Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 468 Pretoria, 11 June / Junie 2004 No. 26422

AIDS HELPLINE: 0800-0123-22 Prevention is the cure

For purposes of reference, all Proclamations, Government Notices, General Notices and Board Notices published are included in the following table of contents which thus forms a weekly index. Let yourself be guided by the Gazette numbers in the righthand column:

CONTENTS

and weekly Index

Alle Proklamasies, Goewermentskennisgewings, Algemene Kennisgewings en Raadskennisgewings gepubliseer, word vir verwysingsdoeleindes in die volgende Inhoudsopgawe ingesluit wat dus 'n weeklikse indeks voorstel. Laat uself deur die Koerantnommers in die regterhandse kolom lei:

INHOUD

en weeklikse Indeks

PROCLAMATION

by the

President of the Republic of South Africa

No. 31, 2004

THE PRESIDENCY

AWARD OF THE ORDER OF LUTHULI

It is hereby notified that the above-mentioned National Order will be awarded by the President in the categories indicated to the following South African citizens in terms of the rules contained in the Warrants published in Government Gazette No. 25799 of 2 December 2003.

The Order of Luthuli

Category I: Gold

Mr Z.K Matthews (Posthumous)
Mr T.T Nkobi (Posthumous)
Mr Sol Plaatje (Posthumous)
Mr Dan Tloome (Posthumous)

Category II: Silver

Ms Hilda Bernstein
Mr Laloo Chiba
Mr Clarence Makwetu
Mr Mapetla Mohapi (Posthumous)
Ms Josie (Palmer) Mpama (Posthumous)
Mr Billy Nair

Ms Rita Ndzanga
Mr Joe Nhlanhla
Mr Reggie September
Mr Steve V. Tshwete (Posthumous)

Category III: Bronze

Ms Amina Cachalia
King Frans Rasimphi Tshivhase (Posthumous)

THE PRESIDENCY

AWARD OF ORDER OF BAOBAB

It is hereby notified that the above-mentioned National Order will be awarded by the President in the categories indicated to the following South African citizens in terms of the Rules contained in the Warrants published in Government Gazette No. 24155 of 06 December 2002.

The Order of the Baobab

Category I: Gold

Dr Fabian Ribeiro (Posthumous)

Category II: Silver

Dr Brigalia Bam
Rev Helenard J (Allan) Hendricks
Ms Dora Ndaba
Ms Jean Sinclair (Posthumous)

Category III: Silver

Ms Mirriam Cele
Ms Edna Freinkel
Ms Mpho Sibanyoni-Motlhasedi
Prince Cabangukuhle P Zulu

THE PRESIDENCY

AWARDS OF THE ORDER OF THE COMPANIONS OF O.R TAMBO

It is hereby notified that the above-mentioned National Order will be awarded by the President in the categories indicated to the following foreign dignitaries in terms of the Rules contained in the Warrants published in Government Gazette no. 24155 of 06 December 2002.

The Order of the Companions of O.R Tambo

Category I: Gold

Mr Kofi Annan (UN)
Mr Salvador Allende (Chile) (Posthumous)
Mr Martti Ahtisaari (Finland)
Mr Ahmed Ben Bella (Algeria)
Mr Amilcar Cabral (Guinea Bissau) (Posthumous)
Dr Martin Luther King, Jnr (USA) (Posthumous)
Mr Patrice Lumumba (DRC) (Posthumous)
Mr Michael Manley (Jamaica) (Posthumous)
Dr Eduardo Mondlane (Mozambique) (Posthumous)
Dr Augustino Neto (Angola) (Posthumous)
Mr Kwame Nkrumah (Ghana) (Posthumous)
Dr Julius Nyerere (Tanzania) (Posthumous)
Mr Salim Ahmed Salim (OAU)

Category II: Silver

Ms Barbara Castle (UK) (Posthumous)
Mr Ramesh Chandra (India)
Lord Robert Hughes (UK)
Mr Michinek (Sweden)
Mr Boudewijn Sjollema (The Netherlands)
Dr Vasili G Solodovnikov (Russia)
Mr R Steen (Norway)
Mr T Stoltenberg (Norway)
Ms Maxine Waters (USA)

GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF ARTS AND CULTURE
DEPARTEMENT VAN KUNS EN KULTUUR

No. 701 **11 June 2004**

BUREAU OF HERALDRY

APPLICATION FOR REGISTRATION OF HERALDIC REPRESENTATIONS AND OBJECTIONS THERETO

SECTIONS 7, 7A AND 7B OF THE HERALDRY ACT, 1962 (ACT NO. 18 OF 1962)

The undermentioned bodies and persons have applied in terms of section 7 of the Heraldry Act, 1962 (Act No. 18 of 1962), for the registration of their heraldic representations. Anyone wishing to object to the registration of these heraldic representations on the grounds that such registrations will encroach upon rights to which he or she is legally entitled should do so within one month of the date of publication of this notice upon a form obtainable from the State Herald, Private Bag X236, Pretoria, 0001.

1. **APPLICANT:** Brewelskloof Hospital (H4/3/1/3949)

ARMS: On an oval cartouche Murrey, edged Or, a fillet oval annulet, therewithin an enflamed oil lamp, therebelow a chained portcullis, all Or.

2. **APPLICANT:** Western Cape College of Nursing (H4/3/1/4011)

ARMS: Tierced in pairle, Sable, Azure and Gules, a pall Argent, the vertical limb terminating in an inverted pile grady abbaisé, between in chief a lamp Argent enflamed Or, dexter a protea and sinister a disa, all Argent.

MOTTO: IN SERVICE TO HUMANITY

3. **APPLICANT:** Thabang Secondary School (H4/3/1/4015)

ARMS: Azure, between two facetted stars Argent, a pile inverted embowed Or, thereupon another Vert, charged with a double-warded key of the second, the shaft Or and bow to base in the form of a triquetra, and in chief a coronet Or consisting of a circlet heightened of four fleurs-de-lys alternated with as many pearls Argent.

MOTTO: ORA PRONOBIS

4. **APPLICANT:** St. Dunstan's Cathedral (H4/3/1/4022)

ARMS: Argent a cross Azure, between in chief dexter a chalice Or, and in sinister base a pair of pincers Sable. The shield is ensigned of a wreath Azure and Argent, thereupon a grate Or, enflamed Gules.

MOTTO: WE WORSHIP WE WITNESS WE SERVE

5. **APPLICANT:** Congregation of the Oratory of St. Philip Neri – Oudtshoorn (H4/3/1/4026)

ARMS: Azure, a heart enflamed Gules, fimbriated Or, between in chief three eight-pointed faceted stars of the third, placed one and two and in base two protea flowers addorsed, slipped and leaved Or, seeded Argent. The shield is ensigned of three ostrich feathers Azure, ribbed Or.

MOTTO: GOD IS ONS ERNS

6. **APPLICANT:** Laerskool Lorraine (H4/3/1/4030)

ARMS: Azure, a quill pen Argent in bend sinister; over all upon a bend Tenne bordered Or, three alerions Argent.

MOTTO: PERSEVERA

7. **APPLICANT:** Disaster Management Institute of Southern Africa (H4/3/1/4039)

BADGE: On a torteau a triangle Azure bordered Argent.

8. **APPLICANT:** SA Miniature Rugby Union (H4/3/1/4041)

BADGE: On a background Argent, within the upper posts of a set of rugby posts Brunâtre, the crossbar charged with five billets fesswise of Azure, Tenne, Azure, Tenne and Azure, a springbok head and neck and below its mouth a rectangular miniature rugby ball in bend sinister Or, fimbriated Sable.

9. **APPLICANT:** Bapedi King's Council (H4/3/2/739)

ARMS: Argent, a spear and knobkierie in saltire and a plumed staff erect proper, debruised by a traditional oval warrior shield pied at random of Sable and Argent; the whole within a bordure gyronny of eight of Or, Sable, Argent, Vert, Or, Sable, Argent and Vert in clockwise direction. The shield is ensigned of a leopardskin headring, thereupon a porcupine, all proper.

SUPPORTERS: Statant upon a compartment Vert, the bottom edge Or, two leopards Argent.

MOTTO: FETA KGOMO O SWARE MOTHO

10. **APPLICANT:** Jean-Yves de Sainte-Croix de la Sabliere (H4/3/4/767)

ARMS: Tierced in pairle Sable, Gules and Azure, a fillet pall Or, between in chief a fleur-de-lis Or, dexter a Maltese cross Argent and sinister a lion rampant Or, armed and langued Gules; in base two swords in saltire Argent.

CREST: A plume of three ostrich feathers Or.

WREATH AND MANTLING: Dexter: Azure and Or. Sinister: Gules and Or.

MOTTO: PER CRUCEM TRIUMPHANS

11. **APPLICANT:** Christopher Ron Covington (H4/3/4/773)

ARMS: Quarterly Vert and Argent, a Maltese cross counterchanged between two towers Argent, masoned Sable, flying the flag of St. George and two lymphads in full sail, oars in action and pennons flying, all Sable.

CREST: Issuant from a mount of leaved strawberries proper, a demi mountain lion rampant pean, langued Azure, in his sinister paw a Highland targe, and in his dexter paw a Highland basket-hilted sword proper.

WREATH AND MANTLING: Vert and Argent.

MOTTO: INTO THE DEEP

12. **APPLICANT:** Chacko Chandy Neroth (H4/3/4/779)

ARMS: : Purpure, a dove volant Argent beaked and legged and with eyes Or, in its beak an olive branch slipped, fructed and leaved proper; on a chief Argent a lion passant guardant Gules with all claws sheathed except those of the dexter forepaw, armed, langued and with eyes Or, crowned with an Eastern crown also Or.

CREST: Risant from flames of fire proper, a phoenix displayed Purpure armed and with eyes Or, crowned with an Eastern crown also Or, holding in its beak an olive branch slipped, fructed and leaved proper.

WREATH AND MANTLING: Purpure, semé-de-lis Or and Argent.

MOTTO: On a scroll Azure, doubled Or, the motto PAX ET VARIETAS UNIVERSA in letters Sable.

13. **APPLICANT:** Chacko Chandy Neroth (H4/3/4/779)

STANDARD: Flying from a pole topped with a Marthoma Cross Or: in the hoist the arms of Chacko Chandy Neroth and in the fly divided into three compartments by two bends Azure, fimbriated Or, bearing the motto PAX ET VARIETAS UNIVERSA in letters Sable, in the 1st and 3rd compartments Purpure semé-de-lis Or, his badge namely on a heptagon Gules edged Or, a cross flory enwreathed by two

ears of wheat the stalks couped and tied in base in a Wake knot ensigned with an Eastern crown, all Or, and in the second compartment Argent his crest namely on a wreath Purpure and Argent, risant from flames of fire proper, a phoenix displayed Purpure beaked and armed and with eyes Or, crowned with an eastern crown also Or, holding in its beak an olive branch slipped, fructed and leaved proper; the sleeve Purpure and fringed alternately Purpure and Argent.

14. **APPLICANT:** Marius Oelschig (H4/3/4/786)

ARMS: Quarterly, per pale embattled and per fess indented, the peaks embattled Argent and Gules; i, an eagled displayed Sable, armed Or, langued Gules, holding in its dexter claw a sceptre and in its sinister claw an orb all Or; ii, a sword and general's baton in saltire Argent; iii, an artillery field piece Argent; iv, a branch of two proteas Gules, seeded Argent, slipped Vert.

CREST: A lion statant gardant Gules, armed and langued Azure, supporting with its dexter paw an open parachute Argent.

WREATH AND MANTLING: Gules and Argent.

MOTTO: STANDFEST

15. **APPLICANT:** Mark Tapping (H4/3/3/757)

ARMS: Quarterly enhanced, Argent, Azure, Gules and Argent, statant upon the bow of a stringed powder-horn, a swan with wings elevated, collared and with chain pendant counterchanged.

MOTTO: TREOW

16. **APPLICANT:** William Woodruff Dahlberg (H4/3/4/800)

ARMS: Per fess dancetty, Or and Vert, in chief two crosses potent and in base a human heart counterchanged.

CREST: Issuant from a grassy mound proper a dexter cubit arm vested Gules, cuffed Argent, in the hand placed in bend sinister, a white dahlia flower, stalked and leaved proper.

WREATH AND MANTLING: Gules and Argent.

MOTTO: PERSEVERANTIA

17. **APPLICANT:** Andrew Gledhill (H4/3/4/801)

ARMS: Gules, on a bend Or, three lozenges Azure.

CREST: A demi-lion issuant Sable, armed and langued Gules, holding in its dexter paw a mullet inverted, Or.

WREATH AND MANTLING: Gules and Or.

MOTTO: FELIX QUI VITA AMOR

18. **APPLICANT:** Angelo Federico Arcelli (H4/3/4/805)

ARMS: Gules a cross throughout, checky Argent and Azure.

CREST: Issuant from a crest coronet consisting of a circlet Or, embellished with jewels proper, heightened with eight pearls Argent, three ostrich feathers Gules, Argent and Azure.

WREATH AND MANTLING: Dexter: Gules and Argent. Sinister: Azure and Argent.

MOTTO: NON DEEST GENEROSO IN PECTORE VIRTUS

19. **APPLICANT:** BRIAN ROBERT ALLANSON (H4/3/4/808)

ARMS: Or, issuant from a base barry wavy of six Azure and Argent a demi-eagle displayed Gules.

CREST: A demi-eagle displayed Gules.

WREATH AND MANTLING: Gules and Or.

MOTTO: VIRTUTE ET LABORE

20. **APPLICANT:** Herbert Leslie Grandison Howard-Browne (H4/3/4/809)

ARMS: Per saltire engrailed Gules and Or, in chief an earl's coronet proper, in base upon a set of three steps a Latin cross Argent, dexter a Tudor Rose, slipped and leaved Vert, and sinister a protea proper.

CREST: On a battlement Sable, masoned Argent, a dragon statant Gules, holding in his dexter claw a staff erect, flying therefrom a pennant Argent, charged with a cross Gules throughout.

WREATH AND MANTLING: Gules and Or.

MOTTO: JEHOVAH NISSI

21. **APPLICANT:** Lutheran Bapedi Church (H4/3/1/3989)

NAME: LUTHERAN BAPEDI CHURCH

No. 701 11 Junie 2004

BURO VIR HERALDIEK

AANSOEK OM REGISTRASIE VAN HERALDIESE VOORSTELLINGS EN BESWARE DAARTEEN

ARTIKELS 7, 7A EN 7B VAN DIE HERALDIEKWET, 1962 (WET NO. 18 VAN 1962)

Ondergenoemde instansies en persone het kragtens artikel 7 van die Heraldiekwet, 1962 (Wet No. 18 van 1962), aansoek gedoen om die registrasie van hulle heraldiese voorstellings. Enigeen wat teen die registrasie van hierdie heraldiese voorstellings beswaar wil aanteken op grond daarvan dat sodanige registrasie inbreuk sal maak op regte wat hom of haar wettiglik toekom, moet dit binne een maand na die datum van publikasie van hierdie kennisgewing doen op 'n vorm wat van die Staatsheraldikus, Privaatsak X236, Pretoria, 0001, verkrygbaar is.

1. **AANSOEKER:** Brewelskloof Hospitaal (H4/3/1/3949)

WAPEN: Op 'n maroen ovaal, goud gerand, 'n goue ovaalstreepring, daarbinne 'n goud gevlamde silwer olielamp, daarbenede 'n gekettingde valhek, alles van goud.

2. **AANSOEKER:** Western Cape College of Nursing (H4/3/1/4011)

WAPEN: Gaffelsgewys verdeel van swart, blou en rooi 'n silwer gaffel die vertikale been eindigend in 'n trapvormige verlaagde punt, tussen in die skildhoof 'n goud gevlamde silwer olielamp, regs 'n protea en links 'n disa ook silwer.

WAPENSPREUK: IN SERVICE TO HUMANITY

3. **AANSOEKER:** Thabang Secondary School (H4/3/1/4015)

WAPEN: In blou, tussen twee gefasetteerde silwer sterre, 'n ingeboë goue punt, daarop 'n ander van groen belaai met 'n dubbelgebaarde silwer sleutel, die skag van goud en die oor na die skildvoet in die vorm van 'n triquetra, en in die skildhoof 'n goue kroon bestaande uit 'n hoofring verhoog van vier fleurs de lis afgewissel met dieselfde getal silwer pêrels.

WAPENSPREUK: ORA PRONOBIS

4. **AANSOEKER:** St. Dunstan's Cathedral (H4/3/1/4022)

WAPEN: In silwer 'n blou kruis tussen in die skildhoof regs 'n goue drinkbeker en in die skildvoet links 'n swart knyptang. Die skild is oortop van 'n wrong van blou en silwer, daarop 'n goue vuurherd, rooi gevlam.

WAPENSPREUK: WE WORSHIP WE WITNESS WE SERVE

5. **AANSOEKER:** Kongregasie van die Oratorium van St. Filip Neri – Oudtshoorn (H4/3/1/4026)

WAPEN: In blou 'n rooi gevlamde hart goud gefimbrieer, tussen in die skildhoof drie agtpuntige gefasetteerde goue sterre, geplaas een en twee, en in die skildvoet twee afgewende proteas, goud gesteel en geblaar, silwer gesaad. Die skild is oortop van drie blou volstruisvere, goud gerib.

WAPENSPREUK: GOD IS ONS ERNS

6. **AANSOEKER:** Laerskool Lorraine (H4/3/1/4030)

WAPEN: In blou 'n skuinslinks geplaaste silwer penveer, oor alles heen op 'n oranje regterskuinsbalk, goud gerand, drie geknotte silwer adelaars.

WAPENSPREUK: PERSEVERA

7. **AANSOEKER:** Disaster Management Institute of Southern Africa (H4/3/1/4039)

KENTEKEN: Op 'n rooi skyf 'n blou driehoek silwer gerand.

8. **AANSOEKER:** SA Miniatuur Rugby Unie (H4/3/1/4041)

KENTEKEN: Op 'n silwer agtergrond, tussen die boonste pale van 'n stel bruin rugbypale, die dwarsbalk belaai met vyf reghoekige blokkies dwarsbalksgewys geplaas van blou, oranje, blou, oranje en blou, 'n springbokkop en nek en onder sy bek 'n skuinslinks geplaaste reghoekige miniatuurrugbybal, van goud, swart gefimbrieer.

9. **AANSOEKER:** Bapedi King's Council (H4/3/2/739)

WAPEN: In silwer voor 'n skuinsgekruiste spies en knopkierie 'n regopgeplaaste gepluimde staf van natuurlike kleur, daaroorheen 'n tradisionele ovaal krygerskild natuurlik gekol van swart en silwer; die geheel binne-in 'n skildsoom gegeer van agt van goud, swart, silwer, groen, goud, swart, silwer en groen in kloksgewyse volgorde. Die skild is oortop van 'n luiperdvel-hoofring, daarop 'n ystervark, alles van natuurlike kleur.

SKILDHOUERS: Staande op 'n groen kompartement, die benede rand goud, twee silwer luiperds.

WAPENSPREUK: FETA KGOMO O SWARE MOTHO

10. **AANSOEKER:** Jean-Yves de Sainte-Croix de la Sabliere (H4/3/4/767)

WAPEN: Gaffelsgewys verdeel van swart, rooi en blou, 'n goue streepgaffel tussen in die skildhoof 'n goue fleur de lis, regs 'n silwer Malteserkruis en links 'n goue klimmende leeu rooi genael en getong; in die skildvoet twee skuinsgekruiste silwer swaarde.

HELMTEKEN: 'n Pluim van drie goue volstruisvere.

WRONG EN DEKKLEDE: Regs: blou en goud. Links: rooi en goud.

WAPENSPREUK: PER CRUCEM TRIUMPHANS

11. **AANSOEKER:** Christopher Ron Covington (H4/3/4/773)

WAPEN: Gevierendeel, groen en silwer, 'n Malteserkruis van die een in die ander tussen twee swart gemesselde silwer torings wat elk die vlag van St. George voer en twee swart galeie in volle vaart, spane in aksie en wimpels wapperend.

HELMTEKEN: Uitkomend uit 'n grond van geblaarde aarbeie van natuurlike kleur 'n halwe bergleeu van teengoudhermelyn, blou getong, in sy linkerklou 'n Skotse Hoogland armskild en in sy regterklou 'n Skotse Hoogland skottelhef-swaard van natuurlike kleur.

WRONG EN DEKKLEDE: Groen en silwer.

WAPENSPREUK: INTO THE DEEP

12. **AANSOEKER:** Chacko Chandy Neroth (H4/3/4/779)

WAPEN: In purper 'n vlieënde silwer duif, gebek, gepoot en met oë van goud, in sy bek 'n olyftakkkie gesteel, gevrug en geblaar van natuurlike kleur; op 'n silwer skildhoof 'n gaande aansiende rooi leeu met al sy naels teruggetrek behalwe dié van sy regtervoorpoot, genael, getong en met oë van goud, en gekroon van 'n Oosterse kroon ook goud.

HELMTEKEN: Uitkomend uit vuurvlamme van natuurlike kleur, 'n purper feniks met vlerke omhoog, gebek en met oë van goud, en gekroon met 'n Oosterse kroon ook goud, in sy bek 'n olyftakkie gesteel, gevrug en geblaar van natuurlike kleur.

WRONG EN DEKKLEDE: Purper, besaai met goue fleurs-de-lis en silwer.

WAPENSPREUK: Op 'n blou lint, goud teruggevou die spreuk PAX ET VARIETAS UNIVERSA in swart letters.

13. **AANSOEKER:** Chacko Chandy Neroth (H4/3/4/779)

STANDAARD: Aan 'n paal getop van 'n Marthoma-kruis van goud: in die broeking die wapen van Chacko Chandy Neroth en in die uitwaaiende gedeelte verdeel in drie kompartemente deur twee blou skuinsbalke, goud gefimbrieer, daarop die spreuk PAX ET VARIETAS UNIVERSA in swart letters, in die eerste en derde kompartemente purper besaai met goue fleurs de lis, sy kenteken naamlik op 'n rooi sewehoek goud gerand, 'n leliekruis binne-in 'n krans van twee koringare die stele afgesnede en in die voet geknoop in die vorm van 'n Wake-knoop, oortop van 'n Oosterse kroon, alles goud, en in die tweede kompartement in silwer sy helmteken naamlik op 'n wrong van purper en silwer uitkomend uit vuurvlamme van natuurlike kleur, 'n purper feniks met vlerke omhoog, gebek genael en met oë van goud, en gekroon met 'n Oosterse kroon ook goud, in sy bek 'n olyftakkie gesteel, gevrug en geblaar van natuurlike kleur; die broekingspyp purper en fraiing afwisselend purper en silwer.

14. **AANSOEKER:** Marius Oelschig (H4/3/4/786)

WAPEN: Gevierendeel, paalsgewys gekanteel en hoekig kanteelvormig getop deursnede, silwer en rooi, i, 'n swart adelaar goud gebek en gepoot, rooi getong wat in sy regterklou 'n septer en in sy linkerklou 'n gekruiste sfeer, alles van goud vashou; ii, 'n skuinsgekruiste swaard en generaalstaf alles van silwer; iii, 'n artillerie-veldkanon van silwer; iv, 'n takkie van twee rooi proteas, silwer gesaad, groen gesteg.

HELMTEKEN: 'n Staande aansiende rooi leeu, blou genael en getong, wat met sy regterpoot 'n oop silwer valskerm ondersteun.

WRONG EN DEKKLEDE: Rooi en silwer.

WAPENSPREUK: STANDFEST

15. **AANSOEKER:** Mark Tapping (H4/3/3/757)

WAPEN: Verhoogd gevierendeel, silwer, blou, rooi en silwer, staande op strik van 'n gesnoerde kruithoring, 'n swaan met vlerke omhoog, gehalsband en met hangende ketting, alles van die een in die ander.

WAPENSPREUK: TREOW

16. **AANSOEKER:** William Woodruff Dahlberg (H4/3/4/800)

WAPEN: Hoekig verdeel van goud en groen, in die skildhoof twee krukkruise en in die skildvoet 'n mensehart van die een in die ander.

HELMTEKEN: Uitkomend uit 'n grasgrond van natuurlike kleur, 'n regtervoorarm, rooi gekleed met silwer mansjet, in die hand, skuinslinks geplaas, 'n wit dalhia, gesteel en geblaar van natuurlike kleur.

WRONG EN DEKKLEDE: Rooi en silwer.

WAPENSPREUK: PERSEVERANTIA

17. **AANSOEKER:** Andrew Gledhill (H4/3/4/801)

WAPEN: In rooi, op 'n goue skuinsbalk, drie blou ruite.

HELMTEKEN: 'n Uitkomende halwe swart leeu, rooi genael en getong, in sy regterklou 'n omgekeerde vyfpuntige goue ster.

WRONG EN DEKKLEDE: Rooi en goud.

WAPENSPREUK: FELIX QUI VITA AMOR

18. **AANSOEKER:** Angelo Federico Arcelli (H4/3/4/805)

WAPEN: In rooi 'n deurlopende kruis, geskaak van silwer en blou.

HELMTEKEN: Uitkomend uit 'n helmkroon bestaande uit 'n goue hoofring versier van edelstene van natuurlike kleur, verhoog van agt silwer pêrels, drie volstruisvere van rooi, silwer en blou.

WRONG EN DEKKLEDE: Regs: rooi en silwer. Links: blou en silwer.

WAPENSPREUK: NON DEEST GENEROSO IN PECTORE VIRTUS

19. **AANSOEKER:** BRIAN ROBERT ALLANSON (H4/3/4/808)

WAPEN: In goud uitkomend uit 'n skildvoet golwend gedwarsbalk van ses, blou en silwer, 'n halwe rooi adelaar met uitgespreide vlerke.

HELMTEKEN: 'n Halwe rooi adelaar met uitgespreide vlerke.

WRONG EN DEKKLEDE: Rooi en goud.

WAPENSPREUK: VIRTUTE ET LABORE

20. **AANSOEKER:** Herbert Leslie Grandison Howard-Browne (H4/3/4/809)

WAPEN: Ingeskulp skuinsgevierendeel van rooi en goud, in die skildhoof 'n graafkroon van natuurlike kleur, in die skildvoet op 'n stel van drie trappe 'n Latynse kruis van silwer, regs 'n Tudorroos gesteel en geblaar van groen en links 'n protea van natuurlike kleur.

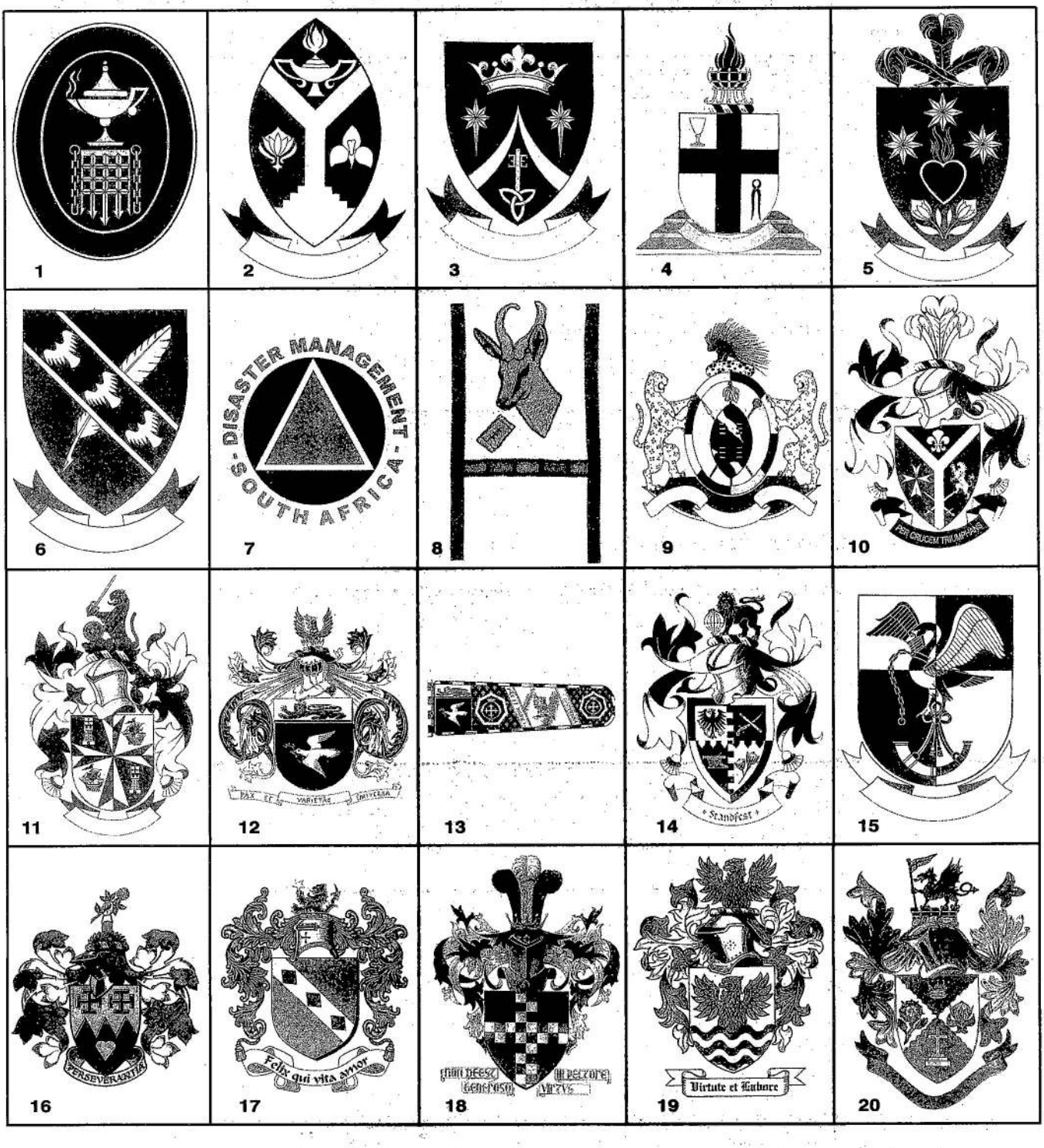
HELMTEKEN: Op 'n swart kanteel, silwer gemessel, 'n staande rooi draak, in sy regterklou 'n silwer staf, wapperend daarvan 'n silwer wimpel belaai met 'n rooi deurlopende kruis.

WRONG EN DEKKLEDE: Rooi en goud.

WAPENSPREUK: JEHOVAH NISSI

21. **AANSOEKER:** Lutheran Bapedi Church (H4/3/1/3989)

NAAM: LUTHERAN BAPEDI CHURCH


1
2
3
4
5
6
DISASTER MANAGEMENT
SOUTH AFRICA
7
8
9
PER CRUCEM TRIUMPHAMUS
10
11
PAX ET VARIETAS UNIVERSA
12
13
Scandfest
14
15
PERSEVERANTIA
16
Felix qui vita amor
17
18
Virtute et Labore
19
20

DEPARTMENT OF HOME AFFAIRS
DEPARTEMENT VAN BINNELANDSE SAKE

No. 693 **11 June 2004**

INSERTION OF SURNAME IN TERMS OF SECTION 23 OF THE BIRTHS AND DEATHS REGISTRATION ACT, 1992 (ACT NO 51 OF 1992)

The Director-General has in respect of the following persons approved the insertion of their surname in italics:

1. Ammoyamma – 1954.07.31 – 152 Skyridge Circle, Chatsworth, 4095 - *Maistry*
2. Ambrabathy – 1949.07.12 – 163 Cardham Drive, Brookdale, Phoenix, 4068 - *Arjunan*
3. Neela – 1949.02.15 – 33 Tweedfern Place, Redfern, Phoenix, 4068 – *Govender*
4. Surugono – 1948.02.01 – 24 Petunia Court, Coco Avenue, Isipingo, 4410 – *Govender*
5. Indrani – 1956.11.29 – P O Box 570, Macina, 3604 – *Pillay*
6. Asurmoney – 1946.09.01 – Road 713, House 67, Montford, Chatsworth, 4092 – *Paddachee*
7. Shoba – 1943.011.02 – 22 Arena Park Drive, Arena Park, Chatsworth, 4092 – *Hanuman*
8. Narain – 1941.10.25 – P O Box 172, Shakaskraal, 4430 – *Haribans*
9. Essop – 1937.12.15 – 41 Lacefern Circle, Redfern, Phoenix, 4068 – *Mohamed*
10. Ruby – 1946.01.09 – 74 Keyford Close, Sunford, Unit 15, Phoenix, 4068 – *Govender*
11. Marrumuthu – 1942.12.17 – 15 Southbury Road, Unit 7, Phoenix, 4068 – *Moonsamy*

DEPARTMENT OF TRADE AND INDUSTRY
DEPARTEMENT VAN HANDEL EN NYWERHEID

No. 714 **11 June 2004**

STANDARDS ACT, 1993
STANDARDS MATTERS

In terms of the Standards Act, 1993 (Act 29 of 1993), the Council of the South African Bureau of Standards has acted in regard to standards in the manner set out in the Schedules to this notice.

All South African standards that were previously published by the South African Bureau of Standards with the prefix "SABS" have been redesignated as South African National Standards and are now published by Standards South Africa (a division of SABS) with the prefix "SANS".

A list of all existing South African National standards was published by Government Notice No. 1373 of 8 November 2002.

In the list of SANS standards below, the equivalent SABS numbers, where applicable, are given below the new SANS numbers for the sake of convenience. Standards that were published with the "SABS" prefix are listed as such.

SCHEDULE 1: ISSUE OF NEW STANDARDS

The standards mentioned have been issued in terms of section 16(3) of the Act.

