

MINUTES
OF THE MEETING OF THE EXECUTIVE COUNCIL UNDER GMO ACT, 1997 HELD ON
26 JANUARY 2010, HARVEST HOUSE ROOM 332, PRETORIA

PRESENT

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

Department of Agriculture, Forestry and Fisheries (DAFF)
 Chairperson of the Advisory Committee (AC) under the GMO Act, 1997
 Department of Environmental Affairs (DEA)
 Department of Health (DoH)
 Department of Trade and Industry (the dti)

APOLOGIES

Mr B Durham

Department of Science and Technology (DST)

VACANT

Representative

Department of Labour (DoL)

IN ATTENDANCE

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

Department of Agriculture, Forestry and Fisheries
 Department of Agriculture, Forestry and Fisheries
 Department of Agriculture, Forestry and Fisheries
 Department of Agriculture, Forestry and Fisheries (secretariat)
 Department of Health
 Department of Agriculture, Forestry and Fisheries
 Department of Science and Technology
 Department of Environmental Affairs

NO.	SUBJECT	RESOLUTION	FOR ATTENTION
1.	OPENING AND WELCOME	The Chairperson welcomed those present to the first meeting of the EC for 2010.	EC Chair
2.	ATTENDANCE REGISTER AND APOLOGIES	The attendance register was circulated to everyone present for signature.	EC Chair

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3.	ADDITIONS TO AND ADOPTION OF THE AGENDA	The agenda was adopted with the following amendments: 5.2 to be omitted from the agenda until further progress is reported 7.7 the addition of COP MOP V	OoR
4.	APPROVAL OF THE RECORD OF PROCEEDINGS OF 4 November 2009	Minutes were amended and approved, with the exception of section 5.3 on commodities, on which all members should submit comments to the OoR.	EC
5.	MATTERS ARISING FROM THE PROCEEDINGS		

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5.4	Pioneer 17/3/1-Pioneer 09/383: Commodity clearance of maize 98140	(i) The EC reserved a decision on this application until all outstanding matters have been addressed. The OoR should also follow up on the status of approval in Argentina and obtain their risk assessment, if available.	OoR
5.5	GM threshold vs. adventitious presence (DoH, Registrar, DEA)	<p>(i) Information regarding labelling and thresholds in different countries were circulated and will be reviewed by all members. Codex Alimentarius information as supplied by DoH was also circulated.</p> <p>(ii) The EC noted that our threshold should be comparable with that of our trading partners. Information should be obtained with regard to GM thresholds of trading partners.</p> <p>(iii) The EC also noted that thresholds are closely linked to adventitious presence. When determining limits, the concept of thresholds should be clearly defined. It should be within the regulatory requirements, taking into account different mandates, transboundary movements/requirements as well as labelling aspects.</p> <p>(iv) The EC noted that the OoR, DoH and DEA will collate information and coordinate the proposed discussion.</p>	OoR, DoH, DEA
5.6	Monsanto - 09/470: Introgression of event MON89034 and MON 89304 x NK603 (Pannar and	(i) The EC noted that concerns raised had been forwarded to Legal Services for further inputs. The applicant should also provide input with regard to highlighted issues. Feedback will be provided as soon as responses from Legal Services and the applicant are received.	OoR

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NO.	SUBJECT	RESOLUTION	FOR ATTENTION
	Linkseed) (Registrar)		
5.7	SASRI-09-013: Trial release of GM Sugarcane (pASNI), SASRI-09-014: Trial Release of GM Sugarcane (pSVPase), SASRI-09-015: Trial release of GM Sugarcane (pAUGdf510/p HAN-UGD) (Registrar)	(i) The EC considered the additional information provided by the applicant as adequate.	OoR, EC
6	Application to be considered by EC Time extensions and amendment to existing permits (Registrar)		
6.1	ARC:VOPI – 09/041: Extension permit, 17/3(3/08/243) Ornithogalum lines A2:1 and A2:4	(i) The EC recommended the approval of ARC: VOPI -09/041: Extension permit 17/3(3/08/243) Ornithogalum lines A2:1 and A2:4 subject to the submission of a more comprehensive annual report and maintaining current permit conditions.	OoR
6.2	Monsanto – 08/382: Request to amend permit conditions (destruction by incineration) Permit number 17/3(3/09/314) (for noting)	(i) The EC approved the request from Monsanto for an amendment to the recommended destruction method from disking into soil to rather destroy via incineration for contained use trials that will be conducted at the proposed facility. The facility where the work will be conducted has an approved incinerator (part of registration of facility). Destruction by means of incineration presents a safer method presenting less risk to the environment.	OoR
6.3	Monsanto – 08/383:	(i) See 6.2	OoR

