) The EC noted that in terms of Plant Breeders Rights (Act No.15 of 1976), cobs from the affected varieties will be subject to evaluation.	OoR
7.5	Permit conditions: Amendment of ARC Contained use of Ornithogalum (17/3(3/08/243)	(i) The EC noted that the ARC-VOPI requested an amendment to their permit conditions. The permit was issued based on number of plantlets indicated in the initial application. The ARC stated that they needed to plant double the indicated plantlets for statistical purposes.	OoR

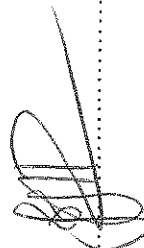
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7.6	GENOK Course	<p>(ii) The EC approved the amendment of the permit conditions to allow for the planting of additional material. The approval is however subject to inspection to confirm the availability of space within the registered facility.</p> <p>(i) The EC noted that DEAT has secured the availability of 10-15 slots for the GENOK course to be presented in Bloemfontein from 28 June to 3 July 2009. These slots will be made available to AC subcommittee members who are interested in attending. The course programme will include topics on the Cartagena Protocol, socio economics and other GM related issues.</p> <p>(ii) The EC noted that DEAT, DoA, and DoH will be requested to participate on day 2 of the workshop in order to provide attendees background on regulatory requirements in terms of GMOs.</p>	OoR DEAT, OoR
7.7	Change in governmental departments	(i) Discussed under 7.1	DEAT, DoA, DoH
8	Date of the next meeting	The date for the next meeting is scheduled for 21 July 2009.	EC members
9	Closure	The meeting was concluded at 13h10.	

Approved 21 July 2009

Approved by Chairperson

Dr J Jaffha
Name



Approved by Registrar

Ms G Christians
Name