Standard No. and year	Title, scope and purport
SANS 105-E03:2004/ ISO 105-E03:1994	*Textiles – Tests for colour fastness – Part E03: Colour fastness to chlorinated water (swimming-pool water).* Specifies a method for determining the resistance of the colour of textiles of all kinds and in all forms to the action of active chlorine in concentrations such as are used to disinfect swimming pool water.
SANS 216-2-1:2004/ CISPR 16-2-1:2003	*Specification for radio disturbance and immunity measuring apparatus and methods – Part 2-1: Methods of measurement of disturbances and immunity – Conducted disturbance measurements.* Specifies the methods of measurement of disturbance phenomena in general in the frequency range 9 kHz to 18 GHz and especially of conducted disturbance phenomena in the frequency range 9 kHz to 30 MHz.
SANS 274:2004/ ISO 10006:2003	*Quality management systems – Guidelines for quality management in projects.* Gives guidance on the application of quality management in projects.
SANS 815-2:2004	*Shoulder-ended and groove-ended pipe systems – Part 2: Groove-ended steel pipes, fittings, and couplings.* Covers the specific requirements for groove-ended, rolled or cut steel pipes of nominal size from 25 mm to 300 mm, and the fittings and the couplings associated with these pipes.
SANS 1518-1:2004	*Transport of dangerous goods – Design requirements for road vehicles and portable tanks – Part 1: Requirements applicable to all vehicles.* Specifies requirements for all road vehicles of GVM equal to or exceeding 3 500 kg (including trailers) that transport goods classified as hazardous in terms of SANS 10228. Requirements regarding electrical equipment, braking equipment, fire prevention and fighting equipment, placard holders and document storage are covered. Additional requirements are also prescribed for vehicles that transport specific loads.
SANS 1518-2:2004	*Transport of dangerous goods – Design requirements for road vehicles and portable tanks – Part 2: Requirements for road tank vehicles.* Specifies requirements for the design of road tank vehicles (including battery vehicles, fibre-reinforced plastics tanks, vacuum-operated waste tanks and vehicles transporting demountable tanks) for the transport of dangerous goods classified in terms of SANS 10228. Requirements regarding use, construction, and service and structural equipment are covered. Coding of tanks and battery vehicles is given, and inspection and testing procedures are prescribed.
SANS 1700-2-21:2004/ ISO 5855-1:1999	*Fasteners – Part 2: Screw threads – Section 21: Aerospace – MJ threads – General requirements.* Specifies the general requirements for MJ threads used in aerospace construction. Determines the basic triangular profile for MJ threads and gives a system for designating the diameter and pitch combinations.
SANS 1700-2-22:2004/ ISO 5855-2:1999	*Fasteners – Part 2: Screw threads – Section 22: Aerospace – MJ threads – Limit dimensions for bolts and nuts.* Specifies limit dimensions for MJ threads for bolts and nuts of nominal diameter 1,6 mm to 39 mm for use in aerospace construction.
SANS 1700-18-12:2004/ ISO 15981:2002	*Fasteners – Part 18: Rivets – Section 12: Open end blind rivets with break pull mandrel and protruding head – AIA/AIA.* Specifies dimensional and mechanical characteristics and application data for open end blind rivets with break pull mandrel and protruding head, with an aluminium alloy body (AIA) and an aluminium alloy mandrel (AIA) and with nominal diameters, *d*, from 2,4 mm up to and including 6,4 mm.
SANS 1700-18-13:2004/ ISO 15982:2002	*Fasteners – Part 18: Rivets – Section 13: Open end blind rivets with break pull mandrel and countersunk head – AIA/AIA.* Specifies dimensional and mechanical characteristics and application data for open end blind rivets with break pull mandrel and countersunk head, with an aluminium alloy body (AIA) and an aluminium alloy mandrel (AIA) and with nominal diameters, *d*, from 2,4 mm up to and including 6,4 mm.
SANS 1700-18-14:2004/ ISO 15983:2002	*Fasteners – Part 18: Rivets – Section 14: Open end blind rivets with break pull mandrel and protruding head – A2/A2.* Specifies dimensional and mechanical characteristics and application data for open end blind rivets with break pull mandrel and protruding head, with austenitic stainless steel body (A2) and an austenitic stainless steel mandrel (A2) and with nominal diameters, *d*, from 3 mm up to and including 5 mm.

Standard No. and year	Title, scope and purport
SANS 1700-18-15:2004/ ISO 15984:2002	*Fasteners – Part 18: Rivets – Section 15: Open end blind rivets with break pull mandrel and countersunk head – A2/A2.* Specifies dimensional and mechanical characteristics and application data for open end blind rivets with break pull mandrel and countersunk head, with an austenitic stainless steel body (A2) and an austenitic stainless steel mandrel (A2) and with nominal diameters, *d*, from 3 mm up to and including 5 mm.
SANS 1700-18-16:2004/ ISO 16582:2002	*Fasteners – Part 18: Rivets – Section 16: Open end blind rivets with break pull mandrel and protruding head – Cu/St or Cu/Br or Cu/SSt.* Specifies dimensional and mechanical characteristics and application data for open end blind rivets with break pull mandrel and protruding head, with a copper body (Cu) and either a steel (St) or a bronze (Br) or a stainless steel (SSt) mandrel and with nominal diameters, *d*, from 3 mm up to and including 4,8 mm.
SANS 1700-18-17:2004/ ISO 16583:2002	*Fasteners – Part 18: Rivets – Section 17: Open end blind rivets with break pull mandrel and countersunk head – Cu/St or Cu/Br or Cu/SSt.* Specifies dimensional and mechanical characteristics and application data for open end blind rivets with break pull mandrel and countersunk head, with a copper body (Cu) and either a steel (St) or a bronze (Br) or a stainless steel (SSt) mandrel and with nominal diameters from 3 mm up to and including 4,8 mm.
SANS 1700-18-18:2004/ ISO 16584:2002	*Fasteners – Part 18: Rivets – Section 18: Open end blind rivets with break pull mandrel and protruding head – NiCu/St or NiCu/SSt.* Specifies dimensional and mechanical characteristics and application data for open end blind rivets with break pull mandrel, protruding head, with a nickel copper body (NiCu) and either a steel (St) or a stainless steel (SSt) mandrel and with nominal diameters, *d*, from 3,2 mm up to and including 6,4 mm.
SANS 1700-18-19:2004/ ISO 16585:2002	*Fasteners – Part 18: Rivets – Section 19: Closed end blind rivets with pull mandrel and protruding head – A2/SSt.* Specifies dimensional and mechanical characteristics and application data for closed end blind rivets with break pull mandrel and protruding head, with an austenitic stainless steel body (A2) and a stainless steel mandrel (SSt) and with nominal diameters, *d*, from 3,2 mm up to and including 6,4 mm.
SANS 1884-1:2004	*Holding pens for temporary housing of animals – Part 1: Holding pens for wild herbivores at auctions and in quarantine facilities.* Specifies the minimum requirements for holding pens for wild herbivores at game auctions and in quarantine facilities. Concentrates on constructional and containment aspects, and does not cover animal management methods. Also does not cover temporary field pens, holding pens for animals in zoos or abattoirs, or holding pens used for housing of trained elephants.
SANS 1920:2004	*Mixtures of copper azole compounds for timber preservation.* Specifies the requirements for a concentrated mixture of copper azole compounds (in a liquid form) that, when diluted, is intended for use as a timber preservative. Provides the methods for determining the copper and tebuconazole content of the chemical compound.
SANS 8009-1:2004/ ISO 8009-1:1997	*Reusable rubber contraceptive diaphragms – Part 1: Classification, sampling and requirements.* Gives a classification of, and specifies requirements for, reusable rubber diaphragms (hereafter called diaphragms) supplied in consumer packages for contraceptive use.
SANS 8009-2:2004/ ISO 8009-2:1985	*Reusable rubber contraceptive diaphragms – Part 2: Determination of size.* Specifies a method for determining the size of reusable rubber contraceptive diaphragms.
SANS 8009-3:2004/ ISO 8009-3:1985	*Reusable rubber contraceptive diaphragms – Part 3: Determination of dome thickness.* Specifies a method for determining the dome thickness of reusable rubber contraceptive diaphragms.
SANS 8009-4:2004/ ISO 8009-4:1996	*Reusable rubber contraceptive diaphragms – Part 4: Freedom from visible defects.* Specifies two alternative methods for determining visible defects in reusable rubber contraceptive diaphragms: inspection over a lamp and inspection by inflation. The methods are of equal validity.
SANS 8009-5:2004/ ISO 8009-5:1996	*Reusable rubber contraceptive diaphragms – Part 5: Determination of tensile properties.* Specifies a method for determining the tensile properties of the dome of reusable rubber contraceptive diaphragms.
SANS 8009-6:2004/ ISO 8009-6:1985	*Reusable rubber contraceptive diaphragms – Part 6: Determination of deterioration after accelerated ageing.* Specifies methods for determining the resistance of reusable rubber contraceptive diaphragms to deterioration.
SANS 8009-7:2004/ ISO 8009-7:1985	*Reusable rubber contraceptive diaphragms – Part 7: Determination of compression resistance of coil spring and flat spring diaphragms.* Specifies a method for determining compression resistance of coil spring and flat spring reusable rubber contraceptive diaphragms.
SANS 8009-8:2004/ ISO 8009-8:1985	*Reusable rubber contraceptive diaphragms – Part 8: Determination of twisting during compression of coil spring and flat spring diaphragms.* Specifies a method for determining twisting during compression of coil spring and flat spring reusable rubber contraceptive diaphragms.
SANS 8009-9:2004/ ISO 8009-9:1985	*Reusable rubber contraceptive diaphragms – Part 9: Packaging and labeling.* Specifies requirements for the packaging and labelling of reusable rubber contraceptive diaphragms.
SANS 8009-10:2004/ ISO 8009-10:1985	*Reusable rubber contraceptive diaphragms – Part 10: Recommendations for storage.* Gives recommendations on storage conditions for reusable rubber contraceptive diaphragms to be considered by manufacturers and distributors.
SANS 10007:2004/ ISO 10007:2003	*Quality management systems – Guidelines for configuration management.* Gives guidance on the use of configuration management within an organization; applies to the support of products from concept to disposal.
SANS 10406:2004	*Transport of dangerous goods – The reprocessing of previously certified packaging.* Specifies the procedures for the reprocessing of previously certified packaging for the transport of dangerous goods, to ensure that the reprocessed packaging meets agreed upon quality standards and that the safe transport of goods packaged in such packaging is not compromised. Reprocessing includes three principal categories of activities: remanufacturing, reconditioning and repair.

Standard No. and year	Title, scope and purport
SANS 10993-4:2004/ ISO 10993-4:2002	*Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood.* Describes a classification of medical and dental devices that are intended for use in contact with blood, the rationale for structured selection of tests according to specific categories and the principles and scientific basis of these tests. Detailed requirements for testing cannot be specified because of limitations in the knowledge and precision of tests for interactions of devices with blood.
SANS 11043-2:2004/ ISO 1043-2:2000	*Plastics – Symbols and abbreviated terms – Part 2: Fillers and reinforcing materials.* Specifies uniform symbols for terms referring to fillers and reinforcing materials. It includes only those symbols that have come into established use and its main aim is both to prevent the occurrence of more than one symbol for a given filler or reinforcing material and to prevent a given symbol being interpreted in more than one way.
SANS 19114:2004/ ISO 19114:2003	*Geographic information – Quality evaluation procedures.* Provides a framework of procedures for determining and evaluating quality that is applicable to digital geographic datasets, consistent with the data quality principles defined in SANS 19113. It establishes a framework for evaluating and reporting data quality results, either as part of data quality metadata only or as a quality evaluation report. It is applicable to data producers when providing quality information on how well a dataset conforms to the product specification, and to data users attempting to determine whether or not the dataset contains data of sufficient quality to be fit for use in their particular applications. Although this standard is applicable to all types of digital geographic data, its principles can be extended to many other forms of geographic data such as maps, charts and textual documents.
SANS 20084:2004/ ECE R84:1991	*Uniform provisions concerning the approval of passenger cars equipped with an internal combustion engine with regard to the measurement of fuel consumption.* Applies to the measurement of the fuel consumption indicated by the manufacturer, from all internal combustion engined vehicles of category M1 and of category N1, having a maximum total mass less than 2 tons.
SANS 20926:2004/ ISO/IEC 20926:2003	*Software engineering – IFPUG 4.1 Unadjusted functional size measurement method – Counting practices manual.* Specifies the International Function Point Users Group (IFPUG) Release 4.1 unadjusted Functional Size Measurement Method. It provides a clear and detailed description of function point counting, a foundation to ensure that counts are consistent, guidance to allow function point counting of Functional User Requirements from the deliverables of popular software development methodologies and techniques, and a framework to enable automated support for function point counting. The provisions of this standard can be applied by anyone using function point analysis for software measurement. It was designed for use by persons new to function point counting as well as those with intermediate and advanced experience.
SANS 50081-1:2004/ EN 81-1:1998	*Safety rules for the construction and installation of lifts – Part 1: Electric lifts.* Specifies the rules for the construction and installation of permanently installed new electric lifts, with traction or positive drive, that serve defined landing levels, that have cars designed for the transportation of persons, persons and goods, are suspended by ropes and chains, and move between guide rails inclined at an angle not exceeding 15° to the vertical.
SANS 50730-1:2004/ EN 730-1:2002	*Gas welding equipment – Safety devices – Part 1: Incorporating a flame (flashback) arrestor.* Specifies requirements for safety devices in gas welding equipment for fuel gases and oxygen or compressed air incorporating a flame (flashback) arrestor. Covers requirements for the design and material of safety devices. Provides test procedures for gas tightness and pressure resistance and methods of type testing.
SANS 61029-2-11:2004/ IEC 61029-2-11:2001	*Safety of transportable motor-operated electric tools – Part 2-11: Particular requirements for mitre-bench saws.* Deals with combined mitre-bench saws intended for cutting non-ferrous metals such as aluminium, wood or similar materials with a blade diameter not exceeding 350 mm.
SANS 61643-341:2004/ IEC 61643-341:2001	*Components for low-voltage surge protective devices – Part 341: Specification for thyristor surge suppressors (TSS).* Designed to limit overvoltages and divert surge currents by clipping and crowbarring actions. Such components are used in the construction of surge protective devices, particularly as they apply to telecommunications. Contains information on terms, letter symbols and definitions, basic functions, configurations and component structure, service conditions and fault modes, rating verification and characteristic measurement.
SANS 61939:2004/ IEC 61939:2000	*Saw tables for use as saw benches – Tables for hand-held circular saws with a maximum saw-blade diameter of 315 mm – Safety requirements.* Deals with tables for hand-held circular saws with a maximum saw-blade diameter of 315 mm for use as circular saw benches.
SANS 62271-203:2004/ IEC 62271-203:2003	*High-voltage switchgear and controlgear – Part 203: Gas-insulated metal-enclosed switchgear for rated voltages above 52 kV.* Specifies requirements for gas-insulated, metal-enclosed switchgear in which the insulation is obtained by an insulating gas, other than air, at atmospheric pressure, for alternating current of rated voltage above 52 kV, for indoor and outdoor installations and for service frequencies up to and including 60 Hz.
SANS 201468:2004/ ETSI ES 201468:2002	*Electromagnetic compatibility and Radio spectrum Matters (ERM); Additional ElectroMagnetic Compatibility (EMC) requirements and resistibility requirements for telecommunications equipment for enhanced availability of service in specific applications.* Contains additional EMC requirements for telecommunications network equipment where higher performance is required to guarantee enhanced availability of service in specific applications. Covers emission, immunity and resistibility requirements of the equipment.
SANS 300132-2:2004/ ETSI EN 300132-2:2003	*Environmental Engineering (EE); Power supply interface at the input to telecommunications equipment – Part 2: Operated by direct current (dc).* Contains requirements for the output performance of the direct current (dc) power equipment at the interface 'A', and the input of the telecommunications equipment connected to interface 'A', powered by dc. Aims at providing compatibility between the power supply equipment and the power consuming telecommunications equipment, and also between different system blocks connected to the same power supply.
SANS 300132-3:2004/ ETSI EN 300132-3:2003	*Environmental Engineering (EE); Power supply interface at the input to telecommunications equipment – Part 3: Operated by rectified current source, alternating current source or direct current source up to 400 V.* Contains requirements for the output performance of the power equipment at the interface A3, and the input of the telecommunications equipment connected to interface A3. Aims at providing compatibility between the power supply equipment and both the telecommunications equipment, and the different load units connected to the same interface A3 (e.g. datacom equipment).

Standard No. and year	Title, scope and purport
SANS 301489-11:2004/ ETSI EN 301489-11:2002	*Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services – Part 11: Specific conditions for terrestrial sound broadcasting service transmitters.* Covers the assessment of transmitters, exciters, and any associated ancillary equipment dedicated for radio broadcasting services, in respect of ElectroMagnetic Compatibility (EMC). Specifies the applicable test conditions, performance assessment and performance criteria for terrestrial sound broadcasting transmitters and their associated ancillary equipment.
SANS 301489-14:2004/ ETSI EN 301489-14:2003	*Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services – Part 14: Specific conditions for analogue and digital terrestrial TV broadcasting service transmitters.* Covers the assessment of analogue and digital transmitters, exciters, and any associated ancillary equipment dedicated for television broadcasting services, in respect of ElectroMagnetic Compatibility (EMC). Specifies the applicable test conditions, performance assessment and performance criteria for analogue and digital terrestrial television broadcasting transmitters and their associated ancillary equipment.
SANS 301489-15:2004/ ETSI EN 301489-15:2002	*Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services – Part 15: Specific conditions for commercially available amateur radio equipment.* Covers the assessment of commercially available amateur radio equipment, and associated ancillary equipment, in respect of ElectroMagnetic Compatibility (EMC). Specifies the applicable EMC tests, the methods of measurement, the limits and the performance criteria for radio equipment intended for use by radio amateurs within the meaning of the Radio regulations, and associated ancillary equipment, which is commercially available.
SANS 301489-19:2004/ ETSI EN 301489-19:2002	*Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services – Part 19: Specific conditions for Receive Only Mobile Earth Stations (ROMES) operating in the 1,5 GHz band providing data communications.* Covers the assessment of Receive Only Mobile Earth Stations (ROMES), as defined in annex A, and associated ancillary equipment in respect of ElectroMagnetic Compatibility. Specifies the applicable test conditions, performance assessment and performance criteria for ROMES and associated ancillary equipment.
SANS 301489-20:2004/ ETSI EN 301489-20:2002	*Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services – Part 20: Specific conditions for Mobile Earth Stations (MES) used in the Mobile Satellite Services (MSS).* Covers the assessment of Mobile Earth Stations (MES), as defined in annex A used within Satellite radio services, and ancillary equipment in respect of ElectroMagnetic Compatibility. Specifies the applicable test conditions, performance assessment and performance criteria for MES and for the associated ancillary equipment.

SCHEDULE 2: AMENDMENT OF EXISTING STANDARDS

The standards mentioned have been amended in terms of section 16(3) of the Act. The number and date of a standard that has been superseded appear in brackets below the new number. In the case of an amendment issued in consolidated format, the edition number of the new (consolidated) edition appears in brackets below the number of the standard.

Standard No. and year	Title, scope and purport
SANS 177:2004/ ISO 1519:2002 (SABS ISO 1519:1973)	*Paints and varnishes – Bend test (cylindrical mandrel).* Specifies an empirical test procedure for assessing the resistance of a coating of paint, varnish or related product to cracking or detachment from a metal substrate (or both), when subjected to bending round a cylindrical mandrel under standard conditions.
SANS 193:2004 (Ed. 2.1)	*Fire dampers. Consolidated edition incorporating amendment No. 1.* Amended to update the definition of "acceptable", to allow the use of a resettable link in the release system, to include a reference to annex B, to change "differential" to "difference" in table 1 and "must" to "shall" in 6.6.6, to correct the equation for the calculation of the rate of airflow in the air-leakage test, and to update the referenced standards.
SANS 199:1972	*Cylinder shut-off valves for liquefied petroleum gas. Amendment No. 9.* Amended to make provision for the use of liquefied petroleum gas cylinders (fitted with internally mounted valves) with a water capacity of 15 kg.
SANS 284:2004 (Ed. 2.4)	*Spades and shovels. Consolidated edition incorporating amendment No. 4.* Amended to update referenced standards; update the definition for "acceptable"; add the clause "Normative references"; renumber the clauses and figures; update the scope and remove the "NOTE" which referred to appendices.
SANS 911:2004 (Ed. 3.2)	*Natural fibre ropes. Consolidated edition incorporating amendment No. 2.* Amended to update referenced standards and to add appendix C on quality verification.
SANS 1091:2004 (SABS 1091:1975)	*National colour standard.* Identifies a number of colours for use in various industries, mainly for colour identification and coding. The selected colours are linked to the Natural Color System. The Natural Color System (NCS) describes colour perceptions that appear to belong to the surface of a material, provided the surface is not perceived to be metallic or fluorescent. The system does not include colours that appear to belong to translucent or luminescent objects (so-called volume colours and luminous colours), nor does it include other visual properties of the surface layer, such as gloss and texture. An NCS notation does not describe the physical or chemical properties of an object.
SANS 1186-3:2004 (Ed. 1.2)	*Symbolic safety signs – Part 3: Internally illuminated signs. Consolidated edition incorporating amendment No. 2.* Amended to replace reference to SANS 166 with SANS 7253.
SANS 1329-1:2004 (Ed. 2.4)	*Retro-reflective and fluorescent warning signs for road vehicles – Part 1: Triangles. Consolidated edition incorporating amendment No. 4.* Amended to replace reference to SANS 166 with SANS 7253 and SANS 5147 with SANS 279.
SANS 1329-2:2004 (Ed. 2.5)	*Retro-reflective and fluorescent warning signs for road vehicles – Part 2: Abnormal load vehicle signs. Consolidated edition incorporating amendment No. 5.* Amended to replace references to SANS 166 with SANS 7253 and SANS 5147 with SANS 279.

Standard No. and year	Title, scope and purport
SANS 1329-5:2004 (Ed. 1.3)	*Retro-reflective and fluorescent warning signs for road vehicles – Part 5: Retro-reflective chevron decals. Consolidated edition incorporating amendment No. 3.* Amended to replace references to SANS 167 with ISO 11341, SANS 5022 with SANS 175, SANS 5156 with ISO 2810, and SABS ISO 9001, SABS ISO 9002, SABS ISO 9003 with SANS 9001.
SANS 1401-1:2004 (SABS 1401-1:2002)	*Woven cotton and similar household fabrics and articles – Part 1: Basic requirements for piece-goods and made-up articles.* Covers the definitions, basic requirements and requirements for packing, labelling, marking, and the inspection and testing of woven cotton and similar household fabrics and made-up articles whose specific requirements are covered by the relevant individual parts in the remainder of this standard.
SANS 1401-2:2004 (SABS 1401-2:1983)	*Woven cotton and similar household fabrics and articles – Part 2: Winter sheeting, sheets and pillowcases.* Covers the specific requirements of three types of raised sheeting fabric, and articles in the form of winter sheets and pillowcases for household use.
SANS 1401-3:2004 (SABS 1401-3:1983)	*Woven cotton and similar household fabrics and articles – Part 3: Cotton sheeting, sheets and pillowcases.* Covers the specific requirements of four types of cotton sheeting fabric, and articles in the form of sheets and pillowcases for household use.
SANS 1401-4:2004 (SABS 1401-4:1983)	*Woven cotton and similar household fabrics and articles – Part 4: Polyester-and-cotton sheeting, sheets and pillowcases.* Covers the specific requirements of six types of polyester-and-cotton sheeting fabric, and articles in the form of sheets and pillowcases for household use.
SANS 1401-5:2004 (SABS 1401-5:2001)	*Woven cotton and similar household fabrics and articles – Part 5: Terry towelling, towels, and other terry weave articles.* Covers the specific requirements of five types of cotton terry towelling fabric, and articles in the form of bibs, face cloths, napkins, towels and bathmats for household use.
SANS 1401-6:2004 (SABS 1401-6:1983)	*Woven cotton and similar household fabrics and articles – Part 6: Cotton curtain fabrics.* Covers the specific requirements of two types of cotton fabric suitable for curtaining for household use.
SANS 1401-7:2004 (SABS 1401-7:1983)	*Woven cotton and similar household fabrics and articles – Part 7: Cotton curtain lining.* Covers the specific requirements of two types of cotton fabric suitable for curtain linings for household use.
SANS 1401-8:2004 (SABS 1401-8:1983)	*Woven cotton and similar household fabrics and articles – Part 8: Bedspread fabrics and bedspreads.* Covers the specific requirements of three types of cotton fabrics and articles in the form of bedspreads for household use.
SANS 1401-9:2004 (SABS 1401-9:1983)	*Woven cotton and similar household fabrics and articles – Part 9: Cotton flannelette duster fabric and dusters.* Covers the specific requirements of one type of cotton flannelette fabric and articles in the form of dusters for household use.
SANS 1401-10:2004 (SABS 1401-10:1983)	*Woven cotton and similar household fabrics and articles – Part 10: Cotton ticking.* Covers the specific requirements of two types of cotton fabric suitable for mattress ticking for household use.
SANS 1401-11:2004 (SABS 1401-11:1983)	*Woven cotton and similar household fabrics and articles – Part 11: Featherproof fabrics.* Covers the specific requirements of two types of cotton fabric suitable for use in the manufacture of feather pillows for household use.
SANS 1401-12:2004 (SABS 1401-12:1983)	*Woven cotton and similar household fabrics and articles – Part 12: Kitchen cloth fabric and kitchen cloths.* Covers the specific requirements of four types of cotton kitchen cloth fabric, and made-up kitchen cloths for household use.
SANS 1401-13:2004 (SABS 1401-13:1983)	*Woven cotton and similar household fabrics and articles – Part 13: Cotton huckaback towelling and towels.* Covers the specific requirements of one type of cotton huckaback towelling fabric, and articles in the form of hemmed or roller towels for household use.
SANS 1401-14:2004 (SABS 1401-14:1983)	*Woven cotton and similar household fabrics and articles – Part 14: Cotton table-cloth fabric, table-cloths, and table napkins.* Covers the specific requirements of three types of cotton fabric, and articles in the form of table-cloths and table napkins for household use.
SANS 1401-15:2004 (SABS 1401-15:1983)	*Woven cotton and similar household fabrics and articles – Part 15: Cotton dishcloth fabrics and dishcloths.* Covers the specific requirements of three types of cotton fabric, and articles in the form of dishcloths for household use.
SANS 1439:2004 (Ed. 2.3)	*Automotive upholstery fabrics. Consolidated edition incorporating amendment No. 3.* Amended to change the designation of SABS standards to SANS standards, to change the definition of "acceptable" and to update certain test methods.
SANS 1459:2004 (Ed. 1.4)	*Traffic lights. Consolidated edition incorporating amendment No. 4.* Amended to replace references to SANS 167 with ISO 11341 and SANS 5159 with SANS 2409.
SANS 1519-2:2004 (Ed. 1.1)	*Road signs – Part 2: Performance requirements for road signs. Consolidated edition incorporating amendment No. 1.* Amended to replace references to SANS 166 with SANS 7253, SANS 167 with ISO 11341; and SABS ISO 9001, SABS ISO 9002, SABS ISO 9003 with SANS 9001.
SANS 1653:2004 (Ed. 1.2)	*Automotive carpeting. Consolidated edition incorporating amendment No. 2.* Amended to update the definition of "acceptable", to change the test methods for breaking strength and colour fastness to rubbing, to delete annex D and to insert the bibliography as a separate item.
SANS 1671-2:2004 (Ed. 1.1)	*Welding of thermoplastics: Machines and equipment – Part 2: Electrofusion welding. Consolidated edition incorporating amendment No 1.* Amended to replace the normative reference SABS 152 (withdrawn) with SANS 60947-3/IEC 60947-3.
SANS 1777:2004 (Ed. 1.2)	*Photoelectric control units for lighting (PECUs). Consolidated edition incorporating amendment No. 2.* Amended to update normative references, and to replace reference to SABS SM 182 with reference to ISO 11341.

Standard No. and year	Title, scope and purport
SANS 4074:2003/ ISO 4074:2002	*Natural latex rubber condoms – Requirements and test methods. ISO technical corrigendum No. 1.* Corrected to change the definition of acceptance quality limit; thickness; untreated condoms; requirements to mechanical properties; requirements for clinical data; minimum stability requirements; principle; radius to figure G1; note to tensile strength; temperature to controlled environment; requirements to annex G; procedure for conducting accelerated ageing studies; analysis of accelerated ageing data to estimate provisional shelf-life; background to applying the time-temperature superposition method; to delete the words "distribution curves: in "Test report"; to delete reference to annex P; to add a sentence to the note referring to the calculation of condom thickness in annex F; to correct the second paragraph on "Requirements for products proclaiming extra strength; and to change annex L on "Testing for holes".
SANS 5260:2004 (SABS SM 260:1974)	*Textiles – Yarns from packages – Determination of loop strength.* Specifies a method for the determination of the loop strength of packaged textile yarns.
SANS 5270:2004 (SABS SM 270:1974)	*Turns per metre of final folding twist and twist variation of textile yarns.* Specifies a method for the determination of the turns per metre of final folding twist and twist variation of textile yarns.
SANS 10252-1:2004 (SABS 0252-1:1994)	*Water supply and drainage for buildings – Part 1: Water supply installations for buildings.* Establishes general principles for the design, installation and testing of water installations for buildings. It is not applicable to water installations related to air-conditioning systems, industrial processes, specialized plants (including water softening plants), high temperature (exceeding 80 °C) water heating systems, and automatic sprinkler installations.
SANS 20031:1992/ ECE R31:1992	*Uniform provisions concerning the approval of halogen sealed-beam unit (HSB unit) motor vehicle headlamps emitting an asymmetrical passing beam or a driving beam or both. ECE corrigendum No. 1.* Amended to correct referenced clause numbers in Annex 7, and to delete requirements for a front fog lamp. *ECE amendment No. 1.* Amended to change the titles of the annexes and the requirements for conformity of production, to replace the text of annex 5 with new text, and to add a new annex for minimum requirements for sampling by an inspector. *ECE amendment No. 2.* Amended to change the requirements for the preparation of a dirty headlamp for the test of stability of photometric performance. *National amendment No. 1.* Amended to add information that relates to the compulsory application of the standard.
SANS 20057:1995/ ECE R57:1995	*Uniform provisions concerning the approval of headlamps for motor cycles and vehicles treated as such. National amendment No. 1.* Amended to add information to the national foreword that relates to the compulsory application of the standard.
SANS 50081-1:2004/ EN 81-1:1998	*Safety rules for the construction and installation of lifts – Part 1: Electric lifts. EN corrigendum No. 1.* Changed to correct references, wording and figures.
SANS 60335-2-92:2003/ IEC 60335-2-92:2002	*Household and similar electrical appliances – Safety – Part 2-92: Particular requirements for pedestrian-controlled mains-operated lawn scarifiers and aerators. IEC corrigendum No. 1.* Corrected to change the clause numbering for test requirements and to increase the scope for a cutting width.
SANS 60730-1:2004/ IEC 60730-1:2003 (Ed. 2.1)	*Automatic electrical controls for household and similar use – Part 1: General requirements. Consolidated edition incorporating IEC amendment No. 1.* Amended to add a normative annex C on cotton used for the mercury switch test, an informative annex D on heat, fire and tracking (applicable in Canada and USA), to modify the scope to include automatic electrical controls for industrial applications when allowed in the relevant part 2 and to add normative references and definitions.
SANS 60745-2-1:2004/ IEC 60745-2-1:2003 (SABS IEC 60745-2-1:1989)	*Hand-held motor-operated electric tools – Safety – Part 2-1: Particular requirements for drills and impact drills.* Applies to drills and impact drills. Is concerned with safety and takes into account the influence on safety of compounds necessary to achieve a required degree of radio and television interference suppression.
SANS 61044:2004/ IEC TR 61044:2002 (SABS IEC 61044:1990)	*Opportunity charging of lead-acid traction batteries.* Covers the opportunity charging of lead-acid batteries, i.e. the use of free time during a working period to top up the charge and thus extend the working day of a battery whilst avoiding excessive discharge. Gives basic rules and precautions for the use of opportunity-charging of lead-acid traction batteries of vented and valve-regulated types, when the battery manufacturer has not recommended the required operating procedures.

SCHEDULE 3: CANCELLATION OF STANDARDS

In terms of section 16(3) of the Act the following standards have been cancelled.

Standard No. and year	Title
SANS 1518:1996	*Transportation of dangerous goods – Design requirements for road tankers*
SANS 1556-3:1992	*ISO metric screw threads – Part 3: MJ threads for aerospace use*
SANS 1569:1992	*Motor vehicle safety: Rear-view mirrors installed on category L motor vehicles without bodywork*
SANS 1570:1992	*Motor vehicle safety: Braking on category L motor vehicles*
SANS 1607:1998	*Electromechanical watt-hour meters*
SANS 5406:1973	*Colour fastness of textiles to chlorinated water (such as used in swimming baths)*
SANS 7811-3:1995	*Identification cards – Recording technique – Part 3: Location of embossed characters on ID-1 cards*
SANS 7811-4:1995	*Identification cards – Recording technique – Part 4: Location of read-only magnetic tracks – Tracks 1 and 2*

Standard No. and year	Title
SANS 7811-5:1995	*Identification cards – Recording technique – Part 5: Location of read-write magnetic track – Track 3*
SANS 10301:1998	*Mobile elevating work platforms or buckets (MEWPS)*
SANS 10376:2002	*The inspection and testing of elevating platforms*
SANS 60651:2001	*Sound level meters*
SANS 60804:2000	*Integrating-averaging sound level meters*

SCHEDULE 4: ADDRESSES OF SABS OFFICES

The addresses of offices of the South African Bureau of Standards where copies of standards mentioned in this notice can be obtained, are as follows:

1. The President, South African Bureau of Standards, 1 Dr Lategan Road, Groenkloof, Private Bag X191, Pretoria 0001.
2. The Manager, Western Cape Regional Office, SABS, Liesbeek Park Way, Rosebank, PO Box 615, Rondebosch, 7701.
3 The Manager, Eastern Cape Regional Office, SABS, 30 Kipling Road, cor Diaz and Kipling Roads, Port Elizabeth, PO Box 3013, North End 6056.
4. The Manager, KwaZulu-Natal Regional Office, SABS, 15 Garth Road, Waterval Park, Durban, PO Box 30087, Mayville 4058.
5. The Control Officer, Bloemfontein Branch Office, SABS, 34 Victoria Road, Willows, Bloemfontein, PO Box 20265, Bloemfontein, 9320.