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6.4	<p>Request to amend permit conditions (destruction by incineration) Permit number 17/3(3/09/315)</p> <p>Monsanto – 09/606: Request to amend permit condition (fallow alley). Permit number 17/3(4/09/242)</p>	<p>(i) The EC approved the request from Monsanto for an amendment of the requirement of the fallow alley allowance. The facility where this current trial is planted only allows for 9m instead of the required 15m fallow alley due to existing layout which forms the basis of a fertilizer trial which has been in existence since 1939. There are however additional measures in place to prevent possible pollination such as rain shields, additional fencing, etc. An inspection has also been conducted to verify whether these measures are sufficient and would not lead to additional risks being created.</p>	OoR
6.5	<p>PPD – 08/005: Amendment to Import Permit (storage facility) (for noting) PPD – 08/006: AND</p>	<p>(i) The EC approved the request from the application for amendment of the storage depot indicated in the initial application. The depot closed permanently in November 2009, and the new facility proposed is registered with MCC for use of storage of investigational products and other pharmaceutical related functions. The facility proposed for amendment had been previously inspected for compliance but another inspection will be done in relation to the current permit.</p>	OoR
6.6	<p>Amendment to Import Permit (storage facility)</p>	<p>(ii) The EC approved that most companies make use of pharmaceutical depots as storage facilities for vaccines. An inspection was conducted last year to confirm that measures are in place at the site and another inspection will be conducted should it be merited or if any further changes occur at the new depot. The change of site has thus far been approved by the MCC.</p>	
6.7	<p>New applications Syngenta – 09/101: Commodity Clearance of triple stacked Maize</p>	<p>(i) The EC reserved a decision on this application until issues raised are addressed in terms of controls, handling, and other requirements that may impact on commodity clearance.</p>	OoR

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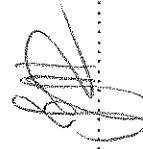
NO.	SUBJECT	RESOLUTION	FOR ATTENTION
	(Bt11xMIR162xGA21)		
6.8	Pioneer – 09/414: Import and Contained Use of Maize event 59122	(i) The EC recommended approval for the application from Pioneer for the import and contained use of maize event 59122 subject to additional requirements as stipulated in the recommendations.	OoR
6.9	Monsanto – 09/673: Import and Trial Release of Canola (RT73)	(i) The EC reserved a decision on this application until the concerns raised have been addressed.	OoR, DEA, AC Chair
7.	General		
7.1	Regulatory and policy development (ALL)	(i) The EC noted that the information about the Consumer Protection Act, 2008 workshop facilitated by AfricaBio which was circulated requesting inputs to be included in the Regulations of this Act. It was indicated that the dti will approach individual departments for inputs, when required.	All
7.2	Non-GM vaccines (Registrar) (for noting)	(i) The EC noted that the OoR had received a request from two applicants who had submitted vaccine applications in terms of Act 36 of 1947. It was recommended by Act 36 officials that confirmation be obtained from Biosafety in terms of the GMO Act as the applicants requested exemption from GMO assessment based on information provided in the application. The information received by the OoR was submitted to an AC member with vaccine expertise to provide an opinion with regard to applicability but also the requirements to be assessed by the Advisory Committee. (ii) The EC noted concerns with regard to the methods of inactivation and how it is ensured that no GMO is present in the final product. Data pertaining to methods used for inactivation and quality testing of the final product should be requested from the applicants. In addition, the applicant should provide a further motivation with reference to the Act why their particular vaccine falls outside the scope of the Act. Clarity should also be provided with regard to the organism from which the protein is derived.	OoR

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NO.	SUBJECT	RESOLUTION	FOR ATTENTION
7.3	Capacity building 2010		
7.3.1	Isolation distance workshop (Registrar)	<p>(i) The EC noted that the proposed workshop on isolation distance had to be postponed.</p> <p>(ii) The EC noted that the DEANorwegian collaboration produced significant information thus far pertaining to isolation distances. The study which focused on MON810 will be concluded by December 2010. This work was done in collaboration with SANBI.</p> <p>(iii) The EC also noted that Biosafety SA conducted a literature study with regard to isolation distance which may also be used as a basis to work on.</p> <p>(iv) The EC noted that the workshop will be co-ordinated between DEA, AC Chair and OoR in order to define parameters to be discussed and addressed at the workshop.</p>	DEA
7.4	COP/MOP 5 (DEA)	(i) The EC noted that COP/MOP 5 will take place from 13 October 2010 in Japan. It was requested that each department prepare a document highlighting their key issues in terms of issues to be discussed. Closer collaboration required between departments to ensure agreement with regard to various issues that will feature at COP/MOP 5. Transit issues will be one of the major points of discussion.	ALL
8.	Date of the next meeting	The date for the next meeting is scheduled for 2 March 2010	
9.	Closure	The meeting was concluded at 13:00	

Approved by Chairperson

Dr J Jaffha
Name



Signature

Approved by Registrar

Ms G Christians
Name



Signature

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