GENERAL NOTICES
ALGEMENE KENNISGEWINGS

NOTICE 1037 OF 2004

DEPARTMENT OF LABOUR

LABOUR RELATIONS ACT, 1995

VARIATION OF SCOPE OF THE NATIONAL BARGAINING COUNCIL FOR THE CLOTHING INDUSTRY

I, Johannes Theodorus Crouse, Registrar of Labour Relations, hereby, in terms of section 58(1) of the Labour Relations, 1995, give notice that the application for the variation of scope of the above-mentioned Council, has been varied as contained in the Annexure hereto.

J T CROUSE
REGISTRAR OF LABOUR RELATIONS

ANNEXURE

The scope of registration of the above-mentioned bargaining council has, in terms of section 58(1) of the Act been varied. With effect from 1 June 2004 the bargaining council is registered in respect of the Clothing Industry as defined hereunder, in the Republic of South Africa.

"Clothing Industry" means, without in any way limiting the ordinary meaning of the expression, the industry in which employers and their employees are associated for the making of all classes of the undermentioned items of apparel /clothing/garments:

Belts (manufactured from cloth), braces, brassieres, caps, collars, corsetry, cummerbunds, gloves, handkerchiefs, hats, hosiery (including ladies' stockings, pantihose and socks), knitted outerwear, knitted underwear; nightwear (including pyjamas), outerwear, protective wear (including overalls and wetsuits), scarves, shirts, suspenders, ties (including bowties), and underwear;

A. and includes

1. all operations incidental thereto and consequent thereon and all succeeding processes or operations performed in connection therewith carried on by such employers and any of their employees irrespective of the process or method used in such making and irrespective of whether such processes or operations are performed on the premises of such employers, or elsewhere;

2. all types of hand-sewing operations (including beading and embroidery), whether by hand and/or machine, on garments and/or parts of garments and irrespective of whether or not such operations are performed by such employers and any of their employees or by an establishment or persons undertaking such work on behalf of such employers and any of their employees;

3. any of the aforementioned items made for quantity production tailoring made to the order of any government department, provincial administration, S A Airways, Telkom, Transnet or local authority;

4. any part(s) of garments whether by means of a knitting process or otherwise;

5. design-room services, irrespective of whether or not such services are provided by such employers and any of their employees or by an establishment or persons undertaking such work on behalf of such employers and any of their employees;

6. fully-fashioned and/or semi-fashioned garments knitted on circular, flat or full-fashioned machinery;

7. screen process printing on garments and parts of garments performed in a clothing, textile and/or knitting establishment;

8. tailored outer garments for the execution of special measure orders from dealers whose customers' measurements are taken by or on the responsibility of such dealers;

9. the changing of labels, irrespective of whether or not such operation is performed by such employers and any of their employees or by an establishment or persons undertaking such work on behalf of such employers and any of their employees;

10. the making of button-holes, irrespective of whether or not such operation is performed by such employers and any of their employees or by an establishment or persons undertaking such work on behalf of such employers and any of their employees;

11. the ironing of garments and/or parts of garments irrespective of whether or not such ironing is done in the establishment in which such items were manufactured or in an establishment or by persons undertaking such work on newly manufactured garments on behalf of such employers and any of their employees;

12. the making up of garments from knitted fabric in the establishment in which the fabric was knitted;

13. the making up of sample garments and/or parts of garments, irrespective of whether or not such operation is performed by such employers and any of their employees or by an establishment or persons undertaking such work on behalf of such employers and any of their employees;

14. the marking-in and/or cutting of garments or parts of garments, irrespective of whether or not such operation(s) are performed by such employers and any of their employees or by an establishment or persons undertaking such work on behalf of such employers and any of their employees; and

15. the packing of garments and/or parts of garments irrespective of whether or not such packing is done in the establishment in which such items were manufactured or in an establishment or by persons undertaking such work with newly manufactured garments on behalf of such employers and any of their employees;

16. retail millinery, i.e. the making of hats in shops for sale in such shops and the making of single hats to the measurement of individual persons;

B. but excludes

1. belts, braces, garters, suspenders and armlets manufactured from leather;

2. boxing gloves;

3. retail dressmaking, i.e. the making of single garments to the measurement of individual persons;

4. tailor-made garments for individual persons: Provided such garments are not manufactured in a factory.

NOTICE 1038 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANT) ACT NO. 3 OF 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenant) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the schedule has been lodged with the Director General.

SCHEDULE

Property description of the land affected:	**Portion 3 of the farm De Hoop No. 402 I.T.**
Servitude	**-**
District	**Ermelo**
Province	**Mpumalanga**

Date:	**10 May 2004**
Submitted by:	**Zanele Nkosi**

NOTICE 1039 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANT) ACT NO. 3 OF 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenant) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the schedule has been lodged with the Director General.

SCHEDULE

Property description of the land affected:	**Portion 0 (remaining extent) of the farm Tafelkop No. 270 I.S.**
Servitude	**-**
District	**Ermelo**
Province	**Mpumalanga**

Date:	**10 May 2004**
Submitted by:	**Zanele Nkosi**

NOTICE 1040 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANT) ACT NO. 3 OF 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenant) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the schedule has been lodged with the Director General.

SCHEDULE

Property description of the land affected:	**Portion 22 of the farm Klipplaatdrift No. 504 IS.**
Servitude	**-**
District	**Amersfoort**
Province	**Mpumalanga**

Date:	**10 May 2004**
Submitted by:	**Zanele Nkosi**

NOTICE 1046 OF 2004

DEPARTMENT OF AGRICULTURE
SOUTH AFRICA

GUIDELINE DOCUMENT FOR WORK WITH GENETICALLY MODIFIED ORGANISMS

Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997)

May 2004

Department of Agriculture
Directorate: Genetic Resources
Private Bag X973
Pretoria
0001
Tel: 27 12 319 6253
Fax: 27 12 319 6329

Foreword by Ms Thoko Didiza, MP and Minister for Agriculture and Land Affairs

According to the National Biotechnology Strategy, South Africa can be summarised as follows: "South Africa has a solid history of engagement with traditional biotechnology. It has produced one of the largest brewing companies in the world; it makes wines that compare with the best; it has developed many new animal breeds and plant varieties, some of which are used commercially all over the world and it has competitive industries in the manufacture of dairy products such as cheese, yoghurt, baker's yeast and other fermentation products".

However, in spite of the achievements from traditional biotechnology, South Africa has failed to extract value from the more recent advances of the technology, such as genomics, bioinformatics and proteomics. The majority of South Africans have not benefited from recent advances in biotechnology, largely due to the political history of the country where large sectors of the population could not access services and technologies in order to respond to agricultural challenges.

The National Biotechnology Strategy is designed to stimulate growth of biotechnology industries within South Africa to enable us to take full advantage of this technology and in turn maintain sustainable development. In order to achieve this successfully, a governmental agency will champion biotechnology, built human resources proactively and develop scientific and technological capabilities in this field. In addition, successful commercialisation of public sector-supported research and development (R&D) will require strong linkages between institutions within the National System of Innovation and a vibrant culture of innovation and entrepreneurship, assisted by incubators, supply-side measures and other supporting programmes and institutions.

Government has identified agriculture as one of the sectors of the economy that require special attention because of its potential to contribute to the objectives of higher growth rates and job creation, but also for its potential in addressing other national imperatives such as improved access to and affordable health care, sufficient nutrition at low cost and the protection of our rich environment. With the vision of a united and prosperous agricultural sector, the Department of Agriculture acknowledges the diversity of the agricultural sector and aims to ensure a place and role for all farmers in a united sector. This includes sectors taking advantage of genetic engineering, provided that the technology is applied in a regulated manner.

All activities with genetically modified organisms in South Africa are regulated under the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). This Act provides for measures to promote the responsible development, production, use and application of genetically modified organisms to ensure that all activities involving the use of genetically modified organisms are carried out in such a way as to limit possible harmful consequences to the environment. The Act also makes provision for the determination of requirements and criteria for risk assessments that will ensure that genetically modified organisms are appropriate and do not present a hazard to the environment or human and animal health.

The GMO Act is administered by the Directorate Genetic Resources within the national Department of Agriculture and makes provision for a Registrar, two regulatory bodies, i.e. the Advisory Committee and Executive Council, and inspectors. The Registrar is responsible for administration of the Act, the Advisory Committee for evaluation of risk assessment data within every application and the Executive Council for taking a decision on whether a specific activity should be authorised or not. Inspectors appointed in terms of the Act monitors authorised activities with GMO's across the country.

Sections 4 and 5 of the Act stipulate the objectives, powers and duties of the Executive Council. One provision made in Section 5 is the development and publication of guidelines for all uses of GMO's. It is in accordance with this provision, as well as the aim to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms, that the Department of Agriculture has, through the assistance and recommendations

of the Advisory Committee and Executive Council, produced the guidelines provided for in this document.

These guidelines aim to provide general information on the provisions of the Act, functioning of the bodies appointed in terms of the Act, how applications are processed and provide assistance to the applicant on how to apply for a permit. The guidelines will aid in public understanding of the administration of the Act and increase transparency towards the regulation of GMO's in SA. I therefore want to express my sincere gratitude and appreciation to the Advisory Committee and Executive Council, and the Registrar for GMO's, for their commitment in developing these guidelines.

CONTENTS PAGE

1. Introduction

1.1 The national Department of Agriculture has prepared the following guideline document in consultation with the Advisory Committee and the Executive Council appointed under the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). All activities involving genetically modified organisms (GMO's) are subject to the Regulations under Section 20 of the GMO Act.

1.2 These guidelines complement the Regulations of the GMO Act, are in accordance with the regulations and the Act and should be utilised in conjunction with the regulations and the Act. These guidelines also provide information on risk assessment and risk management procedures.

1.3 The Annexures to the guidelines contain information on specific topics discussed in the document. Please take note that these guidelines are not exhaustive and will be updated when necessary and to include new scientific information, particularly when the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) has been reviewed. Application forms for any activity with GMO's in South Africa can be obtained from the Department of Agriculture's website at www.nda.agric.za.

1.4 All risk assessments will be approached in a precautionary way and that every decision on a proposed activity will be taken on a case-by-case basis.

1.5 To obtain further information on any of the sections contained in the guidelines or on completion of the application forms, please contact the office of the Registrar.

National Department of Agriculture
Directorate Genetic Resources
Private Bag 973
Pretoria
Tel: +27 012 319 6536
Fax: +27 012 319 6329
E-mail: SMGRM@nda.agric.za

2. Responsibilities

2.1 Responsibilities of applicant/permit holder

a) To comply with all applicable regulations established in SA.
b) To prepare a folder for submission to the Registrar with each application for experimental release or commercial production including all pertinent and required information on the GMO to be released.
c) Ensure that persons involved in distribution of a GMO product are adequately trained, such that they are capable of providing a user with advice on efficient and safe use. This also applies in the event that the distributor is at arms length to the owner of the product.
d) Notify the Registrar of any problem related to the release and use of the GMO, voluntarily corrective action and, when requested by Registrar, help to find solutions to any problem.

2.2 Responsibilities of companies/farmers growing GMO's

2.2.1 Farmers should:

a) Maintain appropriate records of GMO varieties, area planted and pesticide use.
b) Respect and obey indications and requirements related to risk management, including refugia and other agronomic practices, intended to prevent or delay the evolution of resistance in pests.

c) Comply with any signed agreement regulating the production, saving and distribution of GMO.
d) When growing GMO's, which involve the use of a pesticide, follow the regulatory rules for the particular pesticide and specific use.
e) Adhere to all other regulations regarding handling and cultivation of plants.

3. Potential effects resulting from activities with GMO's

3.1 The potential impact that activities with GMO's can have on the environment and human health can be categorised in mainly three sections. These include –

i) Intended and unintended phenotypic changes
ii) Intended and unintended ecological effects
iii) Intended and unintended effects on human health and welfare.

3.2 The different potential effects are outlined in Table 1 (Source: Manual for assessing ecological and human health effects of genetically engineered organisms – Reference 9.9). This table lists six general classes of potential and intended phenotypic modifications, representative kinds of intended or unintended ecological effects resulting from the modifications, and a few examples of affected human enterprises and matters of environmental protection.

3.3 The aim of this table is to remind the user of the great range of alterations and effects that need to be considered when planning an activity with GMO's. Please note that the effects resulting from a single modification may not necessarily be confined to only one category and the applicant should consider all possible effects that a modification can have.

This table is not exhaustive and new data will be incorporated when necessary.

Table 1: The relationship between the potential and intended phenotypic modifications, unintended or intended ecological effects and effects on human health and welfare.

TYPE OF EFFECT	EXAMPLES OF POTENTIAL/INTENDED PHENOTYPIC CHANGES	EXAMPLES OF INTENDED/UNINTENDED ECOLOGICAL EFFECTS	EXAMPLES OF EFFECTS ON HUMAN HEALTH AND WELFARE
Metabolism	▪ Individual growth rates ▪ Energy metabolism, pathways and rates ▪ Photosynthetic and chemosynthetic pathway structures and rates ▪ Rates of nutrient uptake and cycling ▪ Amounts and types of nutrients used ▪ Use of pollutants as nutrients, and pollution degradation ▪ Nitrogen fixing pathways and rates ▪ Carbon dioxide consumption ▪ Tolerance of elevated CO_2 ▪ Expression of novel proteins or metabolites, and increased metabolic wastes ▪ Production of antibiotics, or biological toxins such as that from *Bacillus thuringiensis* (Bt toxin) ▪ Antibiotic or pesticide resistance	▪ Altered feeding rates and efficiencies ▪ Altered rates of nutrient cycling and biological energy transfers ▪ Altered rates of photosynthesis and carbon fixation and plant productivity ▪ Modified rates and patterns of nitrogen fixing ▪ Shifts in competitive abilities among species ▪ Changes in the degree of pesticide and antibiotic resistance among target and naturally occurring species, and spread of antibiotic resistance genes by lateral transfer ▪ Release of antibiotics, toxins, or increased concentration of novel metabolites ▪ Decrease or increase of biological diversity	▪ Changes in agricultural productivity ▪ Changes in forest production and timing of tree harvesting cycles ▪ Changes in stock composition and productivity of fisheries ▪ Increased dependence on aquaculture ▪ Increased intensity and variety of food allergies due to novel proteins, hormones or other metabolites, or altered levels of normal proteins and hormones and other metabolites

TYPE OF EFFECT	EXAMPLES OF POTENTIAL/INTENDED PHENOTYPIC CHANGES	EXAMPLES OF INTENDED/UNINTENDED ECOLOGICAL EFFECTS	EXAMPLES OF EFFECTS ON HUMAN HEALTH AND WELFARE
Tolerance of physical factors	▪ Temperature ▪ Humidity or moisture ▪ Soil chemical and physical properties, including nutrients and water potential ▪ Light intensity ▪ Salinity ▪ pH (acid/base) ▪ Water chemistry ▪ Pressure ▪ Oxygen, carbon dioxide, and other gases such as those of anaerobic environments ▪ Toxic chemicals/pesticides/antibiotics ▪ Heavy metals (e.g. mercury	▪ Geographical relocation, expansion or concentration of preferred habitats for species and ecological communities ▪ Changed species/population phenology (seasonal timing of life cycles), including patters of growth, development, and breeding ▪ Altered geographical ranges of species ▪ Altered patterns of dispersal and migration ▪ Increased and change in routes and extent of biomagnification (concentration) of toxic substances, including heavy metals ▪ Changed composition and diversity of ecological communities	▪ Change in geographical or local constraints on crop production ▪ Changes in geographical or local constraints on disease vectors, pathogens, pests or pollinators ▪ New threats or persistence and abundance of terrestrial and aquatic wildlife ▪ Increased invasiveness of noxious or weedy species ▪ Loss of genetic diversity in natural populations
Morphology or architecture of organisms	▪ Animal shape, size, colour ▪ Internal and surface geometry of unicellular algae and protozoa ▪ Antigenicity of disease organisms and parasites ▪ Skeletons and appendages ▪ Leaf shape, pattern of plant nodal extension and branching, flower structure, branching and frond geometry of macrophytic algae ▪ Spines, hairs, trichomes and other protective devices ▪ Bacteria cell-wall characteristics ▪ Mosaic segments of virus ▪ Cell structure, organs, organ systems ▪ Unicellularity, multicellularity	▪ Altered species interaction: predator/prey, herbivory, competition ▪ Mate recognition ▪ Changes in bacterial cell walls and some antibiotic resistances ▪ Altered virus/host interaction ▪ Changed crop plant architecture ▪ Increase or decrease in plant protection against pathogens and herbivores	▪ Increase or decrease in virulence of pathogens ▪ Gains or losses in plant yields through changes of achritechture (e.g. dwarf varieties of rice and wheat) ▪ New problems in conservation ▪ New opportunities for horticultural innovation

TYPE OF EFFECT	EXAMPLES OF POTENTIAL/INTENDED PHENOTYPIC CHANGES	EXAMPLES OF INTENDED/UNINTENDED ECOLOGICAL EFFECTS	EXAMPLES OF EFFECTS ON HUMAN HEALTH AND WELFARE
Behaviour	▪ Reproduction ▪ Territoriality ▪ Migration, navigation or orientation ▪ Chemosensory abilities, including pheromones and allochemicals ▪ Motility/locomotion ▪ Animal communication ▪ New kinds and levels of plant secondary compounds ▪ Colonisation ▪ Phatogenicity of bacteria, virus and fungi ▪ Mutualisms/coevolution ▪ Pollination ▪ Photoperiodism ▪ Foraging patterns and feeding specialisation and rates ▪ Social behaviour, communicable and co-operative living, "altruism"	▪ Altered breeding patterns and cycles, and mate-recognition systems ▪ Change in population abundance and species assemblages ▪ Altered population dynamics and phenology ▪ Changes in self-compatibility and incompatibility of plants ▪ Changes in rates, plant species spectrum, and effectiveness of pollination ▪ Increases and decreases in pathogenicities and patterns of disease transmission	▪ Changes in local and geographical patterns of abundance of wildlife, game and commercially harvested species ▪ Alterations in agricultural productivity ▪ Increase or decrease in human, animal and plant health as behaviours of pathogens, disease vectors and pollinators change
Factors controlling or regulating natural populations	▪ Novel disease resistance ▪ Reduced predation or parasitism ▪ Habitat preferences, extensiveness of preferred and secondary habitats ▪ Antibiotic or biocide sensitivity and resistance ▪ Extinction, local or global ▪ Increases or decreases in fitness	▪ Altered population and community dynamics ▪ Release from pre-existing ecological limits or establishment of new limits ▪ Changed disease transmission ▪ Lateral transfer of antibiotic and toxin resistances among bacteria ▪ Changed tropic interactions ▪ Increase or decrease in pest and pathogen populations and the attendant problems	▪ Decline or loss of therapeutic effectiveness of antibiotics ▪ Origin of new pests, weeds and pathogens (especially plant virus modification)
Demography, life history, population	▪ Population fitness ▪ Average life cycle patterns (simple or complex)	▪ Altered population and community dynamics ▪ Shifts in the composition of ecological	▪ New problems in pest and pathogen control ▪ Epidemiological problems

TYPE OF EFFECT	EXAMPLES OF POTENTIAL/INTENDED PHENOTYPIC CHANGES	EXAMPLES OF INTENDED/UNINTENDED ECOLOGICAL EFFECTS	EXAMPLES OF EFFECTS ON HUMAN HEALTH AND WELFARE
genetics and evolution	▪ Mode of reproduction: sexual, asexual, or alternating between these two ▪ Frequency of reproduction ▪ Average rates and patterns of embryonic and larval development ▪ Patterns of metaphorphesis ▪ Age of reproductive maturity and age of last reproduction ▪ Fertility and fecundity ▪ Survival rates with age (survivorship), average longevity ▪ Net and intrinsic rates of change in population size and density ▪ Age-structure of population ▪ Social organisation, kin selection and inclusive fitness ▪ Substratum affinities ▪ Patterns of dormancy, diapause, aestivation, hibernation, and spore and seed banks ▪ Sex, sex ratios, mating types ▪ Population genetic structure, genetic recombination within populations ▪ Genotype-environment interactions and correlation ▪ Pathogens host ranges ▪ Vector host ranges and competence ▪ Geographical arrays of conspecific populations (metapopulations) ▪ Specialised genetic exchange (sexual) mechanisms of bacteria (transduction, transformation, conjugation, retrotransposons, conjugative transposons, other mobile elements) ▪ Gene flow among conspecific populations ▪ Hybrid zones and geographical clines ▪ Genetic exchange between species and phylogenetic lineage	communities and local biological diversity ▪ Increased or decreased fitness of populations ▪ Increased or decreased pop8ulation sizes and dentsities ▪ Increased or decreased populations fluctuations, population stability ▪ Altered age-structure in populations ▪ Micro-evolutionary changes set in motion in the GMO population or surrounding natural populations ▪ Changes in spatial and temporal distribution of population and species ▪ Altered genetic structure of the GMO population and their parental populations, if the two are sympatric (conspecific introgression) ▪ Increase interspecies hybridisation ▪ GMO evolution due to mutation, genetic exchange and natural selection	▪ Commercially harvested and/or game species yield change ▪ Conservation and wildlife management practices require adjustment ▪ Design of wildlife refuges and nature preserves require reconsideration and possibly change ▪ Mitigation procedures become necessary to protect biological diversity and the genetic diversity of natural populations

4. Possible routes of dispersal into the environment

When compiling an application to conduct a certain activity with GMO's, the applicant must consider all possible routes by which the GMO may be dispersed into the environment, through the duration of the activity, regardless of whether the dispersal was intended or unintended, in order to determine the appropriate level of containment required.

4.1 Natural routes of dispersal

- Flowing water
- Subsurface flowing water
- All birds, flying animals (bats), earthworms (arthropods), spiders (arachnids), etc.
- Wind
- Terrestrial vertebrates, especially mammals (fur)
- Terrestrial and flying insects
- Rafting on logs and larger floating islands broken away from shorelines, on lakes, rivers and seas
- Ocean and lake currents
- Atmospheric circulation with subsequent deposition as rain, etc.
- Autonomous locomotion
- Tornadoes, cyclones, hurricanes, floods, etc.
- Influent/makeup water
- Effluent/drawdown water
- Waste slurries
- Aerosols

4.2 Routes of dispersal due to human activity

- Shipping at sea and on large lakes and rivers
- Via ballast water and sediments
- On all the surfaces and crevices of boats below the water line
- On surfaces above the water line
- Floating oil and gas drilling platforms
- Aircraft
- Ground transport (including agricultural equipment such as tractors)
- Recreational boats
- Containers used to transport live organisms
- Containers used to transport food
- Transport of crop seeds, cuttings, and nursery stock
- On and in human bodies or clothing
- Trash, refuse or garbage
- Agricultural livestock
- Sewage systems
- Navigation canals allowing active dispersal of mobile organisms
- Transfer of water between municipalities and regions, for domestic and industrial use and irrigation
- On cleaning materials and in dust

5. Risk assessment

i) Before any activity with GMO's may be undertaken, an identification of risks to human health and the environment and the potential impacts of the GMO should be undertaken. This process is called risk assessment. Risk assessments should be conducted on a case-by-case

and step-by-step basis. For e.g. one cannot assume that because it is regarded as low risk to release GM-sorghum in the United States, that it is also safe in Africa, its centre of origin. The step-by-step principle refers to the fact that during initial work with an organism, where little is known and there is a high level of uncertainty, a conservative approach to risk management would normally be adopted. However, every opportunity should be taken to gather data on the performance of the GMO under the more restrictive conditions in order to be able to form judgements about the future safety if the control measures are relaxed.

ii) A properly conducted risk assessment should reveal all hazards posed by the GMO, a comprehensive description of such hazards, how the identified hazards could be realised, the likelihood and frequency that harm will result should the hazards be realised and, an overall evaluation of the risk and the type, significance and magnitude of impacts should the hazards be realised.

iii) The level of detail to be considered during a risk assessment will depend on circumstances. All risk assessments have to be "suitable and sufficient". For a simple operation involving a well-known and well-understood organism, the hazards will be relatively low and may it be possible to declare the result of the assessment almost at first glance. For a complex operation involving dangerous organisms about which there is a lot of uncertainty, the assessment will have to be extensive and may involve the acquisition of new data.

iv) Note that it is always permissible to assume the worst and act accordingly if there are any doubts present when performing the assessment. In other words, if there is a range of risk for a given organism and activity within which you are uncertain of the level of risk, you may simply choose to apply control measures appropriate to the upper bound of the range applicable.

v) A risk assessment should always be reviewed if there is any reason to suspect that the initial assessment is no longer applicable due to significant changes in the activity, or the acquisition of new scientific knowledge.

5.1 Risk assessment with regard human health aspects

This section deals in general with the issues that need to be considered when determining the effects of a GMO on human health. The following issues should be taken into account –

a) Possible modes of exposure (i.e. skin contact, ingestion, inhalation of aerosols, etc.)
b) Concerns with regard to
   - Toxic, allergenic and pathogenic effects
   - Product hazards.
   - Transfer of antibiotic resistance, etc.
c) Concerns related to human activities, such as –
   - diseases caused and mechanism of pathogenicity, including invasiveness and virulence.
   - communicability.
   - infective dosage.
   - host range, possibility of alteration.
   - possibility of survival outside of human host.
   - presence of vectors or means of dissemination.
   - biological stability
   - antibiotic resistance patterns.
   - allergenicity
   - availability of appropriate therapies, etc.

(d) Susceptibility of humans exposed to the GMO (e.g. immunosuppressed status)

Although there are various methods available to undertake risk assessment for human health, one can make use of the Brenner Scheme, which deals primarily with human health issues. More information on this Scheme can be found in Section 5.4.1.

5.2 Risks related to food safety

Additionally to the elements indicated above, the following information would be required to conduct an assessment of the safety of food derived from GMO's. Please note that the provisions of the GMO Act deal only with live GMO's. Once the organism has been processed in such a way that viable organisms are no longer involved, such as in processed foods, the safety issues no longer fall under the GMO Act, but under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act no. 54 of 1972), administered by the Department of Health. Additionally, the Department of Health is responsible for Regulations governing labelling of GM foods.

Notwithstanding the above, food and feed safety assessments of GMO's will be conducted according to the principles and guidelines for risk analysis of foods derived from modern biotechnology, in accordance with the procedures as proposed by the Department of Health and Codex, while the GMO is being assessed under the GMO Act. The Department of Health may be contacted at –

Director: Food Control
Department of Health
Private Bag X828
Pretoria
0001
Tel: +27 12 312 0186
Fax: +27 12 326 4374
E-mail: ventert@health.gov.za

Although the following paragraphs mainly focus on the products derived from plants, other types of foods derived from GMO's should also be considered. These include probiotic food supplements containing micro-organisms and meat derived from genetically modified animals.

5.2.1 General requirements for food safety assessments

In order to facilitate the evaluation of data, the following information is requested and according to the format below.

a) Summary
The applicant should submit a comprehensive summary of all results.

b) Data
The applicant should submit a complete package of the data required for food safety assessments. The data should be concisely presented.
- Each volume should contain a table of contents, mentioning the title and page numbers.
- An index of each package of data must be provided in a separate volume should more than one volume be submitted.
- The contents must be entered under the appropriate headings. Each entry should include the date of submission, originating laboratory, company name, author, title of the paper and location in the submission (page and volume number).

c) Reporting of data
The format and content of the reports should be as follow –

- Each report should include a copy of the Good Laboratory Practice (GLP) certificate and must provide
  - the name of the study director,
  - date of completion,
  - statements on Good Laboratory Practices and Quality Assurance (QA),
  - signature of the senior scientific responsible person, and
  - certification by the applicant, or an authorised agent of the applicant, as a complete and unaltered copy of the report provided by the test laboratory.
- Summary of the test results
- Full description of the test procedures and methods, including deviations and reasons for the deviations.
- Reporting of the results and evaluation of specific tests including all data, information and analysis done.
- Discussion of positive and negative results. Explanations must be given, based on sound scientific principles. Conclusions arrived at by the study author must be included.
- Appropriate statistical methods shall be used to summarise experimental data, to express trends, and to evaluate the significance of differences in data obtained from different test groups. All data averages or means shall be accompanied by standard deviations.
- References must be supplied for the statistical and other methods employed for analysing data, any for any published literature used in developing the test protocol, performing the testing, making and interpreting the observations, and compiling and evaluating the results.
- A description of the testing method must be supplied. Toxicological methods described by the OECD and the US-EPA are specific requirements. For chemical analysis the Collaborative International Pesticide Analytical Council (CIPAC) or the AOAC International is preferred.

d) Literature studies
The following information is required when literature is submitted to substantiate the submission –
- A copy of the journal article or the publication
- Motivation for the inclusion of the published information
- Assessment of the published information
- Reference to the published data in the assessment at appropriate places in the text.

e) Registration status
Full details of the registration status in other countries, specifically with respect to food safety.

5.2.2 Codex Alimentarius Commission

The Codex Alimentarius Commission approved the following documents –

a) Principles for the risk analysis of foods derived from modern biotechnology.
The framework is as follow –
- Description of the recombinant-DNA plant
- Description of the host plant and its use as a foodstuff
- Description of the donor organism
- Description of the genetic modification(s)
- Characteristics of the genetic modification(s)
- Safety assessment:
  - Expressed substances (non-nucleic acid substances)
  - Compositional analysis of key components
  - Evaluation of metabolites

- Food processing
- Nutritional modifications

▪ Other considerations

b) Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants, including the assessment of possible allergenicity.

c) Guidelines for the conduct of food safety assessments of foods produced using recombinant-DNA micro-organisms.

In line with Codex Alimentarius Commission, the Department of Health accepts these Principles and Guidelines as policy documents. The applicant should study these documents when compiling an application that involves food safety issues.

5.2.3 Additional data and information on food safety issues

a) Exposure assessment
An exposure assessment based on South African food intake data must be submitted. This must be accompanied by a calculation of the Safety Factor.

b) Use of antibiotic marker genes
An assessment of the presence of antibiotic marker genes must be conducted. The availability of any clinically used antibiotics in South Africa must be a specific consideration.

c) Animal feed
A food safety assessment is applicable to all applications for licensing of a genetically modified organism, whether applied to food and/or feed (i.e. commodity clearance).

5.3 Environmental risk assessments

i) The main objective of an environmental risk assessment of GMO's is to identify possible effects on the environment from growing these plants. Risk identification is only the first step in a conventional risk assessment, the other steps being risk characterisation (magnitude of the risk), exposure assessment (in this context an estimate of likelihood or frequency of identified risks) and finally risk communication.

ii) Risk assessment takes into account the results of the three steps to provide an estimation of the likelihood of any adverse effect occurring, as well as an estimate of the magnitude of harm that might result. This risk assessment may be quantitative or qualitative. The latter has prevailed in previous cases with approval of GMO's, because the complexity of biological systems makes it difficult to pursue a quantitative approach. Much of the needed information for a risk assessment can be obtained from practical experience with traditional crops growing in the same environment, but in some cases further experimentation is needed particularly regarding gene flow and fitness.

iii) In accordance with the Act, the applicant is required to deliver the relevant information and the Executive Council will then base their evaluation upon this information, combined with expert opinions (Advisory Committee) and public input. The objective of the following section is, however, only to identify potential adverse ecological risks to the environment.

5.3.1 Delimitation

This section of the guidelines is confined to dealing with the environmental risk assessment of GM-plants and is based on a strictly scientific and technical approach. The risk assessment must be performed on a case-by-case basis and adapted to the local conditions and agricultural production system. Relevant aspects related to GMO's such as food and feed safety, pleiotropic effects associated with transgenes, ethical concerns and socio-economic consequences are not considered in this section.

5.3.2 Potential risks of GM-plants, in particular herbicide resistant crops (HRC) and insect resistant crops (IRC).

Kindly note that undertaking a risk assessment may also include potential benefits from the introduction of the GMO, and not only negative effects, in order to provide for a balanced view.

i) The GM-plant may establish itself beyond its agricultural boundaries and growing season and become a weed in the succeeding crops.
ii) The GM-plant may inter-cross with non-transgenic relatives growing in the same or adjacent areas, depending on cross pollination characteristics and agents such as wind or by insects. In some instances where the population size of native relatives is low, genes from the transgenic crop may come to dominate the native population and lead to their extinction. The compatibility between the HRC/IRC and non-target species is of utmost importance in this regard. In the instance of the GM-plant crossing with wild relatives, this should be considered in context of (a) inter-crossing that might already have occurred between the non-transgenic crop and the wild relative (are the risks any different in the case of a GM crop?) and (b) any likelihood of real adverse effects on the environment as a result of such inter-crossing.
iii) The GM-plant may have botanical identical or closely related species that can hybridise with the plant, either in the adjacent ecosystems or in the agro-ecosystem. Hybridisation could lead to the spread of introduced genes into non-transgenic crops, gene stacking in volunteer plants and transfer of introduced traits to weedy or wild species.
iv) The continued use of HRCs with their associated herbicide over large areas for several years may unintentionally change the composition of the weed flora by selecting for naturally tolerant weeds. This is particularly important in monocultures or in cropping systems with limited crop rotation or minimum tillage. However, this is only valid if it takes into account the potential impact of changes in herbicide usage compared with the current situation. Herbicides have been used routinely in agriculture for many years so the issue of herbicide resistance in weeds is not new.
v) The potential beneficial and negative effects of HRC and IRC should be mentioned (e.g. less loss of topsoil as a result of minimal tillage in the case of HRC, and less impact on non-target insects through the use of IRC as an alternative to indiscriminate chemical spraying)
vi) The engineered traits may increase fitness of volunteers or weedy hybrids, thus making a crop turn into a weed that can interfere with future crop production or aggravating the negative impact of existing weed species. The incorporation of resistance into a non-target species may also alter its competitive ability and displace other native species.
vii) Intensive use of GM-plants to control pests or diseases may result in the selection of insect or microbial strains resistant to this method of control.

5.3.3 General information desirable for risk assessment of GM-plants

i) Information related to the GMO
- Taxonomic description and scientific name
- Cultivar's name
- Diagnostic phenotypic and genetic markers
- Description of geographic distribution and of the natural habitat of the plant
- Potential for gene flow and exchange with other plants
- Ecological and physiological traits
  - Generation time in natural ecosystems, sexual and asexual reproductive cycle
  - Information on survival, including the incidence of volunteers and the ability to form perenniating structures (propagules)
- Pollination mechanism (s)
- Longevity of pollen or seed
- Methods of vegetative reproduction
- Any mechanism to limit propagation (e.g. male sterility)
- History of previous releases or uses of the GMO

ii) Information inserted genetic material in the GMO and related to the genetic modification process
- Methods used for the modification
- Description of the inserted genetic material and vector construction
- Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question
- Description of genetic trait(s) or phenotypic characteristics, particularly new traits and characteristics which may be expressed or no longer expressed
- Stability of the genetic trait(s)
- Rate and level of expression of the new genetic material
- Cumulative effects of more than one insert in the event (e.g. stacked events, such as MON810 x NK603)
- Description of identification and detection techniques

iii) Information on the receiving environment
- Geographical location of the site
- Proximity to protected habitats or areas
- Proximity to compatible, related species
- Climatic characteristics and flora and fauna of the region
- Description of target and non-target ecosystems likely to be affected
- Any known planned developments or changes in land use in the region which could influence the environmental impact of the released crop
- Description of ecosystems to which the GMO could be disseminated
- Distance from human settlements
- Prevailing winds
- Proximity of surface water

iv) Information related to the interactions between the GMO and the environment:
- Characteristics affecting survival, multiplication and dissemination
- Studies of the behaviour and characteristics of the GMO and their ecological impact
- Post release genetic transfer capability from the GMO into organisms in the affected ecosystems
- Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMO
- Description of genetic traits, which may prevent or minimise dispersal of genetic material.
- Routes of biological dispersal and known or potential modes of interaction with the dissemination agent.

v) Potential environmental impact
- Potential for excessive population increase in the environment
- Competitive advantage of the GMO in relation to the unmodified recipient
- Anticipated mechanism and result of interaction between the released plant and wild and weedy relatives
- Known or predicted effects of non-target organisms on the environment, impact on population levels of all potential competitors.

5.3.4 Information required with regard to the conditions of experimental release

i) Description of the proposed release including the purposes and foreseen products
ii) Foreseen dates of the release and time planning of experiment including frequency and duration of release
iii) Size of the site
iv) Method to be used for the release
v) Quantities of GMO to be released
vi) Method of cultivation and description of general agricultural practices
vii) Post-release treatment of the site

viii) Techniques which will be applied for the elimination or inactivation of the GMO upon experiment completion

ix) Information on and results of previous releases of the GMO, especially at different scales in different ecosystems.

x) Problems associated with volunteer plants
- Is the crop known to leave volunteers in succeeding crops?
- Does the crop have weedy traits?
- What is the characteristic of the volunteer plants?
- Can the volunteer be easily controlled? Explain how.
- Is a herbicide used for the control of non-transgenic volunteers in succeeding crops?
- Is the volunteer able to establish in the wild?
- Does the trait present in the volunteer increase the fitness of the volunteer compared to non-transgenic volunteers?

xi) Hybridisation with weedy or wild relatives
- Is the crop strictly self-pollinating?
- Is the trait maternally inherited?
- Do hybrids occur between the crop and weedy/wild relatives?
- Do these relatives occur in the proximity of the crop?
- Do the relatives and the GM-crop have similar flowering periods?
- Do the GM-crop or relative set seed?
- Is there a severe fitness penalty in the first generation backcrosses?
- Does the trait give hybrids, backcrosses or wild relatives an advantage on arable land or wild habitats?
- Does the hybrid or backcross have the same trait as the GM-crop?
- Can the hybrid or backcross be controlled by means of herbicides or through any other means?
- Is the hybrid or backcross able to survive and establish in the wild?

xii) Hybridisation with non-GM-crops
- Is the crop strictly self-pollinating?
- Is the trait maternally inherited?
- Can pollen be dispersed to and fertilised by other crop varieties?

xiii) Built-up resistance in insects
- Does the GM-crop comprise a minor proportion of the local area planted with non-transgenic varieties of the crop?
- Does the GM-crop contain different ingredients active against the harmful insect?
- Is expression of the trait confined to a selected growth stage of the crop and how long does this growth stage last?
- If resistance occurs, is expression of the trait associated with a significant fitness penalty for any resistant insects?
- Can resistant insects be controlled by other control measures?

xiv) Dispersal in time and space

The transfer of genes involves hybridisation, and is followed by the subsequent establishment and persistence of the hybrid. The transfer of genes to different entities, i.e. non-transgenic crops, wild non-weedy relatives, weedy relatives and volunteers may be influenced by the following elements-
- Transfer of genes to non-transgenic crops:
  - Consider the release of pollen and the possibility of male sterility
  - The proximity between crops relative to pollen dispersal distance
  - Synchrony of flowering
  - Seed set of the crop
- Release of pollen to wild non-weedy relatives:
  - Identification of the centre of origin or diversity of the crop
  - Presence of wild relatives in the natural habitat of the non-GM crop
  - The release of pollen from the GM-crop (male sterility)
  - Presence of cross compatible wild species

- Proximity in distance between crop and natural habitat
- Synchrony of flowering
- Will the transferred trait control insects, which are natural enemies of the wild species?
- Whether the insect is a significant constraint to the abundance of the wild species.

• Transfer of genes to wild relatives
- Release of pollen from the crop (effect of male sterility)
- Presence of cross compatible weedy species
- Synchrony of flowering
- Seed set
- Seeds that will survive and be incorporated into seed banks. Deposits into seed banks will be influenced by (a)seed dormancy after seed shed and (b)cultural practices (post harvest harrowing)
- GM-hybrids being backcrossed into wild species. This will depend on (a) the first generation of backcrosses and (b) the presence of the wild species and GM-hybrids in succeeding crops.
- GM-wild species which are not suffering from a fitness penalty. This occurrence will depend on the potential of these species to become a problematic weed problem, and it will require an increased fitness compared to non-transgenic weeds.

• Transfer of genes to volunteers
- The management of GM-volunteers is in most cases no different than those practices used for non-transgenic volunteers.
- Considerations should be given to whether the GM-volunteer may become a weed problem under conventional circumstances, posing difficulties to control.
- It should be determined whether the GM-volunteer's seed have the potential to accumulate in the soil and build up a persistent seed bank.

xv) Possibility of the GMO becoming a weed outside agriculture
- The possibility of GMO's becoming weeds outside agriculture depends on whether volunteer plants can establish as feral populations in neighbouring non-agricultural areas.
- It should be determined is the volunteer plant have biological and ecological attributes that will make it invasive of natural habitats
- Determine whether the trait does indeed confer any advantage to the crop outside agricultural boundaries.

xvi) The presence of seed banks

The presence of a seed bank can influence the environmental risks imposed by the GM-crop in the following manner:
- A seed bank may enable a weed or volunteer to spread in time.
- A seed bank may facilitate
  - Cross breeding of volunteer and succeeding crops of the same species by allowing the crop to grow as a volunteer
  - Cross breeding of volunteer and compatible weedy species by allowing the crop to come into contact with the weed in a succeeding crop
  - Emergence of volunteers which may not be controlled by the herbicide to which the GM crop was resistant

xvii) Development of resistance in other potentially harmful organisms
- Planting of GM-crops and using a selective set of herbicides may result in new selection pressures on weeds for herbicide tolerance.
- Similarly a selective pressure for the development of resistance may develop in certain insects.

xviii) Effects on non-target organisms
- Non-target organisms can range anything from the following –
  - Insects harmed from direct feeding on the crop
  - Insects harmed from feeding on pollen dispersed from the crop to the leaf surface of host plants

- Predators to harmful organisms, which are feeding on insects that are negatively affected by the GM-crop
- Predators feeding on insects which are not negatively affected by eating the GM-crop, but the toxins from the GM-crop affect the predators negatively
- Predators feeding on weed species which are controlled during planting of GM-crops.

- Micro-organisms or other soil dwelling organisms harmed by metabolising debris from the GM-crop.
- The applicant should determine the extent to which non-target organisms will be affected, positively and negatively, when introducing the GMO into the receiving environment. If the introduction will lead to a noticeable fluctuation in the population size of the organisms and have a major positive or negative impact for the natural or agro-ecosystems, this should be addressed in the application.
- Due to a lack in knowledge of many of the effects on non-target organisms, the applicant should consult scientific experts to conduct an evaluation of the impact that the organism has on non-target organisms. This should be done on a case by case basis.

5.3.5 Information required in the case of application for placing in the market

i) Name of product and names of GMO contained therein
ii) Name and address of manufacturer in country of origin
iii) Specificity of the product including the appropriate environment and geographical area of the country for which the product is suited
iv) Estimated production or import to the country
v) Proposed packaging (to prevent unintended release during storage or at a later stage)
vi) Proposed labelling in the official language(s) of the country including information on handling and agricultural use.

5.3.6 Information on monitoring and control of release

Extensive international discussions are ongoing regarding traceability with respect to food. The Codex Ad Hoc Task Force on Foods derived from Biotechnology reached consensus on the following: Article 21 of the Principles for the risk analysis of foods derived from modern biotechnology – risk management reads: "Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods: reference materials; and, tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring in circumstances as indicated in paragraph 20'

Paragraph 20 reads " post marketing monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered on a case-by-case basis, during risk assessment and its practicability should be considered during risk management. Post market monitoring may be undertaken for the purpose of:

- verifying conclusions about the absence or the possible occurrence, impact and significance of the potential consumer health effects; and
- monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact"

Monitoring is therefore subjected to a need for monitoring identified in the risk assessment.

Possible monitoring aspects to take into consideration are -
i) Methods for tracing the GMO and monitoring its effects
ii) Specificity, sensitivity and reliability of monitoring techniques
iii) Techniques for detecting transgenes introgressed into non-target plants

iv) Methods and procedures to avoid and minimise the spread of the GMO beyond the site of release or the designated area for use
v) Methods and procedures for controlling the GMO in case of unexpected spread.

5.4 Environmental risk assessment of genetically modified micro-organisms

i) This part is intended to provide guidance on the risk assessment, for environmental safety, of work with modified bacteria, fungi, cell cultures, etc. The risk assessment must include the identification of any potential harmful effects, characteristics of the proposed activity, the severity of the potential harmful effects and the likelihood of them occurring. After the assessment is complete, appropriate containment and control measures must be indicated.

ii) Risk assessments of genetically modified micro-organisms will vary in the amount of detail necessary to draw conclusions about the hazards related to the activity, the likelihood that they will give rise to harm and the control measures required. Simple activities involving low hazard, well-known and well-understood organisms may normally need less detailed considerations than complex activities involving hazardous and less familiar organisms. For example, the risk assessment of an activity that involved the cloning of viral polymerase genes to replace the polymerase gene of a pathogenic virus would be considered as complex and would therefore at least require (for each construct) consideration of the following factors:

- the properties of the parental virus, including the extent to which the infectivity or tissue tropism of the virus may be limited at the level of expression of the virus polymerase;
- the known properties of each of the polymerase genes being cloned;
- the likelihood that each gene would substitute for the function of the wild-type polymerase;
- details of the precise manner in which each gene would be cloned and the consequences that this might have for the expression of the gene as compared to the wild-type polymerase;
- the likelihood that the modified virus may have an altered tropism or infectivity.

iii) For detailed information and guidance in conducting risk assessments of activities with micro-organisms, the Regulations on Hazardous Biological Agents of the Health and Occupational Safety Act, 1993 should be consulted.

iv) In addition to selecting appropriate control measures, the risk assessment procedure includes the classification of all activities involving genetically modified micro-organisms into one of four risk groups (classes), i.e. Risk Group 1, Risk Group 2, Risk Group 3 and Risk Group 4. The assignment to a risk group must be made on the basis of the outcome of the risk assessment process. More details on the classification of activities are contained in paragraph 5.4.2.

v) Recognising that containment measures form a continuum rather than four discrete levels, many activities will require control measures, which fall somewhere between two levels. For instance, the risk assessment may show that an activity requires laboratory level 2 containment with the addition of negative air pressures and HEPA filtration of extract air. This implies that the activity lies between levels 2 and 3. In such a case the classification should be to the higher level (in this case containment level 3)

5.4.1 Risk assessment of genetically modified micro-organisms using the Brenner Scheme

i) As mentioned before, the risk assessment of genetically modified micro-organisms involves the assignment of appropriate containment and control measures on the basis of both human health and environmental factors. In the majority of cases the containment and control measures appropriate for the protection of human health and safety will also be sufficient to protect the environment.

ii) One method of assessment that may be used by the applicant to provide for the protection of human health and safety, is the Brenner Scheme. This scheme provides a method to determine the risks associated with a particular combination of inserted DNA, vector and host organism.

iii) Although the Brenner system can be extremely useful, it should be pointed out that there are instances where it does not give a reliable indication of the appropriate containment level. Examples include:

- Cloning of genes that alter or exacerbate existing pathogenic traits, e.g. pathogenic determinants, or clinical use of the antibiotic resistance genes whose dissemination might prejudice clinic use of the antibiotic
- Work with host strains where there is uncertainty over the level of attenuation
- Work that does not involve a construct formed in a classical way, from a plasmid vector and an inserted coding sequence, e.g. deletion mutants, certain cell fusion.

iv) Please note that this scheme does not constitute a complete risk assessment, but only gives an indication of the level of containment appropriate for human health. Furthermore, this is not the only manner in which risk assessments may be conducted and other methods may be used.

v) The Brenner scheme considers three characteristics of the GMO before a decision can be made on an efficient containment level, viz. –

A. Access

- The access factor is an indication of the likelihood that the GMO could enter and survive in a human. Depending on the GMO, various routes of entry should be considered, as well as the properties of the vector.
- The value assigned under this section should also take into account the structure and stability of the vector in the final GMO, the frequency of mobilisation and the capacity of the final GMO to colonise a human.
- If the attenuated or disabled strain of an acknowledged pathogen is used, data supporting an alteration of the hazard group of the pathogen must be made available with the application.
- Please refer to Table 2 for indications of the most appropriate access factor for a particular GMO/vector combination.

Table 2: Access factors for host/vector combinations

Vector	Host		
	Especially disabled[1]	Disabled or non-colonising[2]	Pathogenic, colonising or wild type [3]
Non-mobilisable[4]	10^{-12}	10^{-9}	10^{-3} /1
Mobilisation defective[5]	10^{-9}	10^{-6}	10^{-3} /1
Self mobilisable[6]	10^{-3}	10^{-3}	1

[1] *Especially disabled host* means one whose growth requires the addition of specific nutrients not available in humans or outside of the culture media and is sensitive to physical conditions or chemical agents present in man or the environment. This definition applies to certain specific organisms with an extended history of safe use, as well as some strains of *E. coli* K12 and cell or tissue culture systems where the vector does not have the ability to infect or transfer DNA to other cells.
[2] *Disabled or non-colonising hosts* means a multiple auxotroph or their host which is unlikely to persist in the gut, lung or survive outside of the culture media, e.g. most strains of *E. coli* aK12 and other species.
[3] *Pathogenic or colonising hosts* includes all other hosts. A value of 1 applies if it is pathogenic or non-pathogenic but able to colonise humans. A value of 10^{-3} is appropriate if it is wild type and capable of survival outside of culture.
[4] *Non-mobilisable vectors* are Bom^-, (Nic^-), Mob^-, and Tra^-. They include E *coli* plasmid vectors such as pUC, pAT153, pACYC184, pBR327 and pBR328 and their derivates.
[5] *Mobilisation defective vectors* are usually Bom^+ but Mob^- and Tra^-. They include *E. coli* plasmid vectors such as pBR322, pBR325, RP4DI, pACYC177 and p15A and their derivates.

B. Expression

- Expression is a measure of the anticipated or known level of expression of the inserted sequence.
- A probability of 1 is appropriate when the expression system is designed to produce at a maximum rate (include all systems which produce either >10% soluble protein or >200mg l^{-1} protein) in the host.
- Please refer to Table 3 for examples of expression factors that might be applied to an initial cloning experiment on the basis of the known properties of the promoters contained in the vector or insert and their likely activity in the GMO.
- Some vector systems utilise a promoter which is not recognised by normal host RNA polymerases, e.g. T3, T7 or SP6 promoters. When cloning into these vectors, the expression factor should be that appropriate for the level of expression, which is anticipated in the absence of the correct polymerase, i.e. 10^{-6} or 10^{-9}.

Table 3: Relative values for the expression factor for an initial cloning experiment.

	Expression factor
Deliberate in-frame insertion of expressible DNA downstream of a strong promoter (e.g. P_L, P_R, *tac, trp, lac, Cm)* with the intention of maximising expression (e.g. vectors pDS-5, pUC8-I, pUC9-I).	1
Insertion of expressible DNA downstream of a strong promoter (see above) with no attempt to maximise expression.	10^{-3}
Insertion of expressible DNA into a site of limited promoter activity (e.g. *Bla* promoter in pBR322)	10^{-6}
Insertion of expressible DNA at a site specifically engineered to prevent expression (e.g. pDOC55, pNH series)	10^{-9}
Non-expressible DNA, e.g. DNA with no foreseeable biological effect or gene containing introns which the host is unable to process.	10^{-12}

C. Damage

- This factor is a measure of the likelihood of harm being caused to a person by exposure to the GMO.
- This factor should be considered independently from the Access and Expression factors. However, this factor becomes mostly important when these factors allow for a significant dose of the active product to be generated within the body of the exposed person.

- The assessment of potential damage should be linked to the known or suspected biological activity and to the levels and nature of the product required to elicit this activity.
- The Damage factor should in particular reflect health considerations such as the activity of the expressed protein and any toxic, allergenic or pathogenic effects caused by the GMO. Attention should also be given to bacterial or human fusion proteins, which might induce autoimmune disease in persons, sensitised to the protein.
- The biological activity of a product may be dependant on the host cell system in which the product is expressed, and the full biological activity of other molecules will be dependant on post-translational modifications, glycosylation or renaturation, which will only be achieved in certain host organisms (usually animal cells)
- Consideration should also be given to whether the protein is synthesised as an inactive fusion product or not.
- Table 4 contains examples that might be of use when assigning the appropriate damage factor.

Table 4: Recommended values for Damage factors

	Damage factor
A toxic substance or pathogenic determinant that is likely to have a significant biological effect	1
A biological active substance which might have a deleterious effect if delivered to a target tissue, OR a biological inactive form of a toxic substance which, if active, might have a significant biological effect	10^{-3}
A biologically active substance which is very unlikely to have a deleterious effect or, for e.g. where it could not approach the normal body level (e.g. less than 10% of the normal body level).	10^{-6}
A gene sequence where any biological effect is considered highly unlikely either because of the known properties of the protein or because of the levels encountered in nature.	10^{-9}
No foreseeable biological effects (e.g. non-coding DNA sequence)	10^{-12}

D. Assignment of containment

- An indication of the GMO's potential to cause harm to human health is determined by multiplying the individual values allocated under Access, Expression and Damage.
- This value can be used to assign a particular containment level, making use of Table 5.
- The containment levels that are indicated in this table might be used when considering the likelihood of harm from occurring, as it largely determines the level of exposure to the GMO.

Table 5: Provisional containment levels for human health

Overall value	Containment level
10^{-15} or lower	1
10^{-12} or lower	2
10^{-9} or lower	3
10^{-6} or lower	3 or 4*
Greater than 10^{-6}	4

* case by case

5.4.2 Classification of biological agents

i) Biological agents can be classified, based on their inherent risks, into different risk groups, which are analogous to the levels of containment. These classifications presume ordinary circumstances in the research laboratory or growth in small volumes for diagnostic and experimental purposes.

ii) The classification into risk groups and the derivation of containment and control measures, though related, are separate procedures. Nevertheless, most group 1 genetically modified micro-organisms will probably only require containment level 1. If the organism is classified into group 2 and the assessed level of containment is above level 1, then both classification and containment level should be checked to make sure that they are correct. It is quite possible that they are; assignments to a particular containment level do not determine the classification of the GMO.

iii) In classifying GMO's (as opposed to any other class of biological agent) the classification must consider the following –

- The recipient or parental organism (host)
- The vector
- The insert (cloned) DNA
- The final GMO

iv) The inherent risks of biological agents (conventional or genetically modified) are further determined on the basis of several factors. These factors include:

- the severity of disease it cause
- the routes of infection
- its virulence and infectivity
- the existence of effective therapies
- possible immunisation
- presence/absence of vectors
- quality of the agent and whether the agent is indigenous
- possible effects on other species.

v) In the following paragraphs a brief outlay is given of the precautions applicable to each of the containment level. However, please take note that these containment levels are designed for micro-organisms and cannot be extended to other GMO's. For further guidance and more information on the classification of hazardous biological agents, please consult the Regulations for Hazardous Biological Agents of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), available at the following address:

The Registrar
Department of Labour
Private Bag X117
Pretoria
0001
Tel: +27 +12 309 4374
Fax: +27 +12 320 5112

a) Criteria for classification into Risk Group 1
   - Agents posing low individual and community risk.
   - A biological agent that is unlikely to cause disease in healthy workers or animals.

b) Criteria for classification into Risk Group 2
- Agents posing moderate individual risk and limited community risk.
- An agent (pathogen) that can cause human or animal diseases but, under normal circumstances, is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment.
- Laboratory exposures to these agents rarely cause infection leading to serious disease; and effective treatment and preventative measures are available.
- The risk of spread of these agents is limited.

c) Criteria for classification into Risk Group 3
- Agents posing a high individual risk but low community risk.
- A pathogen that usually causes serious human or animal disease, or which can result in serious economic consequences.
- A pathogen that does not ordinarily spread by casual contact from one individual to another.
- Pathogens that can be treated by anti-microbial or anti-parasitic agents.

d) Criteria for classification into Risk Group 4
- Agents posing a high individual risk and high community risk.
- A pathogen that usually produces very serious human or animal disease, often untreatable.
- A pathogen that may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or by casual contact.

Table 6 illustrates the group classification and the corresponding range of possible containment levels:

Table 6: Containment levels applicable to each risk group

Risk Group	**Containment level necessary to control risk**
Risk Group 1	Level 1 (or less)
Risk Group 2	Level 1 + additional measures from containment level 2 Level 2 (without additional measures)
Risk Group 3	Level 2 + additional measures from containment level 3 Level 3 (without additional measures)
Risk Group 4	Level 3 + additional measures from level 4 Level 4 (with or without additional measures)

For more information on the requirements at each containment level please refer to next section – Containment of biohazards.

5.4.3 Containment of biohazards

5.4.3.1 Physical containment levels – small scale use

Four levels of containment appropriate to the four risks groups for infectious agents used in small scale, are defined below. Each containment level indicates the physical requirements as well as the operational requirements necessary. It remains the responsibility of the principal investigator or laboratory director and institution to require a higher level of containment for specific manipulations if these manipulations will appreciably increase the hazard of infection. For quick reference on the

most important containment measures required at different levels, please refer to Table 7 at the end of this section.

The requirements listed below are based on the containment levels as stipulated in the Regulations on Hazardous Biological Agents of the Health and Occupational Safety Act. However, additional requirements may have been incorporated into each level.

i) Containment level 1

- Applies to basic laboratories handling Risk Group 1 agents.
- Requires no special design features beyond those suitable for a well-designed and functional laboratory.
- Biological safety cabinets are not required.
- Work may be done on an open bench top and containment achieved through the use of normal practices employed in a basic microbiology laboratory.

a) Physical requirements
   - The facility may be a room separated from public areas by a door, which remains closed at all times.
   - Coating on walls, ceilings, furniture and floors should be cleanable.
   - There may be no windows that can open near working areas or containment equipment, and which are equipped with fly screens.
   - There are no special air handling requirements beyond those concerned with proper functioning of the biological safety cabinets and those required by building codes.
   - Hand-washing facilities must be provided preferably near point of exit.
   - Separate hanging areas for street clothing and laboratory coats should be provided.
   - Eye wash stations may be required by local statute.

b) Operational requirements
   - Basic laboratory safety practises should be followed.
   - Where chemical disinfection procedures are practised, effective concentrations and contact times must be employed.
   - Chemical disinfectants must be replaced regularly.

ii) Containment level 2

- Suitable for work with agents from Risk Group 2.
- In addition to requirements of containment level 1 the following are required:

a) Physical requirements
   - The laboratory does not have to be separated from other activities in the same building.
   - Post a biohazard sign with appropriate information on entrance to lab, if required by risk assessment.
   - Laboratory furnishings and work surfaces must be impervious and readily cleanable.
   - Coat hooks should be provided near the exit.
   - An autoclave should be available in or near the laboratory.
   - Laboratory doors must be self-closing.
   - Access should be restricted to authorised personnel only

b) Operation requirements
   - Class I or II biological safety cabinets are appropriate for all manipulations of agents, which may create aerosols.
   - Biological safety cabinets (follow SABS specifications – Annexure 10.3) must be tested and certified according to separate standards.

- Air from cabinets may be recirculated to the room only after passage through a HEPA filter.
- Centrifugation must be carried out using closed containers or aerosol proof safety heads or cups that only open in biological safety cabinets.
- Animals/insects, which have been experimentally infected, must remain in the laboratory or appropriate containment facility.
- An emergency plan for handling spills of infectious materials must be developed and ready for use whenever needed.
- Workers must be educated and drilled in the emergency plan.
- Vacuum lines used for work involving the agent must be protected from contamination by HEPA filters.
- Laboratory coats are to be worn only on the laboratory area and not outside. Coats that fasten in front are permissible.
- Special care should be taken to avoid contact of infectious materials with skin, e.g. wearing of gloves.
- Contaminated glassware may not leave the containment; decontamination must be carried out using procedures that are effective.
- If there is no autoclave or incinerator in the laboratory: contaminated glassware should be wiped off with disinfectant, chemically or double bagged and transport to the autoclave in durable, leak-proof containers which are closed and wiped of with disinfectant before leaving the laboratory.
- Service personnel and cleaning staff who enter the laboratory must be informed of the hazards they might encounter. Cleaning staff must only clean the floor. Laboratory staff have the responsibility for rendering the facility safe for routine cleaning. Periodic disinfection should be done at regular intervals.
- Cleaning and maintenance staff should receive immunisation and medical surveillance if appropriate.

iii) Containment level 3

- Suitable for work with agents from Risk Group III.
- Laboratory staff must receive special training in the safe handling and manipulation of the agents used in the laboratory.
- The laboratory must undergo annual performance evaluation, testing and verification.
- The laboratory requires special design and construction.

a) Physical requirements
The following conditions are required in addition to containment levels 1 and 2

- The laboratory should be located away from general work areas and have controlled access from other areas.
- Entrance must be through a lockable changing room with self-closing doors.
- A body shower should be within the containment perimeter.
- Air in the laboratory should be held at negative pressure relative to the surrounding areas at all times in such a way that a directional airflow is created by air entering through all entry and exit areas.
- The laboratory should be provided with a dedicated supply and exhaust system that is sealed.
- Air discharged may not be circulated back into either the air supply system of the laboratory, or the building or adjacent buildings.
- Provided there is a dedicated sealed exhaust system, air may be exhausted from the laboratory to the exterior of the building without HEPA filtration. At the discharge point the exhausted air must be dispersed away from the air intake and populated areas.
- When air is exhausted by means of a dedicated exhaust system, it must be passed through HEPA filters before discharging into the main building exhaust air ventilation-

system. This exhaust housing must be designed to allow in situ decontamination, and pass annual testing and certification by aerosol challenge and scan techniques.

- A control system must be in place that ensures that the laboratory does not become positively pressurised relative to the surrounding area.
- When the supply of air is not provided by a dedicated system, airtight back-draft dampers or HEPA filters must be installed in the supply system. The supply must be interlocked with the exhaust system.
- Biological safety cabinets must be installed in a manner that does not interfere with the air balance of the cabinet or room. Thimble unit connections are recommended.
- A dedicated hand-washing sink with foot, knee or automatic controls should be located near the exit.
- A pass-through or stand-alone autoclave should be located in the work zone.
- Laboratory furnishings must be kept to a minimum.
- Work surfaces must be impervious, readily cleanable and resistant to chemical disinfectants.
- Seal all penetrations for services in the floors, walls and ceiling.
- Air supply or exhaust systems should be provided with manual dampers at room perimeter that may be closed as required to permit gas decontamination.
- Water supply to the laboratory should be provided with reduced pressure back flow preventers.
- HEPA filters should be fitted on all ventlines.
- Dunk tanks may be provided at the containment perimeter.
- Sink and floor drains must be piped separately to the main building drain and appropriately labelled. Floor drains are not recommended.
- Infectious materials must never be placed in sinks or floor drains.
- Autoclave condensate drains should have closed connections and go directly to a sanitary sewer.
- Animal care facilities for small animals: disposal of wastes will not differ from other contaminated laboratory materials.
- Laboratory windows should be sealed and unbreakable.
- Backup power must be provided to critical items.

b) Operational requirements
The following conditions are required in addition to the requirements for containment levels 1 and 2

- Staff must be fully trained in handling pathogenic and other hazardous material, as well as in the use of safety equipment, disposal techniques, the handling of contaminated waste and emergency procedures.
- Staff must change to dedicated solid front clothing on entry to facility, removed on completion of work and autoclaved prior to laundering.
- Personal protective clothing (head covers or foot covers) must be used.
- Appropriate respiratory protection should be considered depending on the infectious agents involved.
- Showers may be required depending on the infectious material used.
- Personal belongings may not be taken into the laboratory.
- Gloves must be worn.
- All activities involving infectious materials must be conducted in biological safety cabinets or appropriate combinations of personal protective and physical containment devices.
- Centrifugation should be conducted in closed containers using aerosol proof safety heads or cups that are loaded and unloaded in the cabinets.
- Effective disinfectants should be available at all times.
- Store all Risk Group 3 agents in the containment level 3 facility.
- Effective pest control programme must be in effect.

- Written protocols must be provided and posted within the laboratory outlining operational protocols, waste disposal, disinfection procedures and emergency responses.
- An existing medical surveillance programme appropriate to the agents used, which includes serum storage for all personnel, must be working in the laboratory. A reporting structure should be in place for accidents and exposures to infective agents or other incidents or unusual occurrences in the operation of the laboratory.
- Authorised maintenance and service personnel must abide by the same operational protocols as laboratory staff and be accompanied by staff when entering the laboratory.
- Containment level 3 facilities and systems must be tested for contamination capability upon completion of construction and at least annually thereafter.

iv) Containment level 4

- Physical and operational requirements are highly specified.
- This is the highest level of containment and represents an isolated unit functionally independent of other areas.
- Requires an airlock for entry and exit, Class III biological safety cabinets or positive pressure ventilated suits, a laboratory support area and a pressure ventilation system in addition to the physical and operational requirements of containment levels 1-3.

a) Physical requirements
- A laboratory physically separated from other laboratories or consists of an isolated zone, which is monolithic in construction with all penetration to floors, walls and ceilings sealed with non-shrinking sealant.
- A laboratory designed to accommodate a minimum of 2 persons at all times, all laboratory equipment, long term storage of cultures and maintenance of infected animals.
- Entry must be through an airlock system, with manual alarm overrides available.
- Change rooms must be contiguous with the containment perimeter of the structure and have a personnel shower and/or a chemical shower.
- All drain traps must be kept filled with an effective disinfectant and be connected to a liquid waste effluent system.
- All air access to any sewer and ventilation lines must be fitted with HEPA filters or equivalent equipment.
- All gas services must be fitted with HEPA filters, equivalent equipment or back-flow preventers to prevent egress of contaminated material.
- Water supply systems must be provided with back-flow preventers.
- All windows must be sealed and be of break resistant glass.
- A double door autoclave preferable serviceable from the outside of the facility. The autoclave should have read-out charts inside and outside the laboratory and have operating controls inside the laboratory.
- A dunk tank which is chemically resistant and of a suitable size for the passage of anticipated laboratory materials may be required for Class III cabinet lines laboratories, if indicated by the risk assessment.
- Dedicated hand-washing sink with foot, knee and automatic controls should be located near the exit.
- The facility must be equipped with a two-way intercom system.
- A closed circuit television system should also be considered.
- All liquid effluent from the facility must enter a waste effluent treatment system for sterilisation, which is mechanically and biologically monitored.
- Ventilation must occur by an independent, dedicated, sealed supply and exhaust air system, which is not recirculated.

- Exhaust air must pass through at least 2 HEPA filters mounted in series in sealed housings designed to allow in situ decontamination and testing by aerosol challenge techniques.
- Supply and exhaust systems must maintain directional (inward) airflow and pressure differentials and interlocked to prevent pressurisation in the event of exhaust fan failure.
- A supply air system must be equipped with HEPA filter.
- The facility should be fully equipped with manometers and other monitoring devices and audible and visual alarms capable of being monitored by both laboratory and maintenance staff.
- The facility should be provided with Class I, II or III tested and certified biological safety cabinets, which must be installed in an manner that does not interfere with the air balance of the cabinet or room.
- If a positive-pressure-ventilated-suit type of operation is used, a life support system with full alarming, back-up breathing air, emergency power and a chemical shower facility are required. Positive pressure suits must be used whenever agents are worked with outside a Class III cabinet.
- Alarms, ventilation and other critical systems must be on separate electrical circuits with an emergency backup.
- A support area adjacent to Level 4 containment facility is required for all non-hazardous laboratory manipulations.

b) Operational requirements
- Only fully authorised personnel may enter the laboratory; all must sign a logbook and maintain and record all entries electronically.
- A competent person should be outside the laboratory at all times when work is undertaken to assist during an emergency.
- Wearing of protective clothing, gloves and impermeable footwear are required, no street clothing may be worn under the protective clothing. On exit personnel must shower and re-dress in street clothing.
- Keep small laboratory animals and insects under experimentation in ventilated cabinets having all output air HEPA filtered.
- Special care should be taken with regard to large animals.
- Store all Level 4 agents within the containment zone.
- Remove all materials through an autoclave or placed it in a double, unbreakable sealed container, the outside of which will be disinfected.
- Where equipment and apparatus are not compatible with heat sterilisation, materials may be removed via dunk tanks or air locks with suitable decontamination procedures.
- All manipulations must be performed in Class III biological safety cabinets or in Class I or II biological safety cabinets used in conjunction with one-piece, positive-pressure-ventilated suits.
- Prepare contingency plans for emergencies, which may include responses to biological, toxic or hazardous spills, and fire and life-threatening situations must be prepared and reviewed by all personnel.
- A written reporting system for laboratory accidents and exposures must be in effect.
- Implement a serum storage programme for all laboratory and support personnel along with a full medical surveillance and treatment programme.
- Level 4 facilities and its systems must be tested for containment capability upon completion of construction and annually thereafter.

Table 7: Containment and control measures for small-scale activities with GM-micro-organisms.

Containment and Control Measures	Containment Level 1	Containment Level 2	Containment Level 3	Containment Level 4
Building / Physical Measures:				
The workplace separated from other activities in the same building	No	No	Yes	Yes
The workplace maintained at an air pressure negative to atmosphere	No	No, unless mechanically ventilated	Yes	Yes
Input air and extract air to the workplace are to be filtered using HEPA or equivalent	No	No	Yes, on extract air	Yes, on input and double (2 stage in series) on extract air
Surfaces impervious to water easy to clean and resistant to acids, alkalis, solvents and disinfectants	Yes, for bench	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
An observation window, or alternative present so that occupants can be seen	No	No	Yes	Yes
Efficient vector control e.g. rodents and insects	No	Yes, for animal containment	Yes, for animal containment	Yes
The workplace sealable to permit fumigation	No	No	Yes	Yes
Effluent from sinks and showers collected and inactivated before release	No	No	Optional	Yes
Work Practice Measures:				
Biohazard signs and level of work posted	No	Optional	Yes	Yes
Access restricted to authorised persons only	No	Yes	Yes	Yes
Personnel trained in both routine and emergency procedures	Yes	Yes	Yes	Yes
Laboratory door closed when work is in progress	Optional	Optional	Yes, should be locked when room is unoccupied	Yes, door to be kept locked
Personal protective equipment protective clothing Gloves RPE	 Yes Optional No	 Yes Optional No	 Yes Optional No	 Yes Yes Yes
Protective clothing decontaminated before laundering	No	Optional	Yes	Yes
Smoking, eating, drinking	Yes	Yes	Yes	Yes

Containment and Control Measures	Containment Level 1	Containment Level 2	Containment Level 3	Containment Level 4
and the application of cosmetics prohibited in workplace				
Laboratory to contain its own equipment	No	No	Yes, so far as is reasonably practicable	Yes
Equipment and control measures tested and maintained	Yes	Yes	Yes	Yes
Viable material, including any infected animal, to be handled in biological safety cabinet or isolator or other suitable container	No	Yes, where aerosol produced	Yes, where aerosol produced	Yes (Class III cabinet)
Monitoring for the relevant organisms outside	Optional	Optional	Yes	Yes
Safe storage of GMO's	Yes	Yes	Yes	Yes, secure storage
Contaminated waste to be inactivated prior to disposal	Optional	Yes, by validated means	Yes, by validated chemical or physical means	Yes, by validated physical means
Autoclave available in the laboratory	Optional	Optional	Optional	Yes, double ended
Incinerator for disposal of animal carcasses	Optional (for animal containment)	Accessible (for animal containment)	Accessible (for animal containment)	Yes, on site (for animal containment)
Decontaminated and washing facilities provided	Yes	Yes	Yes	Yes
Personnel shower before leaving laboratory	No	No	Optional	Yes

*Optional indicates that the requirement is to be determined based on the risk assessment

5.4.3.2 Physical containment levels – large-scale/industrial use

This guidance does not preclude the use of other approaches. Where there is no specific requirement, alternative methods may be applied so long as the risks are adequately controlled. Please note that large-scale processes should be considered in terms of their unit operations and that a number of engineering control measures may be required.

As in the case with containment at small scale, please consult the Regulations on Hazardous Biological Agents of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), available from the Department of Labour at the address indicated below.

Department of Labour
Private Bag X117
Pretoria
0001
Tel: +27 +12 309 4374
Fax: +27 +12 320 5112

For quick reference on the appropriate containment for activities at large scale, please refer to Table 8 at the end of this section.

i) Containment Level 1

- Follow the measures as described by Basic Laboratory Safety Practices (Annexure 10.1).
- Good hygiene must be applied at all times.
- Containment will be determined by the degree to which contact of the GMO with humans and the environment needs to be limited, and should be based on the risk assessment.

(a) Physical requirements

- Production or factory floor areas must be separated from offices, laboratories and other facilities.
- Good hygiene is advisable and buildings must be easily cleanable.
- Mechanical ventilation is not normally needed, although it may be used. For some processes a positive air pressure is needed to maintain product integrity. Consider localised airflow units which give product and operator protection.

(b) Operational requirements

- Viable GMO's should be contained in a system, which includes physical barriers to separate them from the general environment. The need for a closed system will depend on the risk assessment, but is normally not needed.
- Release of the GMO's into the work place and wider environment should be minimised during processes such as addition of materials, mixing or transfer. The acceptable degree of minimisation is to be determined by the risk assessment.
- Seals used on equipment should be designed to minimise release so that contamination of the workplace and wider environment is limited appropriately and harm will not result.
- If the risk assessment indicates that harm may result if viable GMO's are released, they should be inactivated before removed from containment.
- Equipment and control measures should be tested and maintained at appropriate intervals.
- Workers should be trained in both routine and emergency procedures.
- Washing facilities should be provided for personnel.
- Work clothing should be provided if necessary.
- Release of GMO's into the work place should be minimised during sample collection.
- Waste should be disposed of in a safe manner.
- There is no need to treat exhaust gases.
- There is no need for emergency plans, although it is good practice to have procedures drawn up.
- Accidents and incidents should be recorded.
- Monitoring is unlikely; however, where there is risk to human health and environmental safety from process organisms outside the closed system, monitoring for viable process organisms should be carried out.

ii) Containment level 2

(a) Physical requirements

- Activities should be undertaken in controlled areas, which are separated from offices, laboratories and other facilities, and where cross traffic is limited.
- Good standards of hygiene are required.
- The controlled area should be ventilated to minimise air contamination. Mechanical ventilation may also be used.
- HEPA filtration of any input and extract air is usually not needed, but filtration of extract air may be necessary where there is a risk to the wider environment from the release of the GMO.

- Where there is risk from catastrophic loss of containment the facility should be designed to contain spillage of the entire contents of the fermenter.

(b) Operational requirements

- Viable GMO's should be contained in a closed system, which includes physical barriers to separate them from the work and wider environment.
- Pipework and valves should be designed with the emphasis on leak-tightness as well as on cleanability.
- Where the needle/septum method is used procedures should be carefully though out to avoid needle puncture injury.
- Static seals on equipment should be designed so as to minimise release.
- Agitator seals would normally be single or double faced mechanical seals.
- Fixed or retractable instrument sensors may be used.
- Any relief system design needs to be considered carefully, e.g. chains of venting systems. Pressures Vessels Regulations requirements must be met.
- Bulk culture fluids should not be removed from the closed system unless the viable GMO's have been inactivated by validated means.
- Equipment and control measures should be tested and monitored.
- Workers should be appropriately trained in both routine and emergency procedures.
- Access should be restricted to nominated personnel when this is indicated by the risk assessment.
- Hand washing facilities, ideally with foot or elbow operated taps, should be provided. Emergency showers and eye wash stations are useful.
- When indicated by risk assessment, a biohazard sign must be posted at entrances.
- Work clothing should be provided and ideally kept in a separate locker.
- Release of GMO's into the work place should be minimised during sample collection. The receiving container should also be designed to minimise aerosols.
- Infected waste and effluent containing viable GMO's should be inactivated by validated means prior to final discharge.
- Exhaust gases should be treated so as to minimise release.
- Filters should be able to be removed safely for protection of maintenance engineers.
- If indicated by the risk assessment, as a result of any foreseeable accident, the health and safety of persons outside the premises may be affected or if there is any risk to the environment, an emergency plan must be drawn up.
- Accidents and incidents should be recorded and immediately reported to a competent person.
- Where there is risk to human health or environmental safety for process organisms outside the closed system, monitoring for viable process organisms should be carried out.

iii) Containment Level 3

(a) Physical requirements

- Most activities should be carried out in controlled areas that are separated from offices; laboratories and other facilities and which are away from general circulation routes.
- High standards of hygiene should be maintained.
- Where indicated by risk assessment, a continuous airflow into the facility should be maintained when work is in progress.
- Extract air is normally filtered through HEPA filters and must be filtered when there is a risk of harm from not doing so.
- Inlet and extract systems can be alarmed, interlocked and indicated.
- When indicated by risk assessment, the controlled area should be sealable to permit fumigation.
- The facility should be designed to contain spillage of the entire contents of a fermenter.

(b) Operational requirements

- Viable GMO's should be contained in a closed system, which includes physical barriers to separate them from the general environment.
- Inoculation of seed vessels should be performed so as to prevent release, and closed systems such as stainless steel transfer vessels should be used.
- Bulk culture fluids should not be removed from the closed system unless validated chemical or physical methods have inactivated viable GMO's.
- Leak testing should be performed using halogens.
- Workers need to be trained to a high standard in both routine and emergency procedures.
- Access should be restricted to nominated personnel. Access via changing rooms and a system of control, which prevents unauthorised access, should be in place.
- Hand washing facilities should be provided, preferable with foot and elbow operated taps. Emergency showers and eyewash stations are worth considering.
- Biohazard signs must be posted at entrances.
- Protective clothing should be worn and changed provided at each entry into the controlled area.
- Data transferring must preferable occur by electronic means.
- Sampling should be performed using a closed aseptic technique and release of GMO's should be prevented.
- Exhaust gases should be treated so as to prevent release. This will involve HEPA filtration with 0.2μm filter cartridges and often 2 filters in series.
- Spray towers, cyclone separators, off-gassing through disinfectants and impingement filters are not recommended.
- An emergency plan must be drawn up and should include procedures to deal with spillage.
- Accidents, spills and exposures to infective material need to be immediately reported to and recorded by a competent person. All accidents must also be reported to the Health and Safety Executive.
- Monitoring of viable process organisms should be carried out.

iv) Containment level 4

(a) Physical requirements

- Activities to be carried out within purpose built controlled areas, which are physically separated from any other activity.
- Scrupulous levels of hygiene are to be maintained.
- The controlled area must be ventilated to minimise air contamination and an air pressure negative to the atmosphere must be maintained.
- Input and extract air should be filtered through HEPA filters, a single filter for input and two filters mounted in series for extracted air.
- The controlled area must be sealable to permit fumigation.
- The controlled area must be designed to contain the entire content of a fermenter and allow for physical inactivation. Drainage channels are not appropriate.

(b) Operational requirements

- Viable GMO's must be contained in a fully closed system that prevents release.
- Any addition of materials to the closed system or transfer of viable GMO's to other closed systems must be performed so as to prevent release. The use of sterile needle / septum techniques are not to be used.
- Before bulk culture fluids are removed from the closed system, viable GMO's must have been inactivated by validated means.
- Equipment and control measures must be tested and maintained at appropriate intervals.

- Workers must have specific training in working in the facility as well as the use of safety equipment and handling of the GMO's concerned.
- Access must be restricted to authorised personnel only. Entry must be via a changing room/lobby area (airlock), which is itself ventilated and maintained at an air pressure negative to the outside of the facility, but positive with respect to the work area. All entrances need to be locked.
- Decontamination and washing facilities must be provided. Personnel must shower before leaving the controlled area.
- Biohazard signs must be posted at each entrance.
- A complete change of protective clothing must be worn, a change being provided for each entry.
- Data should preferable be transmitted by electronic means.
- Only closed aseptic techniques are acceptable when taking samples with release of GMOS prevented at all times.
- All effluent must be inactivated by validated physical means prior to final discharge.
- All exhaust gases must be HEPA filtered to prevent release.
- Emergency plans must be drawn up and include procedures to deal with spills.
- Accidents, spills and exposures to infective materials are to be immediately reported to and recorded by the competent person or the person responsible who needs to take appropriate measures specified in the local rules. Accidents must also be reported to the Health and Safety Executive.
- A monitoring programme should be instigated in the work area and immediate surroundings.

Table 8: Containment and control measures for large scale activities with GM-micro-organisms

Containment and Control Measures	Containment Level B1	Containment Level B2	Containment Level B3	Containment Level B4
Building Design:				
Closed system located within a controlled area	(Not applicable)	Optional	Optional	Yes, and purpose built
The controlled area adequately ventilated to minimise air contamination	No	Optional	Optional	Yes
The controlled area maintained at an air pressure negative to atmosphere	No	No	Optional	Yes
Input and extract air to the controlled area HEPA filtered	No	No	Optional	Yes
The controlled area sealable to permit fumigation	No	No	Optional	Yes
The controlled area designed to contain spillage of the entire contents of the closed system	No	Optional	Yes	Yes
Fermentation Methods, Equipment and Utilities:				
Viable micro-organisms contained in a system which physically separates the	No	Yes	Yes	Yes

Containment and Control Measures	Containment Level B1	Containment Level B2	Containment Level B3	Containment Level B4
process from the environment (closed system)				
Addition of materials to a closed system and transfer of viable micro-organisms to another closed system performed so as to:	(Not applicable)	Minimise release	Prevent release	Prevent release
Equipment seals designed so as to:	Minimise release (if seals used)	Minimise release	Prevent release	Prevent release
Bulk culture fluids not removed from the closed system unless the viable micro-organisms have been	(Not applicable)	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
Maintenance:				
Equipment and control measures tested and maintained	Yes	Yes	Yes	Yes
Management System/ Work Practices:				
Personnel to be trained in both routine and emergency procedures	Yes	Yes	Yes	Yes
Access restricted to nominated personnel only	No	Optional	Yes	Yes, via airlock
Decontamination and washing facilities provided for personnel	Optional	Yes	Yes	Yes
Personnel shower before leaving the controlled area	No	No	Optional	Yes
Biohazard signs posted	No	Optional	Yes	Yes
Personnel wear protective clothing	Yes, work clothing	Yes, work clothing	Yes	Yes, a complete change
Protective clothing decontaminated before laundering	No	Optional	Yes	Yes
Smoking, eating, drinking and the application of cosmetics prohibited in controlled areas	Yes,	Yes	Yes	Yes
Sampling Procedures:				
Sample collection performed so as to:	Minimise release	Minimise release	Prevent release	Prevent release

Containment and Control Measures	Containment Level B1	Containment Level B2	Containment Level B3	Containment Level B4
Sampling by closed aseptic technique	No	Optional	Yes	Yes
Waste Handling and Gas Emission:				
Effluent from sinks and showers collected and inactivated before release	No	No	Optional	Yes
Effluent treatment before final discharge	Optional	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means
Accidents / Emergency Plans:				
Emergency plans prepared	No	Optional	Yes	Yes
Documented spillage procedures drawn up	Optional	Yes	Yes	Yes
Monitoring:				
Monitoring for processed organisms outside primary containment	Optional	Optional	Yes	Yes

*Optional indicates that the requirement is to be determined based on the risk assessment

5.4.4 Risk assessment of genetically modified viruses and viral vectors

(The term animal includes both vertebrates and invertebrates.)

i) This section is an abbreviated version of the guidelines used by the United Kingdom. For more detailed information please refer to Part 1 and 2 of the *Compendium of Guidance from the Health and Safety Commission's Advisory Committee on Genetic Modification*

ii) The following are basic procedures, which may be followed to conduct an assessment of genetically modified viruses and viral vectors. These procedures include -

a) Determination of the predicted properties of the GM virus in order to assess if there are any potential mechanisms by which it could represent a hazard to human health.

The following aspects should be taken into account -

- Hazards associated with the vector
- Particular care must be given to the assessment of vectors with an actual or potential ability to infect humans or human cells
- Viral vectors with reduced pathogenicity
  - To prevent/minimise exposure to a biological agent that can cause harm, the agent should be substituted by a less hazardous agent wherever practicable.
  - To determine whether a viral vector is adequately disabled, the possibility of reversion or complementation should be considered, and it must be confirmed that the virus is still disabled after the modification.
  - The likelihood of reversion will depend on the mechanism of attenuation – deletant mutants are less likely to revert to wild type than point mutations or conditional lethal mutants.
  - Insertion of a gene into a site of any disabling mutant is expected to reduce the likelihood of recombination events resulting in the generation of a replication

competent virus expressing the gene, and therefore increasing the effective biological containment.
- Experiments using viral vectors that do not usually infect human cells in culture, and for which there is no evidence of human infection, are considered to represent a minimal risk to the operator and a containment level 1 is sufficient to protect human health.

- Hazards arising directly from the inserted gene product
  - The insertion of an additional nucleic acid sequences into viral vector can give rise to potential adverse effects, resulting from the direct effects of an expressed gene product, or as a consequence of an alteration in the overall properties of the GMO.
  - Particular attention should be given to the level of expression and the site of insertion of the gene, and whether it is a known or suspected pharmacological or physiological effect. This should include the possibility of effects other than those being sought in the construction.
  - Particular attention should also be given to inserted sequences which could result in an alteration in growth, replication or differentiation of cells
- Hazards arising from the alteration of existing pathogenic traits
  - Adverse effects may result through the alteration of existing pathogenic traits as a result from the product of an inserted gene acting alongside existing pathogenic determinants, or as a result of the modification of the normal viral genes which affect pathogenicity.
  - The following points should be considered when assessing the hazards arising through the alteration of existing pathogenic traits –
  - Alteration of tissue tropism or the host range (A change may occur in the structure of the receptor binding site and tissue tropism may be affected by alterations in the transcriptional control of viral genes)
  - Increase in the effectivity or pathogenicity (The modified virus may show an altered susceptibility to host defence mechanisms.)
  - Recombination or complementation (The possibility that a recombination or complementation may influence any disabling feature or attenuation of the viral vector after infection.)
  - Availability of prophylaxis or therapy (The possibility that viral susceptibility to anti-viral drugs may be affected by genetic modification.)

b) Consideration of the likelihood that the GM virus could actually cause harm to human health.

Factors that come into play when considering the likelihood, include an analysis of the probability that rare events may occur and a judgement as to the fitness of the modified virus. In some cases it will be possible to assign a frequency to an event – precise, approximate, semi-quantitave or descriptive.

The ability of a GM virus to establish through an in vivo infection and the efficiency of substances in vivo propagation - consideration should be given to the ability of the virus to spread as this could influence the level of containment.

c) The assignment of general control measures necessary to safeguard human health, i.e. the allocation of a provisional level of containment

The first step in assigning control measures is to determine whether the virus is suitable for work in one of the main containment levels. The assignment of a containment level in most cases will correspond to the level of containment appropriate for the parental organism. Where it is predicted that the modified virus will be considerably more hazardous than the parental virus, a higher containment level should be applied.

Once a containment level is indicated, the next step is to decide whether the minimum requirements of the chosen containment level is adequate or whether some additional measures should not be applied. In all cases the principles of good microbiological practice and good occupational safety and hygiene should be applied.

Additionally to the above, the following is recommended for work conducted with viruses capable of infecting human cells –

- Apply measures to prevent cross contamination during laboratory work to minimise the possibility of adverse consequences resulting from recombination or complementation. E.g. do not use the same bottle of medium for culturing different virus infected cell lines, and discourage laboratory workers from sharing bottles of medium.
- Conduct tests to detect the presence of adventitious agents and replication competent virus (RCV) to determine the absence of RCV in virus stocks.
- In order to minimise the risk of accidental colonisation with infected cell lines, users should not infect cultures of their own cells, nor as a general rule, those of their immediate family or other members of the laboratory.
- The responsible person for the laboratory should ensure that there are adequate laboratory rules, which give effective guidance on the maintenance of laboratory discipline and on avoiding accidental inoculation.
- All workers should be trained in good laboratory techniques before commencing work with GMO's and be fully aware of the potential hazards associated with the work.

d) Consideration of the nature of work to be undertaken, and the assignment of additional control measures if required

At this stage of the risk assessment the nature of the work to be conducted must be taken into consideration. Will the work involve any non-standard operations that may involve risks that are not accounted for in the general requirements of a containment level?

If the work will involve non-standard operations that will generate risks that are not accounted for in the provisional containment level, additional control measures should be applied.

e) The identification of hazards to the environment and assignment of additional containment measures to protect the environment.

The primary consideration in this section should be whether the virus is capable of infecting animals. If the virus cannot infect any species other than humans, the risk assessment should include a statement to this effect together with some justification. Risks to the environment can in this case be assumed as negligible.

If the virus may infect any animal, then the risk assessment should consider the risks posed to the environment. Attention should be given to viruses that are known to be pathogenic to wildlife.

Any additional risks to the environment caused by the modification or the inserted sequence should be assessed by consideration of the following points –

- Survivability – will the GM-virus result in an altered survivability in the environment?
- Alteration of tissue tropism or host range – Is the modification likely to alter the tissue tropism or host range of the recombinant virus?
- Increase in infectivity or pathogenicity – Will the GM-virus increase pathogenicity or infectivity? Will there be an altered susceptibility to host defence mechanisms?
- Effects on other organisms – Does the inserted sequence code for a protein with known or suspected inhibitory, detrimental or other physiologically active effects on other organisms?

- Environmental release – Do you know all possible routes of escape into the environment?
- Availability of control agents – Will the virus susceptibility to control agents be affected by the modification? E.g. vaccination or norm immune status.

The possibility of accidental releases and survival of the GMO in the environment must always be considered. If the virus is to be used at high levels of containment because of the potential risks imposed to human health and safety, it is likely that the control measures assigned will also be sufficient to protect the environment.

In the case where the virus is known to have a limited survivability in the environment or is known not to infect South African hosts, the likelihood of the hazard being realised and causing harm, can be considered to be low or effectively zero.

6. Containment measures for GMO's conducted in greenhouses

i) The containment measures that are provided in this section is to serve as a simple and convenient reference on the appropriate biosafety and containment levels applicable for activities with GMO's in a greenhouse. The information in this section was taken from the book by Traynor, Adair and Irwin named *A Practical Guide to Containment* (herein after referred to as the *Guide*. The complete text of this Guide is available in the ISB (Information Systems for Biotechnology) Web site – http://www.isb.vt.edu. Print copies are also available at no charge – order forms may be obtained from the ISB Website, or you can send your request by e-mail to isb@vt.edu. Orders may also be faxed to 540 231 4434.

ii) When activities with genetically modified plants (GM-plant) are to be conducted in greenhouses, the predominant goal of containment is to prevent the GM-plant from escaping into the environment. To assign appropriate containment for activities with GM-plants in greenhouses, the activity must be categorised into a certain biosafety level. In Section 6.1 a brief description is given of each biosafety level, as described in the National Institutes of Health's *Guidelines for Research Involving Recombinant DNA Molecules.* For examples of activities in each level, please refer to Section III of the Guide.

6.1 Biosafety levels

i) Biosafety Level 1 for plants (BL1-P)

This level provides for a low level of containment and activities that normally involve GM-plants that are not able to survive and spread into the environment. Additionally, in the event that the GM-plant is accidentally released into the environment, it would pose no environmental risk.

This level is appropriate for plant-associated GM micro-organisms that cannot spread rapidly and are not known to have any negative effects on either natural or managed ecosystems.

ii) Biosafety level 2 for plants (BL2-P)

Experiments with GM-plants and associated organisms which, if released outside the greenhouse, could be viable in the surrounding environment but would have a negligible impact or could be readily managed, are categorised in BL2-P. This level is therefore required for GM-plants that may exhibit a new weedy characteristic or that may be capable of interbreeding with weeds or related species growing in the vicinity.

Transgenic experiments involving the entire genome of an indigenous infectious agent or pathogen will also be assigned to this level. This level is also appropriate for activities with transgenic plant-associated micro-organisms that are either indigenous to the area and

potentially harmful to the environment but manageable, and to transgenic plant-associated micro-organisms that are exotic but have the potential for causing serious harm to managed or natural ecosystems. BL2-P also applies to experiments using plant-associated transgenic insects or small animals as long as they pose no threat to managed or natural ecosystems.

iii) Biosafety Level 3 for plants (BL3-P)

Facilities designed to accommodate activities at BL3-P are designed to prevent the accidental release of transgenic plants, plant pathogens, or other organisms that have a recognised potential for significant detrimental impact on the environment. This level applies to experiments that involve transgenic plants or organisms that contain genes coding for vertebrate toxins.

Activities that use transgenic microbial pathogens of insects or small animals that associate with plants and has the potential to cause harm to the local environment, will also be categorised within this level.

iv) Biosafety Level 4 for plants (BL4-P)

This level is recommended for activities with certain exotic, readily transmissible infectious agents that are potentially serious pathogens of major South African crops.

v) In Table 9 a comparison of the standard practices for containment of plants in greenhouses, is given for each of the biosafety levels.

Table 9: Containment of plants in greenhouses

BL1-P	BL2-P	BL3-P	BL4-P
Discretionary access; Hinged or sliding entry doors	Access limited to individuals directly involved with experiments; Hinged or sliding entry doors; locks at entry doors	Access restricted to required personnel only; Double set of self-closing, locking doors	Access restricted; secure locked doors (double set of self-closing, locking doors with air-lock); record kept of all entries/exits; clothing change; the only means of entry/exit is via a shower room through airlock
Personnel must read and follow instructions	Personnel must read and follow instructions	Personnel must read and follow instructions	All who entered should be advised of the hazards and safeguards
Procedures followed must be appropriate for the organism	A greenhouse manual must be in place to advise of consequences and outline contingency plans	A greenhouse manual must be in place to advise of consequences and outline contingency plans	A greenhouse manual must be prepared and adopted; Personnel are required to follow contingency plans
Records must be kept of the experiments in the facility	Records must be kept of experiments as well as movement in/out of the greenhouse	Records must be kept of experiments as well as movement in/out of the greenhouse	Records must be kept of experiments as well as movement in/out of the greenhouse
	Containment is required for movement in/out of containment	Containment is required for movement in/out of containment,	Special packaging containment required for movement in/out;

BL1-P	BL2-P	BL3-P	BL4-P
		as well as external decontamination	Airlock or decontamination is required for removal
			Supplies and materials must enter through a special chamber
Must biologically inactivate experimental organisms at the end of the experiment	Must biologically inactivate experimental organisms at the end of the experiment, and de-contaminate gravel periodically	Must biologically inactivate experimental organisms at the end of the experiment (including water runoff), de-contaminate equipment and supplies	Decontaminate experimental materials prior to removal from area by autoclave/other means; All runoff water must be collected and decontaminated
A pest control program must be in place	A pest control program must be in place	A pest control program must be in place	Chemical control program for pests and pathogens must be in place
Appropriate caging and precautions must be in place to prevent escape of motile organisms	Appropriate caging and precautions must be in place to prevent escape of motile organisms	Appropriate caging and precautions must be in place to prevent escape of motile organisms	Appropriate caging and precautions must be in place to prevent escape of motile organisms
	Erect a sign stating restricted experiment in progress, mention plant names, persons responsible and special requirements	Erect a sign stating restricted experiment in progress, mention responsible person, special requirements, and a biohazard symbol if there is a risk to humans	Erect a sign stating restricted experiment in progress, mention responsible person, special requirements, and a biohazard symbol if there is a risk to humans
		Minimise aerosol creation to reduce contamination	Standard microbial procedures to decontaminate equipment and containers must be in place
		Wear protective clothing to minimise dissemination, and wash hands before leaving facility	Street clothing must be removed; complete change into lab clothing which is autoclaved before laundering
			Report and record all accidents
Framing may be aluminium, steel, wood or pipe	Framing may be aluminium, steel, wood or pipe	The structure of the greenhouse should be rigid; a wind resistant frame; internal walls, ceilings and floors should be resistant to liquids and chemicals	The structure should be reinforced; the frame rigid; the walls, floors and ceilings from sealed internal shell that is resistant to liquids and chemicals
Glazing – standard greenhouse glass or	Glazing – standard greenhouse glass or	Glazing – Laminated, strengthened, sealed	Glazing – double-paned, laminated,

BL1-P	BL2-P	BL3-P	BL4-P
plastic material	plastic material		strengthened, sealed
Screening – if used, use standard 30 mesh fly screen	Screening – use standard 30 mesh or higher fly screen	Screening – not permitted	Screening – not permitted
Ventilation – use roof/side vents, fans, cooling pads, fog system	Ventilation – use roof/side vents, fans, cooling pads, fog system	Ventilation – separate negative pressure system; air supply fans with back-flow damper; exhaust air HEPA filtered	Ventilation – Air-conditioned and HEPA filtered; closely monitored negative pressure, no roof or side vent allowed
Benching – any material; solid or porous bottoms	Benching – any material; solid or porous bottoms	Benching – seamless water and chemical resistant bench tops	Benching – seamless water and chemical resistant bench tops
Floors – gravel; soil; concrete; impervious walkways	Floors – impervious material; collection of runoff water may be required, depending on the organism used	Floors – Impervious material; for microbes the runoff water must be collected and decontaminated	Floors – sealed floors as part of the internal shell; runoff collection and decontamination
Drains – discharge into groundwater or sanitary/storm sewer	Drains – discharge into groundwater or sanitary/storm sewer	Drains – make provision for collection and decontamination of runoff	Drains – Runoff collection and sewer vents filtered
	Autoclave must be available	Autoclave must be within the facility; hand washing with hands free on/off; filtered vacuum lines; disinfectant traps for liquid lines	Double-door autoclave; self-contained vacuum system; in-line filters and back-flow protection for all liquid/gas services

More information on the terms glazing, sealing, screening, negative air-pressure, etc. can be obtained in Section IV of the *Guide*.

vi) Greenhouses that offer high-level BL3-P and BL4-P containment are expensive to built and operate. The cost of greenhouse containment at these levels may therefore be prohibitive for many institutions. Other means of high level containment may however be obtained through the use of growth chambers or growth rooms.

6.2 Biological containment

i) Additionally to the containment measures explained above, other precautionary measures can be taken to prevent the unintended dissemination of GMO's from the greenhouse to the environment.

ii) Possible biological containment for GM-plants in greenhouses

One or more of the following procedures can prevent dissemination of genetic material by means of pollen dispersal or seed dispersal:

- Cover/remove flower and seed heads
- Harvest plant material prior to sexual maturity or use male sterile lines
- Control the time of flowering so that pollen shed does not coincide with the receptive period of sexually compatible plants nearby
- Ensure that cross-fertile plants are not within the pollen dispersal range of the experimental plant
- Use genetic modification techniques that localise transgenes in non-propagative parts

iii) Possible biological containment for micro-organisms in greenhouses

Effective physical containment of bacteria, viruses and other microbes can be extremely difficult because they cannot be seen, and once dispersed, cannot be recovered. Biological measures therefore often provide better containment.

The following methods may help to prevent dissemination of genetically modified micro-organisms from greenhouses –

- Avoid creating aerosols when inoculating plants with transgenic microbes
- Provide adequate distance between an infected plant and another susceptible host , especially if the micro-organism can be disseminated through air of by leaf contact
- Grow experimental plants and microbes at a time of the year when nearby susceptible plants are not growing
- Eliminate vectors for insect-borne micro-organisms
- Choose micro-organisms having an obligate association with the host plant
- Genetically disable the micro-organism to minimise survival and reproduction
- Treat or evaporate runoff water

iv) Possible biological containment for insects in greenhouses

Insect and mite containment is very difficult in a greenhouse, however, the following procedures can be used to prevent dissemination of arthropods and other small animals –

- Choose or create non-flying, flight-impaired or sterile strains
- Conduct experiments at a time of year when survival of escaping organisms is impossible
- Choose organisms that have an obligate association with a plant not found in the vicinity
- Treat or evaporate runoff water to eliminate viable eggs and larvae
- Avoid use of small-sized insects in experimental greenhouse cages
- Destroy pollinating insects in experimental cages after pollen transfer to eliminate potential for dissemination of transgenic pollen into the environment

7. RISK MANAGEMENT

i) Risk management with regard to activities involving GMO's will be determined by the results obtained during a risk assessment. Appropriate risk management measures will vary from case to case and should be established in combination with the risk assessment. The type of organisms involved and the manner in which they will be released will also play a role in assigning appropriate risk management measures.

Please note that the measures below are only an indication of possible containment measures that can be used. The applicant may propose the type of measures to be used, however the applicability of the proposed measures and any additional measures will be determined by the Executive Council.

ii) The type of barriers used to obtain containment will in large depend on the type of activity. For e.g. if the aim of the activity is to use the GMO within a laboratory and there is no intention for release, the risk management measures will be different than for activities which involve the deliberate release of the GMO into the environment (trial release). In the case of deliberate release, the aim would not be to obtain containment per se, but to control the risk of potential harm from occurring by implementing appropriate risk management measures.

iii) There are four types of barriers that can be used. Please note that different barriers or a combination of different barriers will be applicable in different situations.

a) Physical or chemical barriers
These barriers are manipulations of the physical or chemical factors, which will induce a 100% mortality in one or more stages during the life cycle of the GMO.

b) Mechanical barriers
Mechanical barriers are made up of mechanical structures, which can be either stationary or moving barriers that will physically keep the GMO from escaping from the activity site. Additionally mechanical barriers can be placed in series at critical locations in the trial site to increase the strength of the barrier.

c) Biological barriers
These are barriers created through measures that would prevent the GMO from reproducing at the site of activity, and would reduce the possibility of survival of the GMO in the environment if released. Biological barriers are usually not sufficient on their own and one needs to add physical, chemical or mechanical barriers to obtain efficient containment.

d) The scale of the project as barrier
This can only be applicable for the research phase of testing a GMO. E.g. if the number of GMO's at the research site were kept so small that an escape into the environment would not impose the risk associated with the identified hazard. If the GMO is a self-fertilising hermaphrodite or a true pathogen, this barrier is not applicable as the escape of only one individual could result in the establishment of a whole population.

7.1 General risk management measures with regard to the deliberate release of GMO's into the environment

This section provides possible risk management measures in order to control the risk of potential harm occurring from a deliberate field release. Please note that the measures listed here are not exhaustive.

a) General risk management measures which may be used for plants
- Reproductive isolation through –
  - spatial separation
  - temporal separation
  - biological prevention of flowering
  - removal of reproductive organs
  - bagging flowers
  - making use of sterile plants
- Controlling the dispersal and persistence of reproductive structures such as seeds.
- Destroying all volunteer plants after harvest for a certain period after completion of the release, with the period depending on the type of plant involved.
- Installation of bird netting if necessary
- Prevention of access to burrowing animals by installing buried liners or suitable barriers

b) General risk management measures which may be used for animals
- Confinement by means of fences, filters, islands or ponds
- Reproductive isolation by using sterile animals
- Isolation from feral animals of the same species
- Controlling the persistence and dissemination of the reproductive structure such as larvae or eggs

- Installation of bird netting if necessary
- Prevention of access to burrowing animals by installing buried liners or suitable barriers

c) General risk management measures which may be used for micro-organisms
- Confinement by using organisms that do not have the ability to grow or survive in the environment
- Minimising gene transfer by using organisms that do not contain self-transmissible mobilisable or transposable genetic elements, or by ensuring that the inserted trait is incorporated into the chromosome.

d) Additional risk management measures that may be used
- Appropriate information and training to personnel involved in the release
- Apply monitoring procedures in such a manner to ensure that efficient steps can be taken in the event of unexpected release
- Control the dissemination and gene flow of the organism from the release site
- Maintain sufficient access control to the release site/facility through -
  - Supplying an ID-badge with a photo of each worker. No person may enter the site/facility without showing the badge.
  - Supply security training to all personnel
  - Installing security alarms
  - Erect signs and warnings at the entry sites
  - Maintain written security plans
  - Maintain adequate records of all activities with in the site or facility
  - Make all visitors sign in and out
  - Accompany all visitors to and from the site/facility.

7.2 Additional risk management options that may be used with herbicide resistant crops (HRC)

The options noted in this section only highlights the management options that may be used to control the development of herbicide tolerance, and does not exclude other risk management measures necessary when conducting a deliberate release with GMO's. Please take note that the options listed here are not the only options available, and the applicant may make use of alternatives.

The following risk management measures may be used –

- Identification of weed problems in the field (i.e. the species present and density of weeds, whether the weed species can easily cross with the GM-crop, what the seed longevity is for the potentially resistant weed)
- The use of cultural or non-chemical weed control methods to decrease selection pressure from the herbicide tolerant crop herbicide (i.e. ploughing prior to sowing, delaying planting an pre-emergence spray with a non-selective herbicide, use crop seed free from weed seed, and prevent seed production in weeds by cutting prior to seed set)
- Rotate with herbicides or use mixtures (i.e. avoid continued use of herbicides having the same mode of action unless it is integrated with other weed control practices, use non-selective herbicides prior to crop emergence to control early flushes of weeds and in case of metabolic resistance, decisions must be made on a case by case basis)
- Tailor the weed control program to weed densities and or economic thresholds
- Follow label instructions provided by the seed supplier, including recommended use rates and application timing.

- Monitor results of herbicide applications while being aware of any trends or changes in the weed population present.
- Maintain detailed field records so that cropping of GM-crops and herbicide history is known.
- If resistance does occur, seek ways to limit further seed production of the tolerant plants by eradicating the remaining weed population if they are growing in patches. This can be done in order to limit build-up and the spread of seed in the soil, and to limit the field to field movement of resistant populations.

7.3 Additional risk management options that may be used with insect resistant crops (IRC)

This section contains recommendations for managing resistance when growing crops modified to convey resistance against insects, however managing insect resistance is not the only aspect to be considered in the risk management strategy proposed for insect resistant crops. This section merely highlights the management options that may be used to control the development of insect resistance per se.

The following risk management measures may be used –

- The use of a refugia (area) of non-GM-crop
- By practising an Integrated Pest Management System to preserve the natural enemies of the harmful insects. The basic principles of integrated control combines biological and chemical control options, i.e. assessment of infestation of insects, control based on thresholds and the protection and usage of the naturally occurring enemies of the harmful insect.
- Monitoring the GM-crop and to contact the seed provider if resistance problems are suspected or experienced.

8. DEFINITIONS AND ABBREVIATIONS

Accident	Any accident involving the unintended general release of a GMO, which could have an immediate or delayed adverse impact on the environment.
Aerosol	Liquid droplets or solid particulars dispersed in a gaseous medium. A gaseous suspension of ultra microscopic particles.
Applicant/notifier	The party (e.g. seed producer or importer, agro-chemical company, farmers' organisation or research institute) that requests permission to deliberately release or introduce a GMO in a country.
Authority	A governmental institution, organisation or entity officially designated in terms of the GMO Act to deal with matters arising from the responsibilities set forth in the Guidelines.
Bacillus thuringiensis (B.t.)	Naturally occurring bacteria present in soil and used successfully by home gardeners and organic farmers to control certain insects. When ingested by a target insect, the protein produced by B.t. controls the insect by disturbing the digestive system.
Biohazard	A potentially dangerous infectious agent.

Biological containment	Genetic or physical impediments to the infectivity and or survival of a micro-organism or eukariotic cell.
Bioproducts	A product derived from or produced by cells or organisms
Competitiveness	A plant's ability to exploit essential elements such as light, water and plant nutrients at the expense of other plants.
Congeners	Refers to species belonging to the same genus.
Conspecific	Refers to individuals or populations of the same species.
Contained use	Any activity in which organisms are genetically modified or in which such GMO's are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment.
Crop production system	A particular agricultural method, including monocultures, rotations and polycultures, and their associated practices such as tillage plant protection and harvesting.
Decontamination	A process whereby viable micro-organisms are removed from solutions, surfaces or materials by filtration, heating, radiation or chemicals.
Eukaryotic cell	A cell with definite nucleus
Ecosystem	A complex of organisms and their environment, interacting as a coherent unit (natural or modified by human activity, e.g. agro-ecosystem) to maintain a flow of energy and to acquire, store and recycle nutrients.
Fitness	Reproductive success or the proportion of genes an individual leaves in the gene pool of a population.
Gene flow	The transfer of genes (specifically, alleles) from one population to another by way of interbreeding of individuals in the two populations.
Gene pool	All of the alleles available among the reproductive members of a population from, which gametes can be drawn.
General release	The introduction of GMO's into the environment by whatever means, where the organisms are no longer contained by any system of barriers and are no longer under any person's control, so that the organisms is likely to survive and be disseminated.

Genetic engineering	The technique of removing, modifying or adding genes to a living organism; also called recombinant DNA (rDNA) technology or genetic modification.
Genetically modified organism (GMO)	An organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both.
Hazard	Intrinsic biological, chemical or physical characteristic of a GMO, which could lead to an adverse impact on the environment.
HEPA filter	High Efficiency Particulate Air filters (99.97% efficient removal of 0.3μm particles).
Herbicide	A chemical substance or mixture of substances designed to control weeds.
Herbicide resistant crop (HRC)	A crop plant that by genetic modification(s) or breeding has acquired resistance towards a herbicide it would otherwise be sensitive to.
Impervious	Not affording passage
Inactivation	Any process that destroy the ability of a micro-organism or eukaryotic cell to replicate.
Infection	Invasion and multiplication of micro-organism in body tissue which may or may not be clinically apparent.
Insect resistant crop (IRC)	A crop that by genetic engineering has become protected from damage by one or more harmful insects.
Insecticide	A chemical substance or mixture of substances that controls insects that harm crop production or prevents their damage.
Introgression	The transfer of genes from one population to another by backcrossing.
Invasiveness	The ability of a plant to spread and become established over large areas, displacing existing vegetation.
Micro-organism	Microscopic living entity, which can be viruses, prokaryotes or eukaryotes.
Marketing	The theory or practise of commercial selling, i.e. supplying or making available to third parties.
Monitoring	The maintaining of regular surveillance over, the checking of, the warning about or the recording of a situation or process.
Pathogen	A biological agent cell capable of producing disease.
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plant or plant products.

Pesticide	Refers to any substance or mixture of substances intended to prevent, destroy or control any pest, including substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest or protect the commodity from deterioration during storage and transport.
Physical containment	The confinement of a micro-organism or eukaryotic cell to prevent or minimise its contact with people and /or the environment.
Procaryotic cell	A cell that is lacking a true nucleus or nuclear membrane.
Trial release	The deliberate release of a GMO into the environment in the open under conditions where the degree of dissemination of the GMO is limited by chemical or physical barriers or by built-in barriers which prevent the survival of such organisms in the environment.
Resistance	In the case of plant populations, their inherited ability to grow and reproduce normally when exposed to high doses or levels of a specific agent (e.g. herbicide or insect attacks), which normally would harm plants.
Risk	The probability of causing or incurring a loss or damage or an adverse impact or a misfortune.
Risk assessment	The qualitative or quantitative evaluation of risks resulting from the release of genetically modified plants or products containing GMO's.
Seed Banks	accumulations of ungerminated seeds in the soil representing the balance between the seed rain (seeds that fall or are dispersed from fruits) and seed losses through germination, predation and death. (Archibold 1989)
Spread	Expansion of the geographical distribution of plants containing a genetically modified gene.
Sterilisation	An act or process of destroying all forms of microbial life on and in an object.
Tolerance	When referred to organisms, it is an increased ability of a biotype to endure damage, survive and reproduce after a limited exposure to a specific stress factor (in this context, herbicide applications or insect attack) compared to other biotypes of the species. Tolerance is often a polygenetic inherited trait.

Transgene	A gene or DNA fragment from one organism that has been stably incorporated into the genome of another organisms of interest.
Transgenic	See Genetically Modified Organism (GMO)
Vector	A plasmid, bacteriophage, etc. that can be used to transfer DNA sequences from one organism to another.
Volunteer	A crop plant regenerated from seed or propagules left after a previous harvest and which can act as a weed in the present crop.
Weed	A plant that is growing where humans do not want it.

9. REFERENCES

9.1 Archibold, O.W. 1989. Seed banks and vegetation processes in coniferous forests. In *Ecology of soil seed banks.* Eds. M.A. Leck, V.T. Thomas, and R.L. Simpson. London: Academic Press.

9.2 Canadian Food Inspection Agency Website Information – Plant Biosafety Office.

9.3 Cartagena Protocol on Biosafety to the Convention of Biological Diversity.

9.4 Compendium of Guidance from the Health and Safety Commission's Advisory Committee on Genetic Modification, Directorate of Science and Technology, UK (www.open.gov.uk)

9.5 Guidelines and Procedures for work with genetically modified organisms - February 1998. Compiled by the South African Committee for Genetic Experimentation (SAGENE).

9.6 Guidelines for the analysis, assessment and management of associated risks – working draft of May 2000. Compiled as part of the International Standards for Ecological Risk Assessment of Herbicide or Insect Resistant Crops

9.7 Guidelines for the Regulation of Veterinary Biologics produced by Biotechnology. Food Production and Inspection Branch, Agriculture Canada. Samagh, B.S. ,1989.

9.8 Laboratory Biosafety Guidelines, 2nd Edition 1996. Health Canada – Health Protection Branch/Laboratory Centre for Disease Control.

9.9 Manual on assessing ecological and human health effects of genetically engineered organisms, Part one: Introductory Materials and Supporting Text for Flowcharts. Compiled by the Scientist' Working Group on Biosafety, 1998. The Edmonds Institute, Washington, USA.

9.10 Manual on assessing ecological and human health effects of genetically engineered organisms, Part two: Flowcharts and Worksheets. Compiled by the Scientist' Working Group on Biosafety, 1998. The Edmonds Institute, Washington, USA.

9.11 Netherlands Guidance Notes. Directive 90/220/EEC (14 November 2000).

9.12 Opinion: European Commission, Opinion of the Scientific Steering Committee: Risk Assessment in a Rapidly Evolving Field - The Case of Genetically Modified Plants. October 2000.

9.13 Paper: Agricultural and Environmental Biotechnology Commissions (UK): Risk Assessment for Releases and Marketing of GMO's in the EU.

9.14 Paper: UK Advisory Committee on Releases to the Environment - Commercial use of GM crops in the UK: The potential wider impact on farmland wildlife.

9.15 TRAYNOR, P.L., ADAIR, D. AND IRWIN, R. 2001. Greenhouse Research with Transgenic Plants and Microbes, A Practical Guide to Containment. Sexton Printing St Paul, Minnesota.

9.16 United Nations Environment Programme (UNEP) International Technical Guidelines for Safety in Biotechnology – December 1995.

9.17 USDA website on Agricultural Biotechnology at www.usda.gov.

10. ANNEXURES

ANNEXURE 10.1

BASIC LABORATORY PROCEDURES

The following procedures are regarded necessary to ensure that all activities within a laboratory are conducted in a safe and precise manner.

1. All laboratory personnel must understand the biological and other hazards with which they will come in contact through their normal work in the laboratory, and be trained in appropriate safety precautions and procedures.
2. A laboratory safety manual must be prepared and adopted. The laboratory director or supervisor is responsible to ensure that the manual identifies known and potential biohazards and specifies practices and procedures to eliminate or minimise such risks.
3. Training in laboratory safety must be provided and competence in safe technique demonstrated before work is allowed with hazardous agents or toxins.
4. Laboratories should have a Biological Safety Officer (BSO) and/or a Biological Safety Committee whose responsibility includes ensuring that all work is carried out in accordance with the safety practices established at the Institution. (Refer to Annexure 10.2)
5. Duties of the BSO should include providing technical advice on safety procedures and equipment, developing emergency plans, conducting safety inspections, providing biosafety training, conducting or supervising testing of containment systems and providing guidance and information related to compliance with pertinent regulations. Refer to Annexure 10.2)
6. Laboratories must be kept neat, orderly, clean and storage of materials not pertinent to work should be minimised.
7. Protective laboratory clothing must be available and worn properly fastened by all personnel, including visitors, trainees and others entering or working in the laboratory. Protective laboratory clothing must not be worn in non-laboratory areas. Suitable footwear with closed toes and heels, preferably with non-slip soles must be worn in all laboratory areas.
8. Gloves must be worn for all procedures that might involve direct skin contact with toxins, blood, infectious materials or infected animals. Hand jewellery, which would interfere with glove functioning, should be removed. Gloves should be removed carefully and decontaminated with other laboratory wastes before disposal. Reusable gloves may be used only where necessary and must be appropriately decontaminated.
9. Eyewear must be worn when necessary to protect the face and eyes from splashes, impacting objects, harmful substances and UV light or other rays.
10. Eating, drinking, smoking, storing food, personal belongings or utensils, applying cosmetics and inserting or removing contact lenses are not permitted in any laboratory work area. Contact lenses should be worn only when other forms of corrective eyewear are not suitable. The wearing of jewellery should be discouraged in the laboratory.
11. Oral pipetting of any substances is prohibited in any laboratory.
12. Long hair must be tied back or restrained.
13. Hands must be washed after gloves are removed, before leaving the laboratory and at any time after handling materials known or suspected to be contaminated.
14. Work surfaces must be cleaned and decontaminated with a suitable disinfectant (e.g. 70% ethanol) at the end of the day and after any spill of potentially dangerous material. Loose or cracked work surfaces must be replaced or repaired.
15. All technical procedures must be performed in a manner that minimises the creation of aerosols.
16. All contaminated or infectious liquid or solid materials must be decontaminated before disposal or reuse. Contaminated materials that are to be autoclaved or incinerated at a site away from the laboratory, must first have the outside of the container disinfected chemically or be double bagged. (E.g. Liquid biohazards should be added to 10% bleach, and incubated for 30 minutes and then autoclaved at 135°C for 20 minutes).
17. Access to the laboratories must be strictly limited, especially containment levels 3 and 4. Decisions on entry into containment level 1 and 2 laboratories should be at the discretion of

the laboratory director or principal investigator. Children under the age of 16 years old should not be permitted in the laboratory or support area. Pregnant women or immuno-compromised people who work in or enter the laboratory should be advised of the associated risks.

18. Hazard warning signs, indicating the risk level of the agents being used, must be posted outside each laboratory, when indicated by the risk assessment. Where infectious agents used in the laboratory require special provisions for entry, the relevant information must be included in the sign. The agent must be identified and the name of the laboratory supervisor and other responsible persons as well as any special conditions for staff entry, must be listed.

19. The use of needles, syringes and other sharp objects should be strictly limited. Needles and syringes should be used only for parenteral injection and aspiration of fluids from the laboratory animals and diaphragm bottles. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Procedures should be performed in a biological safety cabinet; needles should be promptly placed in a puncture-proof container and decontaminated, preferable by incineration or autoclaving, before disposal.

20. All spills, accidents, and overt or potential exposures must be reported in writing to the laboratory supervisor or acting alternate as soon as circumstances permit; this person should file this report with management and the appropriate BSO or committee. Appropriate medical evaluation, surveillance, and treatment should be sought and provided as required. Actions taken to prevent future occurrences should be documented.

21. Baseline serum for laboratory and other at-risk personnel should be collected and stored, if required by the risk assessment. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

22. Laboratory workers should be protected by appropriate immunisation where possible. Levels of anti body considered to be protective should be documented. Particular attention must be given to individuals who are or may become immuno-compromised, as vaccine administration may be different than for immunologically competent adults.

ANNEXURE 10.2

CLASSIFICATION AND OPERATION OF A FACILITY

1. As a preface to this section, it should be noted that the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) and the Hazardous Substances Act, 1973 (Act No. 15 of 1973) place responsibilities on employers and employees in relation to all hazards at work. This includes responsibilities that may arise from genetic modification work. Guidelines and regulations in this regard may be obtained at the following address –

   Department of Labour
   Private Bag X117
   Koedoe Building Room 320
   Pretorius Street
   Pretoria
   0001
   Tel: +27 +12 309 4400
   Fax: +27 +12 320 5112 or 2808

2. A laboratory facility or large-scale facility must be classified as containment level 1,2,3, or 4. The requirements for each containment level are specified in section 5 of the guidelines. A glass house facility must meet the specifications as laid out in section 6.

3. For each facility a responsible person(s) and/or a biological safety officer responsible for the work or particular aspects of work which fall under the Act, must be identified. The person(s) identified as responsible for the work in question must assess, or cause to be assessed, the risk that might arise during work.

4. The Biological Safety Officer should have experience in working within a containment laboratory or with similar practices, but the absence of such experience should not necessarily preclude the appointment of an individual who is otherwise well suited for the position. He/she must be appropriately trained and provided with technical assistance as necessary. Appropriate deputising arrangements should also be made.

5. The Biological Safety Officer must further act as adviser to the head of the establishment or department in all matters relating to the containment of biological hazards and the safety of staff. In the event that the BSO is involved as principal investigator, appropriate deputising arrangements should be made.

6. The Biological Safety Officer should not be the head of the establishment or department.

7. The Biological Safety Officer must carry out regular safety audits and supervise a regular testing program for all exhaust protective cabinets and HEPA filters when these are part of the laboratory equipment.

8. The Biological Safety Officer is to be answerable to the head of the establishment or department, in so far as genetic modification work is concerned, for -

   i) ensuring that the local rules are followed;
   ii) all aspects of training in appropriate laboratory practice;
   iii) investigating all accidents, spillage etc. in the laboratory and taking what action he/she considers necessary. Each incident and the action taken must be recorded, together with the name of the personnel involved;

iv) the safe storage of GMO's, and pathogenic or potentially pathogenic material, and also for ensuring that an inventory of these is maintained;
v) the appropriate transport of all GMO's (transfer of organisms constructed at containment level 2 or above should be recorded);
vi) liaison with the Supervisory Medical Officer;
vii) ensuring that laboratories are appropriately disinfected prior to the start of a new experiment or the entry of maintenance personnel. Appropriate disinfection could range from swabbing down work surfaces to complete fumigation;
viii) physical security of the laboratory.

9. Before agreeing to a new entrant working in a containment laboratory the Biological Safety Officer must be satisfied that the individual concerned is familiar with the local rules and the correct use of the laboratory equipment. The new entrant must have training in good laboratory techniques, preferably externally, but a prescribed period of in-house training may suffice. A responsible member of the laboratory staff must supervise the work of all new entrants.

10. In laboratories for which he/she is responsible, the Biological Safety Officer must maintain a list of all people who are working there.

11. No-one may enter the containment area (other than in an emergency) for cleaning, servicing of equipment, repairs or other activities outside the normal work of the laboratory unless a responsible member of staff has previously been informed and, in containment level 2 or above, laboratory surfaces have been disinfected.

12. The responsible member of staff in charge of experiments is

i) answerable at all times to the Biological Safety Officer for the safe execution of the work in progress and
ii) responsible for ensuring the day-to-day cleanliness of the laboratory.

13. Appropriate protective clothing must be worn in the containment area. When working in an exhaust protective cabinet, gloves should always be worn.

14. Protective clothing designated for use in a containment laboratory must not be worn outside the facility.

15. Each establishment must draw up local rules. The local rules must include information on such matters as:

i) selection and training of laboratory staff and supervision of work;
ii) policy of disinfection (see Annexure 10.4) and procedures for the disposal of potentially infective material;
iii) guidance for ancillary and maintenance staff, contractors and visitors;
iv) maintenance and test procedures for ventilation systems, high efficiency particulate air (HEPA) filter, microbiological safety cabinets (see Annexure 10.3) and other safety equipment;
v) health surveillance which should, where appropriate, include screening procedures including the immune status of the individual, sickness investigation, issues of medical contact cards, immunisation procedures, maintenance of baseline serum samples from staff;
vi) the duties of the biological safety officer.

ANNEXURE 10.3

BIOLOGICAL SAFETY CABINETS

1. Reference should be made to the "Proposed Compulsory Specification for Biological Safety Cabinets (Classes I, II and III)", Government Gazette 15 June 1990, obtainable from SABS under reference no. VC8041 (2001). This gives a full description of the three types of safety cabinets, class I, II and III. The testing and maintenance of these cabinets is also covered in the SABS Code of Practice for the Installation, Post Installation Tests and Maintenance of Biological Safety Cabinets (SABS 0226 2001).

   Both of these standards can be obtained at the following address –

   SABS Standards Sales
   Pretoria
   Tel: 27 12 428 6841 / 6482
   Fax: 27 12 428 6928
   E-mail: sales@sabs.co.za

2. The class II cabinet is designed to control airborne contamination of the work while at the same time reducing the exposure of the operator to airborne particles, which are dispersed inside the cabinet during the work procedures. In the simplified form of cabinet these two functions are achieved by a recirculating downward flow of filtered air over the work area; part of this airflow is exhausted to the atmosphere through a HEPA filter and make-up air is drawn into the cabinet through the open work front.

3. Before a cabinet is selected, the user should assess the need for protection of the work and relate this to the operator protection factor that can be achieved in the prevailing conditions of use. The cabinet must be correctly sited and should be used only by appropriately trained personnel.

4. Careful working procedures will be essential and access to the laboratory should be restricted whilst the cabinet is in operation. The inward airflow that is drawn through the aperture of open-front cabinets (class I and II) can be disturbed by, for example, sudden movements of the arms of the operator, turbulence around the equipment placed inside the cabinet, persons moving across the front of the cabinet, by air movements in the room and changes in air pressure. Disturbances of this kind may affect the level of protection for the operator particularly when a class II cabinet is used since this type generally has a lower inward air velocity through the upper areas of the work front than a class I cabinet. The protection factor provided by the cabinet should therefore be determined. Class I and II cabinets must not be used at containment level 4.

5. Provided that a class II cabinet gives a protection factor of 1.5×10^5 or better (see Government Gazette, 15 June 1990), and if it can be shown that this level is achieved consistently (by testing at regular intervals), a class II cabinet may be used for some work at level 3 where protection of the work is essential. Consideration should always be given however to the use of a class III cabinet that will provide a high level of protection for both the work and the operator.

ANNEXURE 10.4

DISINFECTION

1. Disinfection generally refers to the use of chemical agents to destroy the potential infectivity of a material, but does not imply the elimination of all viable micro-organisms.

2. Effective disinfection is dependent upon the following factors:

   i) The activity : the effectiveness of a particular disinfectant varies with the micro-organism (Table at the end of this Annexure)

   ii) Concentration : the "use-dilution" is the correct concentration for effective disinfection in particular circumstances e.g. spillage, discard jars. The effective concentration may be dependent upon the age of the solution, as once diluted disinfectants lose effectiveness with time.

   iii) Contact : intimate contact for a sufficient period of time must be maintained between the disinfectant and the contaminated article, e.g. air bubbles should be removed from submerged articles.

3. The disinfectants most commonly used are hypochlorites, clear phenols and alcohol. In the following paragraphs more information is on each disinfectant. Less often disinfectants used are aldehydes and surface-active agents.

   i) Hypochlorites
   - ❖ E.g. Jik
   - ❖ Hypochlorites have a wide spectrum of antimicrobial activity and are rapid in action but they are corrosive, inactivated by organic matter and decompose once diluted.
   - ❖ Recommended dilutions are as follows:

General use	:	a solution containing 1000-ppm available chlorine
Discard jars	:	a solution containing 2500-ppm available chorine
Spillage	:	a solution containing 10000-ppm available chlorine

   Organic chlorine-releasing compounds, e.g. chloramine, have the advantage that chlorine is not lost so readily and so exert a more prolonged antimicrobial effect.

   ii) Clear Phenols
   - ❖ E.g. Hycolin, Stericol, etc.
   - ❖ Phenols are non-corrosive and have a wide range of activity but may be ineffective against non-lipid viruses. Some phenols are affected by organic matter and their antimicrobial activity may also be reduced by hard water Phenols should be used at the manufacturer's recommended use-dilution but should not be stored diluted.

   iii) Alcohols
   - ❖ E.g. 70% ethanol, 60% isopropanol
   - ❖ Alcohols give a very rapid kill of bacteria and some viruses, but because they are relatively volatile do not provide a sustained antimicrobial action.
   - ❖ Alcohols are flammable and require appropriate precautions in storage and use. They should not be used in microbiological safety cabinets or on large areas.

   iv) Aldehydes
   - ❖ Formaldehyde as the vapour or the aqueous solution (formalin) is toxic and is not suitable for general purposes. However it is used for fumigating microbiological safety cabinets and certain rooms (e.g. high containment laboratories).
   - ❖ During fumigation containers of other disinfectants should be sealed if the disinfectant is incompatible with the fumigant.

- ❖ Glutaraldehyde is also toxic but has relatively low vapour pressure and is usually used as a solution. It has wide range of activities, including against bacterial spores. It is non-corrosive, but does not readily penetrate organic matter and is not particularly stable once activated.

v) Surface-active agents
- ❖ Only the cationic and amphoteric detergents have any antimicrobial activity, and these are regarded as being more bacteriostatic than bactericidal.
- ❖ They are relatively non-toxic and non-irritant but are inactivated by organic matter and anionic detergents e.g. soap.
- ❖ Quaternary ammonium compounds form the basis of the majority of cationic detergents e.g. Cetrimide, Roccal.
- ❖ Only a limited range of amphoteric detergents has been produced as antimicrobial agents e.g. Tego.

4. When selecting a disinfectant its toxicity to humans and the appropriate health and safety precautions should be considered. Different disinfectants must not be mixed together or used in combination unless the possibility of hazardous reactions or the formation of toxic products has been properly assessed.

5. Arrangements should be made for appropriate procedures and training to ensure that suitable disinfectants, at the correct dilutions are available at the point of use. There are advantages in limiting the number of different disinfectants available in the workplace to the minimum necessary, in order to avoid confusion and to reduce costs. Once a disinfectant has been selected, in-use tests should be carried out to monitor not only the performance of a particular disinfectant but also the way in which it is used, for example to detect dilutions wrongly made up or not made up freshly, the use of dirty containers and incompatible reagents for example, certain type of detergent.

Table: Activities of some common classes of disinfectants (note: the specific activity of a particular disinfectant must be assessed on a case-by-case basis)

	Vegetative Bacteria	**Active against Bacterial spores**	**Fungi**	**Lipid Viruses**	**Non Lipid Viruses**
Hypochlorites	+	+	1	+	+
Phenols	+	-	+	+	2
Alcohols	+	-	-	+	2
Aldehydes	+	+	+	+	+
Surface-active agents	+	-	1	2	2

1. Limited anti-fungal activity.
2. Depends on the virus.

ANNEXURE 10.5

RECOMMENDATION DOCUMENT

The chairperson of each review will compile a recommendation document.
The format of the document will be as outlined below.
(The applicant has to ensure that the necessary information is contained in the application to enable the review committee to comment on each item with regard to the application. Failure to supply all the information will result in the application being withheld until all requested information has been submitted.)

A: Details of the review committee
Provide the full names, institutions and expertise involved in the review committee.

B: Summary of the application
Particulars of the applicant's request
i) Name of the applicant
ii) Title of the application
iii) Reference number given by the Registrar's office
iv) Short description of the applicant's request
- The intended use
- Purpose of the use
- Scale of use

v) Short description of the genetic modification
- What it is?
- How developed?
- Stability of integration?

C: Procedures followed during evaluation of the application
Stipulate all dates and actions involved during the evaluation process from the moment that the review chairperson receives the application.

D: Safety issues assessed:
1. Food and feed:
- Toxicological studies
- Allergenicity studies
- Compositional analysis
- Nutritional analysis
- Pathogenicity
- Feeding trials
- Any other

2. Environment:
- Weediness/invaseness
- Gene flow
- Altered plant pest potential
- Non-target organisms
- Impact on biodiversity
- Any other

E: Non-safety issues
- Experimental design
- Sociological factors
- Economical factors
- Any other

F: Risk management
Proposed risk management measures that should be incorporated into the permit.

G: Recommendation
Provide a recommendation to the Executive Council

H: Appendix
Attach individual review reports

ANNEXURE 10.6

REVIEWERS' CHECKLISTS

This checklist may be used by any member of the sub-committee with the necessary expertise, and may be attached to the report submitted by the reviewer.
These checklists are intended to assist the reviewers, but take note that (a) a particular application may not contain all types of data listed and (b) there may be additional data provided by the applicant, or required by the reviewer, that is not included in this list.

SECTION I – CHECKLIST FOR NORTHERN BLOT DATA

	YES	NO	COMMENT
Does the Northern blot have a figure number and title?			
Are lanes labelled on the blot?			
Does the figure legend describe each lane of the blot, including a description of the following for the RNA that was loaded: ▪ What type of material was loaded (e.g. total purified RNA, poly-A RNA, crude prep, total plant extract)? ▪ Source of the material loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? ▪ Quantity of material loaded in each lane? ▪ Quality of material loaded in each lane?			
Does the text or figure legend describe how RNA was extracted prior to electrophoresis?			
Does the blot have appropriate positive and negative control lanes - ▪ Positive control consisting of a dilution series of control RNA complemented with wild type RNA of the same tissue (this control is especially relevant for blots used to substantiate the absence of expression); ▪ Positive control purified RNA; ▪ Negative control - the unmodified parental line or variety; ▪ Check for loading differences using a probe for a "constitutive" mRNA.			
Is the gel system and Northern hybridisation protocol described in the text or in the cited literature reference? Are any modifications of the cited protocols described in the petition (application) text?			
Is the position of molecular size standards on the gel indicated, and do they cover an appropriate size range for the fragments that are expected to be detected on the blot?			
Is there a description of the probe that was used for the hybridisation? If so, is the description adequate (in the text on in the figure) to enable one to interpret the results?			
If quantitative analysis is performed, has the methodology or citation to such been provided, and have a sufficient number of replicates or samples been tested to determine whether there are differences between samples or treatments?			
Are any superfluous bands or background signals properly explained?			

SECTION II – CHECKLIST FOR SOUTHERN BLOT DAT

	YES	NO	COMMENT
Does the Southern blot have a figure number and title?			
Are lanes labelled on the blot?			
Does the figure legend describe each lane of the blot, including a description of the following for			

	YES	NO	COMMENT
the DNA that was loaded on the gel:			
▪ Type of DNA loaded (e.g. entire plasmid, restriction fragment)? ▪ Source of DNA loaded (e.g. transformation event, tissue, etc.)? ▪ Restriction digestions of DNA prior to loading gel? ▪ Quantity of material loaded in each gel? ▪ Quality of the material loaded in each gel?			
Does the gel have appropriate positive and negative control lanes – ▪ Positive control consisting of a dilution of a series of control DNA complemented by wild type DNA of the same tissue; ▪ Positive control purified transformation vector; ▪ Negative control – the unmodified parental line or variety.			
Is the gel system and Southern hybridisation protocol described in the text or in the cited literature referenced? Are any modifications of the cited protocols described in the petition (application) text?			
Is the position of the molecular size standards indicated, and do they cover an appropriate size range for the fragments that are expected to the detected on the blot?			
Was an entire plasmid used as the probe for the hybridisation? If so, is the plasmid described adequately in the text or in a figure to enable one to interpret the results?			
Was a restriction fragment used as the probe for the hybridisation? If so, is the restriction fragment described adequately in the text or in a figure to enable one to interpret the results?			
Are any superfluous bands or background signals properly explained?			

SECTION III – CHECKLIST FOR RNA DOT BLOT DATA

	YES	NO	COMMENT
Does the Dot blot have a figure number and title?			
Are lanes labelled on the blot?			
Does the figure legend describe each lane of the blot, including a description of the following for the RNA that was loaded: ▪ What type of material was loaded (e.g. total purified RNA, poly-A RNA, crude prep, total plant extract)? ▪ Source of the material loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? ▪ Quantity of material loaded in each lane? ▪ Quality of the material loaded in each lane?			
Does the text or figure legend describe how RNA was extracted prior to blotting onto the solid support?			
Does the blot have appropriate positive and negative control lanes – ▪ Positive control consisting of a dilution series of control RNA complemented with wild type RNA of the same tissue (this control is especially relevant for blots used to substantiate the absence of expression); ▪ Positive control of purified RNA ▪ Negative control – the unmodified parental line or variety.			
Is the blot system and hybridisation protocol described in the text or in the cited literature			

	YES	NO	COMMENT
reference? Are any modifications of the cited protocols described in the submitted text?			
Is there a description of the probe that was used for the hybridisation? If so, is the description adequate (in the text on in the figure) to enable one to interpret the results?			
If quantitative analysis is performed, has the methodology or citation to such been provided, and have a sufficient number of replicates or samples been tested to determine whether there are differences between samples or treatments?			

SECTION IV – CHECKLIST FOR WESTERN BLOT DATA

	YES	NO	COMMENT
Does the blot have a figure number and title?			
Are lanes clearly labelled?			
Does the figure legend describe each lane of the blot, including a description of the following for the protein that was loaded: ▪ What type of material was loaded (e.g. pure, crude, total plant extract)? ▪ Source of the material loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? ▪ Quantity of material loaded? ▪ Quality of the material loaded?			
Is the protein extraction method adequately described in either the text or the legend?			
Is the antibody or antiserum preparation protocol adequately described in the text, including an adequate description of the antigen and its purity? Has the specificity of the antibody or antiserum been determined and described in the text or in a cited literature reference?			
Is the gel system and blotting protocol adequately described in the text or in a cited literature reference?			
Is the position of the molecular weight standards indicated, and do they cover the appropriate range for the proteins expected to be detected on the blot?			
Does the blot include appropriate positive and negative controls – ▪ Positive control consisting of a dilution series of control protein complemented with wild type material of the same tissue (this control is especially relevant for blots used to substantiate the absence of expression); ▪ Positive control of purified protein; ▪ Negative control – the unmodified parental line or variety.			
Was a normal serum control conducted?			
Are any superfluous bands or background signal properly explained?			
If quantitative analysis is performed, has the methodology or citation to such been provided, and have a sufficient number of replicates or samples been tested to determine whether there are differences between samples or treatments?			

SECTION V – CHECKLIST FOR PCR DATA

	YES	NO	COMMENT
Does the PCR gel have a figure number and title?			
Are lanes labelled on the gel?			

	YES	NO	COMMENT
Does the figure legend describe each lane of the gel, including a description of the following for the DNA that was loaded: ▪ What type of material was loaded (e.g. plasmid fragment, amplified DNA)? ▪ Source of the material used in each reaction loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? ▪ Quantity of material loaded? ▪ Quality of material loaded?			
Is the position of the molecular weight standards indicated, and do they cover an appropriate size range for the fragments that are expected to be detected on gel?			
Does the text or figure legend describe how PCR amplification was performed prior to electrophoresis?			
Is there a description of the primers used for amplification in the text or in the figure sufficient to enable one to interpret the results?			
Does the gel have appropriate positive and negative control lanes - ▪ Positive control might demonstrate specificity of the primers and the ability to amplify the appropriate size band; ▪ Negative controls might include amplification with DNA from the unmodified parental line or variety, and amplification in absence of DNA template; ▪ Check for amplification of a control fragment from the plant sample (to show that PCR is working, especially if it is intended to show absence of a specific DNA); ▪ Mix plant DNA with plasmid DNA (I copy control) to demonstrate that the PCR is working properly.			
Was an entire plasmid or a restriction fragment used as the positive control template and is it adequately described in the text or in the figure legend for interpretation of the PCR results?			
Is the gel system and PCR protocol described in the text or in a cited literature reference? Are modifications of a cited protocol described in the text?			

SECTION VI – CHECKLIST FOR ELISA DATA

	YES	NO	COMMENT
Does the table have a number and a title?			
Are all entries clearly identified in the table and described in the text or table legend?			
Is the sample preparation described?			
Is the antibody or antiserum preparation protocol adequately described in the text, including a description of the antigen and its purity? Has the specificity of the antibody or antiserum been demonstrated and described in the text or in a cited literature reference?			
Is the ELISA protocol used described in the text or cited in the scientific literature? Any modifications to a cited protocol must be described.			
Were appropriate positive controls (e.g. purified protein) and negative controls (e.g. normal or preimmune serum, non-transformed plant material) used?			
When ELISA is being used to quantify protein expression in transformed tissues: ▪ Was a method for the determination of protein concentration in tissue samples presented in the text or in a cited literature reference? ▪ Were a standard curve prepared and the limit of detection indicated?			

	YES	NO	COMMENT
▪ Have a sufficient number of replicates or samples been tested to determine whether there are significant differences between samples or treatments? Was statistical analysis performed?			

SECTION VII – CHECKLIST FOR ENZYME ASSAYS

	YES	NO	COMMENT
Does the figure (or table) have a number and title?			
For graphical representations or tables, are the axis or columns labelled and the units indicated?			
Does the scale of the figure accurately represent and allow interpretation of the data?			
Does the legend or text describe: ▪ The substrate and amount used for the reaction? ▪ The quantity and origin of the enzyme? ▪ The temperature and pH?			
Does the text or legend describe the extraction and purification of the enzyme and the degree of purification achieved?			
If the enzyme used in the assay has not been isolated from the transformed plant but is derived from an expression system, has adequate data been presented to demonstrate its substantial equivalence to the plant expressed enzyme?			
Have the assay method and relevant information concerning the enzyme been provided in the text or in a cited literature reference?			
Are appropriate controls included in the assay?			
Has the stability of the enzyme and possible presence of enzyme inhibitors in different tissue extracts been taken into account in the design of the assay or the interpretation of the data?			
When relevant to the safety assessment, have the kinetics of the enzyme been calculated and where possible compared to published data?			
When quantitative analysis is performed, have a sufficient number of replicates or samples been tested to determine whether there are significant differences between samples or treatments? Was statistical analysis performed?			

NOTICE 1047 OF 2004

DEPARTMENT OF AGRICULTURE

Directorate Genetic Resources
Private Bag X973, Pretoria, 0001, South Africa
Tel: 27 12 319 6536; Fax: 27 12 319 6329
E-mail: SMGRM@nda.agric.za

GUIDELINE DOCUMENT FOR USE BY THE ADVISORY COMMITTEE WHEN CONSIDERING PROPOSALS/APPLICATIONS FOR ACTIVITIES WITH GENETICALLY MODIFIED ORGANISMS

Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997)

May 2004

Foreword by Ms Thoko Didiza, MP and Minister for Agriculture and Land Affairs

According to the National Biotechnology Strategy, South Africa can be summarised as follows: "South Africa has a solid history of engagement with traditional biotechnology. It has produced one of the largest brewing companies in the world; it makes wines that compare with the best; it has developed many new animal breeds and plant varieties, some of which are used commercially all over the world and it has competitive industries in the manufacture of dairy products such as cheese, yogurt, baker's yeast and other fermentation products".

However, in spite of the achievements from traditional biotechnology, South Africa has failed to extract value from the more recent advances of the technology, such as genomics, bioinformatics and proteomics. The majority of South Africans have not benefited from recent advances in biotechnology, largely due to the political history of the country where large sectors of the population could not access services and technologies in order to respond to agricultural challenges.

The National Biotechnology Strategy is designed to stimulate growth of biotechnology industries within South Africa to enable us to take full advantage of this technology and in turn maintain sustainable development. In order to achieve this successfully, a governmental agency will champion biotechnology, built human resources proactively and develop scientific and technological capabilities in this field. In addition, successful commercialisation of public sector-supported research and development (R&D) will require strong linkages between institutions within the National System of Innovation and a vibrant culture of innovation and entrepreneurship, assisted by incubators, supply-side measures and other supporting programmes and institutions.

Government has identified agriculture as one of the sectors of the economy that require special attention because of its potential to contribute to the objectives of higher growth rates and job creation, but also for its potential in addressing other national imperatives such as improved access to and affordable health care, sufficient nutrition at low cost and the protection of our rich environment. With the vision of a united and prosperous agricultural sector, the Department of Agriculture acknowledges the diversity of the agricultural sector and aims to ensure a place and role for all farmers in a united sector. This includes sectors taking advantage of genetic engineering, provided that the technology is applied in a regulated manner.

All activities with genetically modified organisms in South Africa are regulated under the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). This Act provides for measures to promote the responsible development, production, use and application of genetically modified organisms to ensure that all activities involving the use of genetically modified organisms are carried out in such a way as to limit possible harmful consequences to the environment. The Act also makes provision for the determination of requirements and criteria for risk assessments that will ensure that genetically modified organisms are appropriate and do not present a hazard to the environment or human and animal health.

The GMO Act is administered by the Directorate Genetic Resources within the national Department of Agriculture and makes provision for a Registrar, two regulatory bodies, i.e. the Advisory Committee and Executive Council, and inspectors. The Registrar is responsible for administration of the Act, the Advisory Committee for evaluation of risk assessment data within every application and the Executive Council for taking a decision on whether a specific activity should be authorised or not. Inspectors appointed in terms of the Act monitors authorised activities with GMO's across the country.

Sections 4 and 5 of the Act stipulate the objectives, powers and duties of the Executive Council. One provision made in Section 5 is the development and publication of guidelines for all uses of GMO's. It is in accordance with this provision, as well as the aim to establish appropriate procedures for the notification of specific activities involving the use of genetically modified

organisms, that the Department of Agriculture has, through the assistance and recommendations of the Advisory Committee and Executive Council, produced the guidelines provided for in this document.

These guidelines aim to provide general information on the provisions of the Act, functioning of the bodies appointed in terms of the Act, how applications are processed and provide assistance to the applicant on how to apply for a permit. The guidelines will aid in public understanding of the administration of the Act and increase transparency towards the regulation of GMO's in SA. I therefore want to express my sincere gratitude and appreciation to the Advisory Committee and Executive Council, and the Registrar for GMO's, for their commitment in developing these guidelines.

CONTENTS

1. SCOPE

1.1 The Advisory Committee for Genetically Modified Organisms as constituted in accordance with Section 10 of the Genetically Modified Organisms Act, 1997 (GMO Act No. 15 of 1997), hereafter, referred to as the Act, is expected to perform all functions as stipulated in Section 11 of the Act.

1.2 Membership of the Advisory Committee as stipulated within the Act, is limited to persons "knowledgeable in those fields of science applicable to the development and release of genetically modified organisms, including knowledge of ecological matters". For example, the fields of science applicable, inter alia, are:

- animal health
- human medicine
- biochemistry
- molecular biology
- ecology
- entomology
- plant pathology
- biotechnology
- virology

1.3. Rationale for the Guidelines

There are several concerns about the consequences of development and deployment of genetically modified organisms, with particular reference to transgenic herbicide-resistant (HR) and insect-resistant (IR) crops. Objections to the use of these transgenic crops rest on several issues related to the associated risks, such as:

- the potential transfer of genes from herbicide resistant crops (HRC) to wild relatives thus creating super weeds;
- possibility of HRC volunteers to become weeds in subsequent crops;
- development of resistance by insect pests to crops with *Bacillus thuringiensis* (Bt) toxin;
- adverse effects on ecological processes and non-target organisms due to massive use of Bt toxin in crops.

All these concerns show the importance of assessment of possible hazards from the use of transgenic HR and IR crops. Assessment is required to decide whether these crops may be introduced and will not pose any hazard to the environment bringing expected benefits to the farmers.

The guidelines describe the process of analysis and assessment of ecological risks associated with the introduction of herbicide resistant crops (HRC) or genetically modified insect resistant (e.g. with genes coding for endotoxins from *Bacillus thuringiensis*) crops (IRC). Furthermore, the guidelines list the responsibilities of governmental authorities, applicant or permit holders and farmers growing HRC and IRC. **The main aim of the guidelines is to provide a framework, in alignment with the GMO Act and the associated regulations, on assessing the ecological risks of HRC/IRCs.**

1.4 Functions of the Committee

1.4.1 In terms of the Act, The Committee shall-

1.4.1.1 act as the national advisory body on all matters concerning or related to genetic modification of organisms;

1.4.1.2 advise, on request or of its own accord, the Minister, the Council, other Ministries and appropriate bodies, on matters concerning GMO's and *inter alia* advise them-

a) on all aspects relating to the introduction of GMO's into the environment
b) on proposals for specific activities or projects concerning the genetic modification of organisms
c) on all aspects concerning the contained use of GMO's
d) on the importation and exportation of GMO's, and
e) on proposed regulations and written guidelines.

1.4.2 liase, through relevant national departments, with international groups or organisations concerned with biosafety; and

1.4.3 invite written comments from knowledgeable persons on any aspect of the genetic modification, which lies within the Committee's brief.

1.4.4 The Committee may appoint subcommittees to deal with specific matters as required.

1.4.5 The Committee shall meet at a minimum on a quarterly basis, and where necessary, schedule other meetings; such meetings shall consist of a quorum based on the majority of members attending.

1.5 Conflict of interest

As stipulated in the Act, a person appointed to the Committee shall immediately recuse himself or herself as a member of the Committee if a subject matter is in issue in which he or she has any direct or indirect interest or if, for any other reason, there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the Committee.

2. PROCEDURE FOR PROCESSING OF APPLICATIONS

All applications received by the Registrar for GMO's within the Department of Agriculture are reviewed according to the following procedure:

2.1 Registrar does a first hand review of the application to determine compliance with the provisions of the Act. If the application is not compliant, the application is referred back to the applicant.

2.2 Once compliant, the application is forwarded to a review committee (expertise nominated by AC chairperson) formed under the Advisory Committee to conduct a review of the proposed activity. The evaluation (assessment) of the review committee includes an evaluation of the risk assessment data, including food safety (if applicable) submitted in the application. The sub-committees conduct these assessments. Conclusions of the assessment are captured in a recommendation report, which is sent to the Registrar on completion of the review.

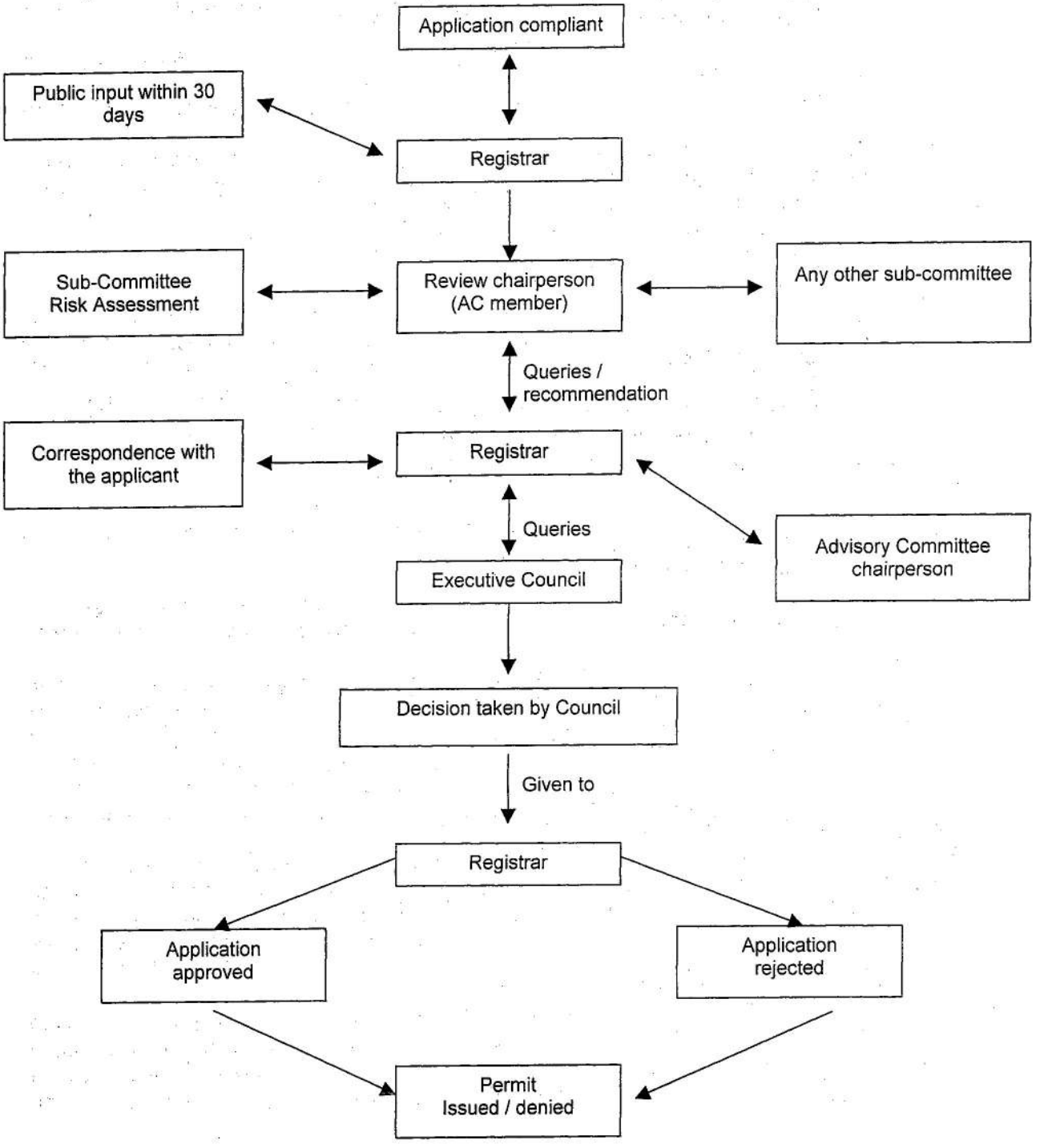
2.3 This phase is only applicable if the review committee raised concerns with regard to the application, or if additional information is requested. The application is referred back to the applicant to address the concerns raised or to supply additional information. The response from the applicant is returned to the Committee. Once all concerns have been addressed, the Committee makes a recommendation on the application to the Executive Council.

2.4 The recommendation document, public input and a copy of the application is forwarded to the Executive Council. The Council considers the application based on the information supplied by the Registrar, but also takes into account the socio-economical impact that the GMO may have. The Council submits its decision in writing prior to, or at a meeting, to the Registrar.

2.5 This phase is only applicable if the Council raised concerns in addition to the concerns raised by the Committee. The Registrar will once again refer the application back to the applicant for clarification. Based on the information received from the applicant and the assessment done by the Council, the application will be approved or rejected.

2.6 If the application is approved, the Council authorises the Registrar to issue a permit to the applicant. This permit will be accompanied by specific containment conditions as prescribed by the Council. If the application was rejected, the Registrar will communicate the decision back to the applicant with reasons for the rejection.

Figure 1: PROCESSING OF HANDLING GMO APPLICATIONS



3. ASSESSMENTS CONDUCTED BY THE ADVISORY COMMITTEE

3.1 Types of applications

In accordance with the scope/objectives stipulated in section 1 above, the Committee shall advise on:

a) Applications to import genetically modified organisms into South Africa;
b) Applications to export genetically modified organisms from South Africa;
c) Applications for contained use (including development, production, distribution, transport) of genetically modified organisms;
d) Applications to deliberately release genetically modified organisms into the environment (trial and general release); and
e) Applications to obtain commodity clearance of genetically modified organisms in South Africa.

Activities with GMO's for research and academic purposes, conducted at containment levels 1 and 2 (determined through a risk assessment conducted by the officer in charge) within a laboratory or growth room in an academic or research facility, are exempted from the requirement of a contained use permit in terms of Regulation 2(2). A contained use permit is required once the research is scaled up from basic research to product development, or when conducting the activities in a greenhouse or when the containment level is 3 and above.

3.2 The review committee

The review committee is a sub-committee established under by the Advisory Committee, and is responsible for the evaluation (risk assessment data) of proposed activities with genetically modified organisms. A review committee shall consists of the following:

- Review chairperson;
- Risk assessment sub-committee, and
- Any other assessment sub-committee (if applicable) required.

3.2.1 The review chairperson

The review chairperson refers to the chairperson appointed to chair the evaluation/assessment of a particular proposal/application for activities with genetically modified organisms. The Registrar selects this chairperson. The review chairperson is therefore any member of the Committee, including the chairperson of the Committee.

The review chairperson consolidates the findings and recommendations of the risk assessment sub-committee into a final recommendation document, which will be copied to members of the sub-committee and to other members of the Committee. The final recommendation document will be accompanied by any other assessment report (if applicable or not incorporated into the risk assessment report). Once the review committee is in consensus about the application, these documents will be forwarded to the Registrar.

It is the responsibility of the review chairperson to ensure that -

(a) the review committee contains the expertise required to enable a good assessment of all safety aspects of the application;
(b) if the committee is lacking certain expertise, inform the Registrar and nominate an appropriate individual with the required expertise;

(c) that every individual on the committee will treat the information submitted to him or her as "confidential business information";
(d) the review is conducted within the time frame allocated by the Registrar.
(e) The recommendation document makes mention of every concern raised by the committee and gives an indication to the Registrar, based on the concerns raised by the committee, on the questions/concerns that should be raised to the applicant.

3.2.2 Risk assessment sub-committee

All proposals/applications for activities with genetically modified organisms shall be evaluated on a case by case basis. Such evaluations shall be scientific and will include an evaluation of the risk assessment submitted in the application, as stipulated by the Act.

Members of this sub-committee shall consist of three individuals with knowledge in the fields of science related to the proposed activity. The review chairperson appoints these individuals, and is responsible for dissemination of the relevant documentation to them.

Each member of the sub-committee must submit a report to the review chairperson within a period of three weeks. This report shall be in the format to enable the review chairperson to compile a recommendation document. The sub-committee may make use of the reviewer's checklist (Annexure A) for recording the conclusions made during their assessment.

3.2.3 Any other sub-committee

Proposals for activities with genetically modified organisms shall be subject to an additional assessment, in addition to the general risk assessment evaluation in paragraph 3.2.2, if deemed necessary by the Advisory Committee and/or Executive Council.

The sub-committee shall be, in collaboration with the Registrar, appointed and supervised by the Advisory Committee or Executive Council. Members of this sub-committee shall receive all documentation regarding the proposed activities from the review chairperson.

4. DEFINITIONS AND ABBREVIATIONS

Applicant/notifier	The party (e.g. seed producer or importer, agro-chemical company or farmers' organization) that requests permission to experimentally release or commercially introduce an HRC/IRC in a country.
Authority	A governmental institution, organization or entity officially designated by the government to deal with matters arising from the responsibilities set forth in the Guidelines.
Bacillus thuringiensis (Bt)	Bacterium species currently used as a microbiological agent to control larvae of *Lepidoptera*, *Diptera* or *Coleoptera*.
Competitiveness	A plant's ability to exploit essential elements such as light, water and plant nutrients at the expense of other plants.

Congeners	Refers to species belonging to the same genus.
Conspecific	Refers to individuals or populations of the same species.
Crop production system	A particular agricultural scheme, including monocultures, rotations and polycultures, and their associated practices such as tillage plant protection and harvesting.
Ecosystem	A complex of organisms and their environment, interacting as a coherent unit (natural or modified by human activity, e.g. agro-ecosystem), irrespective of political boundaries, to maintain a flow of energy and to acquire, store and recycle nutrients.
Fitness	Reproductive success or the proportion of genes an individual leaves in the gene pool of a population.
Gene flow	The transfer of genes (specifically, alleles) from one population to another by way of interbreeding of individuals in the two populations.
Gene pool	All of the alleles available among the reproductive members of a population from which gametes can be drawn.
Genetic engineering	Altering the genetic material of cells or organisms to make them capable of making new substances or performing new functions.
Genetically modified (GM) plant	A plant whose genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Hazard	Intrinsic property of a physical situation (or dangerous substance) which can cause damage to human, animal and/or plant life or health and/or the environment.
Herbicide	A chemical substance or mixture of substances designed to control weeds.
Herbicide resistant crop (HRC)	A crop plant that by genetic modification(s) or breeding has acquired resistance towards a herbicide it would otherwise be sensitive to.

Insect resistant crop (IRC)	A crop that by genetic engineering has become protected from damage by one or more harmful insects.
Insecticide	A chemical substance or mixture of substances that controls insects that harm crop production or prevents their damage.
Introgression	The transfer of genes from one population to another by backcrossing.
Marketing	Supplying or making available to third parties.
Maternal inheritance	The transmission of nuclear and extra-nuclear genes from the mother usually referred to extra-nuclear genes.
Pest	Organisms which are capable of transmitting disease or unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs.
Pesticide	Refers to any substance or mixture of substances intended to prevent, destroy or control any pest, including substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest or protect the commodity from deterioration during storage and transport.
Release	Introduction into the environment of a genetically modified organism (GMO) with or without provisions for containment. Release can be deliberate, experimental, accidental or commercial.
Resistance	In the case of plant populations, their inherited ability to grow and reproduce normally when exposed to high doses or levels of a specific agent (e.g. herbicide or insect attacks), which normally would harm plants.
Risk	The probability of occurrence of a hazard which can cause damage to human, animal and/or plant life or health and/or the environment and its potential economic implications.

Risk assessment	The qualitative or quantitative evaluation of risks resulting from the release of genetically modified plants or products containing GM plants.
Spread	Expansion of the geographical distribution of plants containing a genetically modified gene.
Tolerance	Referred to plants, it is an increased ability of a biotype to endure damage, survive and reproduce after a limited exposure to a specific stress factor (in this context, herbicide applications or insect attack) compared to other biotypes of the species. Tolerance is often a polygenetic inherited trait.
Transgene	A gene or DNA fragment from one organism that has been stably incorporated into the genome of a plant of interest.
Transgenic	See genetically modified (GM) plant.
Vector	A plasmid that can be used to transfer DNA sequences from one organism to another.
Volunteer	A crop plant regenerated from seed or propagules left after a previous harvest and which can act as a weed in the present crop.
Weed	A plant that is growing where it is not wanted by humans.

5. DELIMITATIONS

These guidelines are currently confined to deal with the ecological hazard assessment of HRC and IRCs based on a strictly scientific and technical approach. The hazard assessment must be performed on a case-by-case basis and adapted to the local conditions and agricultural production system. Other relevant aspects related to HRC/IRCs such as food safety, pleiotropic effects associated with transgenes, ethical concerns and socio-economic consequences are not considered in these guidelines.

6. RESPONSIBILITIES

6.1 Responsibilities of applicant/permit holder

a) To comply with all the regulations established by the country where the HRC/IRC will be introduced or grown.

b) To prepare a dossier for submission to the authority with each application for experimental release or commercial production including all pertinent and required information on the HRC/IRC to be released.

c) Ensure that persons involved in distribution of their HRC or IRC product are adequately trained, such that they are capable of providing a user with advice on efficient and safe use.

d) Notify the authorities and voluntarily take corrective action and, when requested by authorities, help to find solutions to any problem related to the release and use of the HRC/IRCs.

6.2 Responsibilities of users (e.g. farmers) growing HRC/IRC

Determination of risks and liability shall be as stipulated in section 17 of the Act. The responsibilities of the cultivator/farmer as the final user of a technology are those stated in the binding labels of HRC/IRC products and any contractual agreement signed with an importer, distributor or supplier of seed and by the regulations associated with the use of pesticides.

6.2.1 Farmers should:

- Maintain appropriate records of HRC/IRC varieties and area planted and pesticide use.
- Respect and obey indications and requirements related to refugia and other agronomic practices intended to prevent or delay the evolution of resistance in pests.
- Comply with any signed agreement regulating the production, saving and distribution of seed from HRC/IRCs.
- When growing HRC/IRCs, which involve the use of a pesticide, follow the regulatory rules for the particular pesticide and specific use.

7. RISK IDENTIFICATION

- The assessment of potential hazards of growing HRC/IRC crops concerns both the crop itself and its impact on the wild flora. Consequently, understanding the interaction between the transgenic crops and all compatible relatives is crucial for a realistic hazard assessment. Consideration may also be necessary to the fauna associated with the crop, especially both insect pests and beneficial organisms.
- The HRC/IRC itself may establish beyond its agricultural boundaries and growing season and become a weed in the succeeding crops.
- The HRC/IRC may pollute the gene pool of non-transgenic relatives growing in the same or adjacent areas, depending on cross pollination characteristics and agents such as wind or by insects. In some instances where the population size of native relatives is low, genes from the transgenic crop may come to dominate the native population and lead to their extinction. The compatibility between the HRC/IRC and non-target species is of utmost importance in this regard.
- The HRC/IRC may have botanical identical or closely related species that can hybridize with the crop, either in the adjacent ecosystems or in the agro-ecosystem. Hybridization could lead to pollution of non-transgenic crops, gene stacking in volunteer plants and transfer of the resistance trait to weedy or wild species.
- The continuous use of HRCs with their associated herbicide over large areas for several years may unintentionally change the composition of the weed flora by selecting for naturally tolerant weeds. This is particularly important in monocultures or in cropping systems with limited crop rotation or **minimum tillage**.
- Intensive use of HRC/IRC may have a detrimental effect on the populations of non-target organisms (i.e. birds, beneficial insects)
- In case of IRC the engineered traits may increase fitness of volunteers or weedy hybrids, thus making a crop turn into a weed that can interfere with future crop

production or aggravating the negative impact of existing weed species. The incorporation of resistance into a non-target species may also alter its competitive ability and displace other native species.

- Intensive use of IRC may select insect strains resistant to the toxins produced by the plant as a result of the genetic alteration.

7.1 The process of risk assessment

- The main objective of an ecological risk assessment of HRC/IRCs is to identify possible adverse effects on the environment from growing these crops. Risk identification is only the first step in a conventional risk assessment, the other steps being risk characterization (magnitude of the risk), exposure assessment (in this context an estimate of likelihood or frequency of identified risks) and finally risk characterization.
- Risk characterization takes into account the results of the previous three steps to provide an estimation of the likelihood by which the adverse effects occur combined with their magnitude. This risk assessment may be quantitative or qualitative. The latter has prevailed in previous cases with approval of genetically modified organisms, because the complexity of biological systems makes it difficult to pursue a quantitative approach. Much of the needed information for a risk assessment can be obtained from practical experience with traditional crops growing in the same environment, but in some cases further experimentation is needed particularly regarding gene flow and fitness.
- In established regulations of HRC/IRCs, the applicant is required to deliver the relevant information and the authorities may then base the evaluation upon this information combined with expert opinions and, sometimes, public hearings of scientific institutions, consumer organizations, NGO's and the general public. The objective of the following guideline is, however, only to identify potential adverse ecological risks to the environment by using simple decision keys.

7.2 Information desirable for risk assessment

a) Information related to the HRC/IRC:
   - Taxonomic description and scientific name
   - Cultivar's name
   - Diagnostic phenotypic and genetic markers
   - Description of geographic distribution and of the natural habitat of the plant
   - Potential for gene flow and exchange with other plants
   - Ecological and physiological traits:
     - Generation time in natural ecosystems, sexual and asexual reproductive cycle
     - Information on survival, including the incidence of volunteers and the ability to form perenniating structures (propagules)
   - Information related to the genetic modification process
     - Methods used for the modification
     - Description of the inserted genetic material and vector construction
     - Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question
   - Information on the inserted genetic material in the HRC/IRC
     - Description of genetic trait(s) or phenotypic characteristics, particularly new traits and characteristics which may be expressed or no longer expressed
     - Characteristics of the vector

- Stability of the genetic trait(s)
- Cumulative effects if the event is a combination of two or more traits (e.g. stacked event such as MON810 x NK603)
- Rate and level of expression of the new genetic material
- Description of identification and detection techniques
- History of previous releases or uses of the HRC/IRC

b) Information on the receiving environment:
   - ➢ Geographical location of the site
   - ➢ Proximity to protected habitats or areas
   - ➢ Proximity to compatible, related species
   - ➢ Climatic characteristics and flora and fauna of the region
   - ➢ Description of target and non-target ecosystems likely to be affected
   - ➢ Any known planned developments or changes in land use in the region which could influence the environmental impact of the released crop
   - ➢ Description of ecosystems to which the HRC/IRC could be disseminated

c) Information related to the interactions between the HRC/IRC and the environment:
   - ➢ Characteristics affecting survival, multiplication and dissemination
   - ➢ Studies of the behavior and characteristics of the HRC/IRC and their ecological impact
   - ➢ Post release genetic transfer capability from the HRC/IRC into organisms in the affected ecosystems
   - ➢ Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the HRC or IRC
   - ➢ Description of genetic traits, which may prevent or minimize dispersal of genetic material.
   - ➢ Routes of biological dispersal and known or potential modes of interaction with the dissemination agent.

d) Potential environmental impact:
   - ➢ Potential for excessive population increase in the environment
   - ➢ Competitive advantage of the HRC/IRC in relation to the unmodified recipient
   - ➢ Anticipated mechanism and result of interaction between the released plant and wild and weedy relatives
   - ➢ Known or predicted effects of non-target organisms on the environment, impact on population levels of all potential competitors.

7.3 Information on the conditions of experimental release:

a) Description of the proposed release including the purposes and foreseen products
b) Foreseen dates of the release and time planning of experiment including frequency and duration of release
c) Size of the site
d) Method to be used for the release
e) Quantities of HRC/IRC to be released
f) Method of cultivation and description of general agricultural practices
g) Post-release treatment of the site
h) Techniques which will be applied for the elimination or inactivation of the HRC/IRC upon experiment completion
i) Information on and results of previous releases of the HRC/IRC, especially at different scales in different ecosystems.

7.4 Information required in the case of notification for placing in the market:

a) Name of product and names of HRC/IRC contained therein
b) Name and address of manufacturer in country of origin
c) Specificity of the product including the appropriate environment and geographical area of the country for which the product is suited
d) Estimated production or import to the country
e) Proposed packaging (to prevent unintended release during storage or at a later stage)
f) Proposed labeling in the official language(s) of the country including information on handling and agricultural use.

7.5 Information on monitoring and control of release:

a) Methods for tracing the HRC/IRC and monitoring its effects
b) Specificity, sensitivity and reliability of monitoring techniques
c) Techniques for detecting transgenes introgressed into non-target plants
d) Methods and procedures to avoid and minimize the spread of the HRC/IRC beyond the site of release or the designated area for use
e) Methods and procedures for controlling the HRC/IRC in case of unexpected spread.

8. Risk assessment

- In assessing potential risks associated with the introduction or planting HRC/IRCs in a particular area or country, a starting point will be to identify the scenarios (agro-ecosystems) under which the crop will be released and select the appropriate procedure to assess the specific risk associated with it.

- Whatever approach is used to identify risks, care should be taken to consider risks to both agronomic and natural ecosystems. As indicated before, any assessment of risk requires a case-by-case study and is location-specific.

- Specific local conditions would determine the relative importance of each type of risk. For example, cropping patterns and landscape could have an important role in the possible escape transgenes, a process that involves hybridization followed by the subsequent establishment and persistence of the hybrid. The likelihood of GM crops and wild relatives forming hybrids is particularly pertinent in the centers of origin and diversity of crops, thus hazards derived from gene flow should be the priority in assessing the overall risk of release of GM crops in these areas. Another special case is that of a crop that has con-specific weeds, which increases the risk of gene movement from the GM-crop.

- An important aspect, besides those mentioned above, that should be considered is the possible impact of HRC/IRCs on non-target organisms (e.g. pollinators, soil fauna or other organisms associated with the crop plant). Planting HRCs, especially over large areas, allowing the application of herbicides not previously used in the conventional crop could impose new selection pressure on weeds leading to the evolution of herbicide resistance. Similarly, exposure to insecticidal toxins from IRCs over long periods could also select for resistance in the target pests and affect predators, parasitoids and other non-target organisms. Side effects of IRCs producing insecticidal toxins are difficult to assess because of lack

of knowledge thus scientific experts should be consulted regarding this on a case-by-case basis.

- The final decision on releasing HRCs and IRCs is ultimately a balance between science, economics, ethics and values, local benefits and public interest. Consequently, the perceived risk sometimes reflects conflicts of interests.

- The use of assessment keys should facilitate arriving to a decision based on scientific knowledge rather than on perceptions, although a quantitative approach is yet to be developed. The keys presented below were designed only as a guide in assessing the ecological risks based on the most likely relevant scenarios. They have limitations and should be considered carefully according to local conditions and experience. It is important to take into account that cropping practices and local environmental conditions and characteristics can affect the risks and how they are assessed or perceived. For example, inter-planting an IRC with unmodified crop plants would affect the rate at which resistant individual could be selected in the target pest population. Also, the level of expression of the toxin in the crop plant can affect the likelihood of survival of slightly resistant individuals.

- The keys are a useful method to begin the process of the risk identification and assessment for IRC/HRCs, but do not in themselves provide the user with a conclusive description of the risks of planting IRC/HRCs. The questions in the keys have been arranged according to increasing magnitude of the risks. Two main possible simplified scenarios are considered:

8.1 *Scenario 1*

The HRC/IRC is to be released in an agricultural system where there are compatible wild relatives or **weed species**.

When a HRC is to be released into an area where there are compatible wild or weedy relatives there is a possibility that the transgenes will escape and introgress into those compatible species. As a result, the wild or weedy relatives (congeneric or conspecific) could become resistant to the herbicide, making them a more noxious agricultural or environmental pest. There is also the possibility that the competitive ability of wild relatives might be altered especially if IR-genes become established in native populations. This possibility is of particular concern when the IRC is to be released into its wild progenitor's center of origin or diversity, which serve as a particularly valuable source of genes for plant breeding. Useful genes might be lost if introgression with transgenic crops results in the replacement of native genes. Under these conditions, assessment should consider all the corresponding keys below:

8.2 Scenario 2

The HRC/IRC is to be released in an agricultural system where there is no risk of gene flow to other species.

Under this scenario, there are three main concerns to consider. Weeds could evolve resistance to the herbicide that the HRC withstands because of the selection pressure imposed by its use. Secondly, management of HRC volunteers in succeeding plantings of the conventional crop or in rotation crops could become increasingly difficult. Third, there is the possibility that insects could evolve resistance to the insecticidal toxin produced by the

IRC, due to increased selection pressure. Initiate the assessment by considering key no. 3 (assessing of volunteers' control) and 4 or 5 (build up of resistance).

When using a key, if you reach a point where you cannot continue any further or there is an indication of "stop", it means that you need to make a decision about a particular risk.

Key 1: Likelihood that the competitive abilities of wild relatives occurring in undisturbed wild-lands will be altered by hybridization with transgenic crops

1. Is the crop only self-pollinating?
If no: Go to No. 2 If yes: Stop, and go to key 3.

2. *Can viable hybrids form between the crop and wild relatives?*
If yes: Go to No. 3 If no: Stop, and go to key 2.

3. *Do these wild relatives occur in the proximity of the crop?*
If yes: Go to No. 4 If no: Stop, and go to key 2.

4. *Do the crop and the wild relatives overlap in flowering periods?*
If yes: Go to No. 5 If no: Stop, and go to key 2.

5. *Do hybrids survive and reproduce in the native habitat*
If yes: Go to No. 6 If no: Stop, and go to key 2.

6. *Does HR/IR trait give hybrids or introgressants a fitness advantage in wild habitats?*
If yes: Go to No. 7 If no: Stop, and go to key 2.

7. *Is the resistance trait maternally inherited?*
If yes: Likelihood of producing new, more competitive native species. If no: Likelihood of producing new, more competitive native species rapidly.

Key 2: Likelihood that a new type of arable weed will be produced by gene flow between the transgenic crop and its relatives:

1. *Do hybrids occur between the crop and any weedy/wild relative?*
If yes: Go to No. 2 If no: Stop, and go to key 3.

2. *Do these weedy/wild relatives occur in the proximity of the crop?*
If yes: Go to No. 3 If no: Stop, and go to key 3.

3. Do the crop and the weedy/wild relatives overlap in flowering periods?
If yes: Go to No. 4 If no: Stop, and go to key 3.

4. *Are the hybrids and/or introgressants highly competitive in arable environments?*
If yes: Go to No. 5 If no: Stop, and go to key 3.

5. *Are hybrids or introgressants herbicide resistant or insect resistant?*
If HR: Go to No. 6 If IR: Go to No. 8.

6. *Can HR hybrids or introgressants easily be controlled by other means besides the herbicides associated with the HRC?*

If yes: Likelihood of losing If no: Go to No. 7
one herbicide.

7. *Is the same herbicide used in succeeding crops?*
If yes: Likelihood of losing If no: Stop and go to key 3.
the only weed control option.

8. *Does the IR trait confer an increased fitness in the wild/weedy relative compared to non-IR relative?*
If yes: Likelihood of increased If no: Stop and go to key 3.
weed problems

Key 3: Likelihood that the transgenic crop will become a volunteer problem on arable land or wild areas:

1. *Is the crop known to leave volunteers in succeeding crops?*
If yes: Go to No. 2 If no: Stop. There should
not be a volunteer problem. Assess hazard of evolution of herbicide or insecticide resistance (keys 4 and 5).

2. *Does the crop have weedy traits?*
If yes: Go to No. 3 If no: Stop, and go to key 4.

3. *Is the volunteer plant expected to be herbicide resistant or insect resistant?*
If HR: Go to No. 4 If IR: Go to No. 6.

4. *Can the HR-volunteer easily be controlled by other means but the herbicides associated with HRC?*
If yes: likelihood of losing If no: Go to No. 5
use of a herbicide.

5. *Is the herbicide used for control of non-transgenic volunteers in succeeding crops?*
If yes: likelihood of losing If no: Stop, and go to key 4
the weed control option (herbicide)

6. *Is the IR-volunteer crop able to establish itself in the wild?*
If yes: likelihood of escapes If no: Go to No. 7
into wild habitats

7. *Can the IR volunteer easily be controlled in succeeding crops?*
If no: Go to No. 8 If yes: Stop, and go to key 5

8. *Does the IR trait confer an increased fitness in the volunteer compared to non-transgenic volunteers?*
If yes: Likelihood of increased If no: Stop, and go to key 5
weed problems

Key 4: Likelihood of build-up of HR-resistant weeds:

1. *Are resistance cases to the herbicide that the HRC withstands or herbicides belonging to the same chemical family or having the same mode of action (MOA) or degradation known*

to occur, or is gene flow possible from HRC to related weedy species, or is the herbicide a new chemical?
If yes: Go to No. 2 If no: Stop. There should be a low hazard of evolution of herbicide resistant weeds, especially if integrated weed management is used.

2. *Is the cropping system primarily a monoculture or the HRC is or will be fully rotated with other crops?*
If monoculture: Go to No. 5 If fully rotated: Go to No. 3.

3. *Is weed management primarily based on an integrated strategy or on chemical control?*
If chemical control: Go to No. 4. If integrated strategy: Stop. Very limited hazard of Herbicide resistance evolution.

4. *Is the MOA of the herbicide used in HRC crop similar or different to that used in the other rotational crops?*
If same: consider likelihood If other: Stop. Very limited of selection for resistant hazard of herbicide
weeds resistance evolution.

5. *Is weed management under the monoculture system primarily dependent on herbicides?*
If yes: Go to No. 6 If no: Stop. Very limited hazard of herbicide resistance evolution.

6. *Is the herbicide to be used in the HRC a new persistent compound or a chemical to be used twice or more in*
cropping cycle?
If yes: consider the likelihood of selecting new resistant weeds. If no: Go to No. 7

7. *Does the herbicide used in HRC share MOA with others in use?*
If yes: Risk of aggravating or If no: Stop. Limited
speeding resistance problems hazard of herbicide resistance evolution.

Key 5: Likelihood of build-up of resistant insects:

1. *Does the IRC comprise a major proportion of the local area planted with non-transgenic varieties of that crop?*
If yes: Go to No. 2 If no: Stop. Limited
hazard of insecticide resistance evolution.

2. *Does the IRC express only a single or few insecticidal-toxin(s) active against the harmful insect?*
If yes: Go to No. 3 If no: Stop. Limited
hazard of insecticide resistance evolution.

3. *Is expression of the IR trait confined to a short lasting selected growth stage of the crop?*
If no: Go to No. 4 If yes: Stop. Limited hazard of insecticide
resistance evolution.

4. *If resistance in insects occurs, is expression of the IR trait associated with a significant fitness penalty for the*
resistant insect?
If no: Go to No. 5 If yes: Stop.

5. *Are resistant insects easily controlled by other control measures?*
If yes: likelihood of losing If no: likelihood of
effect of the IR trait losing the IR trait and specific-toxin based **biological pesticides.**

8.3 Recommendation document

A recommendation document outlining the conclusions made by members of the risk assessment sub-committee shall consist of:

a) *Details of the review committee*
Provide full names, institutions and expertise involved in the review committee.

b) *Summary of the application*
Particulars of the applicant's request:
(i) Name of the applicant
(ii) Title of the application
(iii) Reference number given by the Registrar's office
(iv) Short description of the applicant's request
- The intended use
- Purpose of the use
- Scale of the use

(v) Short description of the genetic modification
- What it is?
- How developed?
- Stability of integration?

c) *Procedures followed during the evaluation of the application*
Stipulate all dates and actions involved during the evaluation process from the moment that the review chairperson receives the application.

d) *Safety issues assessed*
(i) Food and feed
- Toxicological studies
- Allergenicity studies
- Compositional analysis
- Nutritional analysis
- Pathogenicity
- Feeding trials
- Any other

(ii) Environmental
- Weediness/invaseness
- Gene flow
- Altered plant pest potential
- Non-target organisms
- Impact on biodiversity
- Any other

e) *Non-safety issues*
- Experimental design
- Sociological factors
- Any other

f) *Risk management*
Indicate required risk management measures required.

g) *Recommendation*
Note comments from reviewers that were overruled by the review chairperson and the reasons attached thereto.
Make a final recommendation to the Registrar on this application.
Sign the document and indicate the date on which the document is submitted to the Registrar.

h) *Appendix*
Attach review reports of each individual within the review committee.
Any other assessment report (if applicable).

8.4 Any other assessment report

The report of the sub-committee responsible for evaluation of any other aspect related to GMO's, will be included in the conclusions of the recommendation document, as an attachment to the recommendation document or as an additional report to the recommendation document.

This report will be based on an assessment conducted according to the principles and guidelines relevant to the field being investigated.

9. FAST TRACKING (EXTENDED PERMIT) APPLICATIONS

The Registrar may, at his own discretion, fast track any application for an activity involving genetically modified organisms for which a permit had previously been issued under the GMO Act (Regulation 5(12) of the GMO Act). To obtain a permit via the fast track system, the applicant must complete the application form for an extended permit.

An application for an extended permit (fast track) can only be submitted in cases where the particular activity with the GMO concerned has been authorised by the Executive Council on a previous occasion.

10. GRANTING AUTHORISATIONS

The Advisory Committee has no authority to issue, amend or withdraw any permit under the GMO Act. This Committee is purely an advisory body to the Registrar and Executive Council.

Once the Committee is satisfied that the GMO will pose no harm to the environment or lead to a health risk, a recommendation letter, accompanied by the final recommendation document, must be submitted to the Registrar.

The Registrar submits the application with the Committee's recommendations to the Executive Council for final consideration and decision.

ANNEXURE A: REVIEWERS' CHECKLISTS

This checklist may be used by any member of the sub-committee with the necessary expertise, and may be attached to the report submitted by the reviewer.
These checklists are intended to assist the reviewers, but take note that (a) a particular application may not contain all types of data listed and (b) there may be additional data provided by the applicant, or required by the reviewer, that is not included in this list.

SECTION I – CHECKLIST FOR NORTHERN BLOT DATA

	YES	NO	COMMENT
Does the Northern blot have a figure number and title?			
Are lanes labelled on the blot?			
Does the figure legend describe each lane of the blot, including a description of the following for the RNA that was loaded: What type of material was loaded (e.g. total purified RNA, poly-A RNA, crude prep, total plant extract)? Source of the material loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? Quantity of material loaded in each lane? Quality of material loaded in each lane?			
Does the text or figure legend describe how RNA was extracted prior to electrophoresis?			
Does the blot have appropriate positive and negative control lanes - Positive control consisting of a dilution series of control RNA complemented with wild type RNA of the same tissue (this control is especially relevant for blots used to substantiate the absence of expression); Positive control purified RNA; Negative control - the unmodified parental line or variety; Check for loading differences using a probe for a "constitutive" mRNA.			
Is the gel system and Northern hybridisation protocol described in the text or in the cited literature reference? Are any modifications of the cited protocols described in the petition (application) text?			
Is the position of molecular size standards on the gel indicated, and do they cover an appropriate size range for the fragments that are expected to be detected on the blot?			
Is there a description of the probe that was used for the hybridisation? If so, is the description adequate (in the text on in the figure) to enable one to interpret the results?			
If quantitative analysis is performed, has the methodology or citation to such been provided, and have a sufficient number of replicates or samples been tested to determine whether there are differences between samples or treatments?			
Are any superfluous bands or background signals properly explained?			

SECTION II – CHECKLIST FOR SOUTHERN BLOT DAT

	YES	NO	COMMENT
Does the Southern blot have a figure number and title?			
Are lanes labelled on the blot?			
Does the figure legend describe each lane of the blot, including a description of the following for			

	YES	NO	COMMENT
the DNA that was loaded on the gel: ▪ Type of DNA loaded (e.g. entire plasmid, restriction fragment)? ▪ Source of DNA loaded (e.g. transformation event, tissue, etc.)? ▪ Restriction digestions of DNA prior to loading gel? ▪ Quantity of material loaded in each gel? ▪ Quality of the material loaded in each gel?			
Does the gel have appropriate positive and negative control lanes – Positive control consisting of a dilution of a series of control DNA complemented by wild type DNA of the same tissue; Positive control purified transformation vector; Negative control – the unmodified parental line or variety.			
Is the gel system and Southern hybridisation protocol described in the text or in the cited literature referenced? Are any modifications of the cited protocols described in the petition (application) text?			
Is the position of the molecular size standards indicated, and do they cover an appropriate size range for the fragments that are expected to the detected on the blot?			
Was an entire plasmid used as the probe for the hybridisation? If so, is the plasmid described adequately in the text or in a figure to enable one to interpret the results?			
Was a restriction fragment used as the probe for the hybridisation? If so, is the restriction fragment described adequately in the text or in a figure to enable one to interpret the results?			
Are any superfluous bands or background signals properly explained?			

SECTION III – CHECKLIST FOR RNA DOT BLOT DATA

	YES	NO	COMMENT
Does the Dot blot have a figure number and title?			
Are lanes labelled on the blot?			
Does the figure legend describe each lane of the blot, including a description of the following for the RNA that was loaded: ▪ What type of material was loaded (e.g. total purified RNA, poly-A RNA, crude prep, total plant extract)? ▪ Source of the material loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? ▪ Quantity of material loaded in each lane? ▪ Quality of the material loaded in each lane?			
Does the text or figure legend describe how RNA was extracted prior to blotting onto the solid support?			
Does the blot have appropriate positive and negative control lanes – Positive control consisting of a dilution series of control RNA complemented with wild type RNA of the same tissue (this control is especially relevant for blots used to substantiate the absence of expression); Positive control of purified RNA			

	YES	NO	COMMENT
Negative control – the unmodified parental line or variety.			
Is the blot system and hybridisation protocol described in the text or in the cited literature reference? Are any modifications of the cited protocols described in the submitted text?			
Is there a description of the probe that was used for the hybridisation? If so, is the description adequate (in the text on in the figure) to enable one to interpret the results?			
If quantitative analysis is performed, has the methodology or citation to such been provided, and have a sufficient number of replicates or samples been tested to determine whether there are differences between samples or treatments?			

SECTION IV – CHECKLIST FOR WESTERN BLOT DATA

	YES	NO	COMMENT
Does the blot have a figure number and title?			
Are lanes clearly labelled?			
Does the figure legend describe each lane of the blot, including a description of the following for the protein that was loaded: ▪ What type of material was loaded (e.g. pure, crude, total plant extract)? ▪ Source of the material loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? ▪ Quantity of material loaded? ▪ Quality of the material loaded?			
Is the protein extraction method adequately described in either the text or the legend?			
Is the antibody or antiserum preparation protocol adequately described in the text, including an adequate description of the antigen and its purity? Has the specificity of the antibody or antiserum been determined and described in the text or in a cited literature reference?			
Is the gel system and blotting protocol adequately described in the text or in a cited literature reference?			
Is the position of the molecular weight standards indicated, and do they cover the appropriate range for the proteins expected to be detected on the blot?			
Does the blot include appropriate positive and negative controls – Positive control consisting of a dilution series of control protein complemented with wild type material of the same tissue (this control is especially relevant for blots used to substantiate the absence of expression); Positive control of purified protein; Negative control – the unmodified parental line or variety.			
Was a normal serum control conducted?			
Are any superfluous bands or background signal properly explained?			
If quantitative analysis is performed, has the methodology or citation to such been provided, and have a sufficient number of replicates or samples been tested to determine whether there are differences between samples or treatments?			

SECTION V – CHECKLIST FOR PCR DATA

	YES	NO	COMMENT
Does the PCR gel have a figure number and title?			
Are lanes labelled on the gel?			
Does the figure legend describe each lane of the gel, including a description of the following for the DNA that was loaded: ▪ What type of material was loaded (e.g. plasmid fragment, amplified DNA)? ▪ Source of the material used in each reaction loaded (e.g. transformation event, tissue, development stage, any prior treatments to induce gene expression, etc.)? ▪ Quantity of material loaded? ▪ Quality of material loaded?			
Is the position of the molecular weight standards indicated, and do they cover an appropriate size range for the fragments that are expected to be detected on gel?			
Does the text or figure legend describe how PCR amplification was performed prior to electrophoresis?			
Is there a description of the primers used for amplification in the text or in the figure sufficient to enable one to interpret the results?			
Does the gel have appropriate positive and negative control lanes - Positive control might demonstrate specificity of the primers and the ability to amplify the appropriate size band; Negative controls might include amplification with DNA from the unmodified parental line or variety, and amplification in absence of DNA template; Check for amplification of a control fragment from the plant sample (to show that PCR is working, especially if it is intended to show absence of a specific DNA); Mix plant DNA with plasmid DNA (I copy control) to demonstrate that the PCR is working properly.			
Was an entire plasmid or a restriction fragment used as the positive control template and is it adequately described in the text or in the figure legend for interpretation of the PCR results?			
Is the gel system and PCR protocol described in the text or in a cited literature reference? Are modifications of a cited protocol described in the text?			

SECTION VI – CHECKLIST FOR ELISA DATA

	YES	NO	COMMENT
Does the table have a number and a title?			
Are all entries clearly identified in the table and described in the text or table legend?			
Is the sample preparation described?			
Is the antibody or antiserum preparation protocol adequately described in the text, including a description of the antigen and its purity? Has the specificity of the antibody or antiserum been demonstrated and described in the text or in a cited literature reference?			
Is the ELISA protocol used described in the text or cited in the scientific literature? Any modifications to a cited protocol must be described.			
Were appropriate positive controls (e.g. purified protein) and negative controls (e.g. normal or			

	YES	NO	COMMENT
preimmune serum, non-transformed plant material) used?			
When ELISA is being used to quantify protein expression in transformed tissues: ▪ Was a method for the determination of protein concentration in tissue samples presented in the text or in a cited literature reference? ▪ Were a standard curve prepared and the limit of detection indicated? ▪ Have a sufficient number of replicates or samples been tested to determine whether there are significant differences between samples or treatments? Was statistical analysis performed?			

SECTION VII – CHECKLIST FOR ENZYME ASSAYS

	YES	NO	COMMENT
Does the figure (or table) have a number and title?			
For graphical representations or tables, are the axis or columns labelled and the units indicated?			
Does the scale of the figure accurately represent and allow interpretation of the data?			
Does the legend or text describe: ▪ The substrate and amount used for the reaction? ▪ The quantity and origin of the enzyme? ▪ The temperature and pH?			
Does the text or legend describe the extraction and purification of the enzyme and the degree of purification achieved?			
If the enzyme used in the assay has not been isolated from the transformed plant but is derived from an expression system, has adequate data been presented to demonstrate its substantial equivalence to the plant expressed enzyme?			
Have the assay method and relevant information concerning the enzyme been provided in the text or in a cited literature reference?			
Are appropriate controls included in the assay?			
Has the stability of the enzyme and possible presence of enzyme inhibitors in different tissue extracts been taken into account in the design of the assay or the interpretation of the data?			
When relevant to the safety assessment, have the kinetics of the enzyme been calculated and where possible compared to published data?			
When quantitative analysis is performed, have a sufficient number of replicates or samples been tested to determine whether there are significant differences between samples or treatments? Was statistical analysis performed?			

NOTICE 1048 OF 2004

DEPARTMENT OF AGRICULTURE

Directorate Genetic Resources
Private Bag X973, Pretoria, 0001, South Africa
Tel: 27 12 319 6536; Fax: 27 12 319 6329
E-mail: SMGRM@nda.agric.za

TERMS OF REFERENCE FOR SUB-COMMITTEES TO ASSIST THE ADVISORY COMMITTEE IN TERMS OF SECTION 11(2) OF THE GENETICALLY MODIFIED ORGANISMS ACT, 1997

Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997)

May 2004

CONTENTS PAGE

1. Scope

The sub-committees to the Advisory Committee is appointed in terms of Section 11(2) of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).

The functions of the sub-committees are to assist the Advisory Committee in reviewing applications received by the Registrar, therefore to assist the Advisory Committee in performing the functions listed in Section 11(1) of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). Additionally, the sub-committees will deal with specific matters that are beyond the expertise of the Advisory Committee.

In the event that the Advisory Committee needs more clarification on a specific application, the sub-committees appointed to the specific application may be invited to attend the meeting where the relevant application will be discussed. Members of the sub-committees do not form part of the quorum and may therefore not participate in the decision making.

2. Criteria for appointment

2.1 Appointment as member of the Sub-Committees

Members of the sub-committees should include additional expertise to that provided for by the members of the Advisory Committee. This will ensure that the sub-committee serves as a source or pool of expertise that may be called upon by the Advisory Committee when required.

The sub-committee members in the pool shall be selected and nominated by the Advisory Committee, in collaboration with the Executive Council, on the basis of their special expertise in matters relevant to the GMO Act, 1997. Not more than 50 scientists shall be appointed. The Registrar will, upon the recommendation of the Advisory Committee, send official appointment letters to each member.

Additional to the members appointed to the sub-committees, the Advisory Committee may, on its own accord or upon recommendation by the Executive Council, invite written comments of any knowledgeable person (e.g. farmer) to address certain issues within a review. These individuals may also, upon recommendation by the Advisory Committee, be appointed as a member of the sub-committees.

In the event that expertise regarding a specific aspect is not available in South Africa, members of the sub-committee may, upon recommendation by the chairperson of the specific review, consult with international experts. These individuals may also, upon recommendation by the Advisory Committee, be appointed as a member of the sub-committees.

2.2 Sub-committees appointed to conduct a review

To assist the Advisory Committee in reviewing applications for activities with GMO's, a sub-committee will be appointed for each application. More than one sub-committee may be appointed for each review. Each sub-committee will review the application within its own scope. E.g. an environmental safety assessment sub-committee reviews the application with regard to environmental impact and a food safety assessment sub-committee reviews the application with regard to food and feed safety. In light of capacity, a sub-committee may also include expertise to conduct more than one type of assessment, such as both environmental and food and feed safety. Other sub-committees as required by the Advisory Committee or Executive Council, may be appointed to assist in the evaluation of a particular assessment.

Members of all appointed sub-committees to a specific review will report back to the review chairperson.

If the need arise, the chairperson of any review committee, with the consent of the chairperson of the Advisory Committee, may request a meeting to address certain concerns, between the members of the review committee and the applicant in the case of general release applications.

It is the responsibility of the chairperson of a review to ensure that the relevant expertise required for the review is present on the review committee. If expertise in a certain field is required, but cannot be fulfilled by the current members of the sub-committee pool, the chairperson should indicate the situation to the Registrar (in writing), nominate a preferred expert for the review and request the Registrar to appoint the expert for the particular review. The chairperson may not make use of experts that have not been appointed by the Registrar, as these individuals will not be remunerated.

The review chairperson must address al concerns raised by each member within the review committee, and give a clear indication to the Registrar on questions that should be addressed to the applicant. Once the review chairperson has submitted the final recommendation document, the review chairperson will copy the document to each reviewer within the sub-committee. The review chairperson is also responsible to provide feedback to the review committee on the decision taken by the Executive Council.

3. Term of appointment

The members of the sub-committees as referred to in Section 2.1 are appointed for a period of three years. A member of the sub-committees whose period of service has expired shall be eligible for reappointment.

Appointment of the sub-committees to review a certain application will be adhoc; i.e. members appointed will be determined by the expertise required for review of the application.

4. Capacity Building

In the interest of capacity building, members of the sub-committees may, upon recommendation of the Executive Council, be nominated to participate on international bodies. The Council would further make recommendations to the relevant international body regarding the nominated scientist. All invitations and nominations to participate internationally should be channelled through the Registrar's office.

Scientists participating in this manner must commit to capacity building in SA in whatever way the Council feels necessary, and share the experience gained in such undertakings with members of both the Advisory Committee and Executive Council.

5. Timeframe for reviews

Members of the sub-committees have a period of three weeks to conduct an assessment of the application received. On completion of the review, the reviewer must submit a report to the review chairperson indicating all aspects assessed during the review.

Each member of the sub-committee must keep within the timeframe allocated to him or her by the review chairperson. If the member is unable to keep within the timeframe, the member must contact the chairperson of the review committee immediately.

6. Distribution of documents

All documents relevant for the evaluation of a certain application will be sent via courier to each reviewer and the review chairperson. The review chairperson shall, on confirmation of the availability of the sub-committee members to conduct the review, contact the Registrar's office to arrange for a courier service to distribute the documentation to the relevant sub-committee members.

Upon receipt of additional information from the applicant, this information will be directly forwarded to the sub-committees, via courier, from the Registrar's office. The review chairperson will be notified in advance of these proceedings.

In the event that clarity on certain issues with regard to the application can only be resolved through direct communication with the applicant, the review-chairperson may, after notification to the Registrar, contact the applicant directly (via phone, e-mail, or meeting).

On completion of the review, the sub-committee members should send their comments/recommendations to the review chairperson, who will compile a final report to be submitted to the Registrar.

7. Conflict of interest

According to Section 13 of the GMO Act, a person appointed to the sub-committees shall, immediately recuse himself or herself as a member of the sub-committees if a subject matter is reviewed in which he or she has any direct or indirect interest or if, for any other reason, there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the sub-committees.

8. Confidentiality

According to Section 18 of the Genetically Modified Organisms Act, 1997, no member of the sub-committees shall disclose any information acquired by him or her through the exercise or the performance of his or her duties in terms of the GMO Act.

Once finality on an application has been reached through a decision of the Council, or if the applicant withdraws the application, each member of the sub-committee will destroy all relevant documentation in relation to the application in an effective manner.

Each appointed member of the sub-committees shall sign a Deed of Confidentiality. The signed Deeds of Confidentiality will be collected by the Registrar and placed on a register administered by the Registrar's office.

9. Remuneration

The members of the sub-committees shall be, in terms of Section 12(1) of the GMO Act paid such remuneration as determined by the Minister of Agriculture and Land Affairs, in concurrence with the Minister of Finance.

The sub-committees shall be remunerated on the same basis as the members of the Advisory Committee. Payment will therefore be done adhoc, i.e. no work no pay. Hours spent (as indicated below) by the sub-committees on relevant matters of an application should be recorded and submitted via the review chairperson to the Registrar's office.

The Registrar will make direct payments to the sub-committees on a quarterly basis. No review will be paid until a decision on the application has been made by the Executive Council.

The average amount of hours paid for a certain review will be as follow -

(a) Assessment of an application for contained use:
- Member: 4 hours
- Review chairperson: 5 hours

(b) Assessment of an application for trial release:
- Member: 8 hours
- Review chairperson: 9 hours

(c) Assessment of an application for general release/commodity clearance:
- Member: 12 hours
- Review chairperson: 13 hours

NOTICE 1052 OF 2004

INTERNATIONAL TRADE ADMINISTRATION COMMISSION

NOTICE OF INITIATION OF A SUNSET REVIEW OF THE ANTI-DUMPING DUTIES ON ACETAMINOPHENOL ORIGINATING IN OR IMPORTED FROM THE UNITED STATES OF AMERICA (USA), FRANCE AND THE PEOPLE'S REPUBLIC OF CHINA (PRC)

In accordance with the provisions in Article 11.3 of the World Trade Organisation Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade, any definitive anti-dumping duty shall be terminated on a date not later than five years from its imposition, unless the authorities determine, in a review initiated before that date on their own initiative or upon a duly substantiated request made by or on behalf of the domestic industry within a reasonable period of time prior to that date, that the expiry of the duty would be likely to lead to continuation or recurrence of dumping and injury.

On 30 May 2003, the International Trade Administration Commission (the Commission) notified all interested parties, through Notice No. 1560 of Government Gazette No. 24893, that unless a request is made by or on behalf of the domestic industry for the duty to be reviewed prior to the expiry thereof, the anti-dumping duties on acetaminophenol originating in or imported from the USA, PRC, and France, will expire on 18 June 2004. A duly completed application Review Questionnaire was submitted to the Commission on 2 June 2004.

THE APPLICANT

The application was lodged by Fine Chemicals Corporation (Pty) Ltd, being the manufacturer of the subject product in the SACU. The applicant alleges that the expiry of the duty would be likely to lead to continuation or recurrence of dumping and injury. The applicant submitted sufficient evidence and established a *prima facie* case to enable the Commission to arrive at a reasonable conclusion that a review investigation should be initiated.

THE PRODUCT

The product under investigation is Acetaminophenol (Paracetamol), classified under tariff sub-heading 2924.29.05 originating in or imported from the USA, PRC and France.

THE ALLEGATION OF THE CONTINUATION OR RECURRENCE OF DUMPING

The allegation of continuation or recurrence of dumping is based on the comparison between the normal value and the export prices from the USA, PRC and France.

The normal values were determined as follows:

USA
The normal value was based on a price list obtained from a buyer in the USA.

PRC
In terms of the ITA Act China is regarded to be a country where prices are influenced by Government intervention and therefore Section 32(4) of the ITA Act applies.

The Applicant requested that the USA be used as a surrogate for the purposes of determining the normal value in respect of the PRC.

France
The normal value was based on a quotation obtained from a manufacturer in France.

Export prices

USA
The export price was based on the USA exports of the subject product to India. The information was based on the Indian customs and excise statistics.

PRC
The export price was based on a quotation obtained from a manufacturer in the PRC.

France
The export price was based on imports from France to the SACU obtained from the South African Revenue Services (SARS).

On this basis, the Commission found that there was *prima facie* proof of the likely recurrence of dumping if the duties expire.

THE ALLEGATION OF THE CONTINUATION OR RECURRENCE OF MATERIAL INJURY

The applicant alleges and submitted sufficient evidence indicating that there was an increase in imports, price undercutting and that the prices of the imports in question will be suppressing its selling prices. The applicant's information indicated that it will experience a decline in sales volume, profit, output, market share, productivity, employment and a negative effect on cash flow and growth, if the duties expire. It was also indicated that the applicant's market share will decrease at the expense of a corresponding increase in the market share of the dumped goods. On this basis the Commission found that there was *prima facie* proof of the likely continuation and/or recurrence of material injury.

PERIOD OF INVESTIGATION

The period of investigation for purposes of determining the continuation or recurrence of dumping from the exporting countries of origin will be from 1 January 2003 to 31 December

2003. The period of investigation for purposes of determining continuation or recurrence of injury will be from 1 January 1998 to 31 December 2003. An estimate of what the situation will be if the duties expire will also be considered by the Commission.

PROCEDURAL FRAMEWORK

Having decided that there is sufficient evidence and a *prima facie* case to justify the initiation of an investigation, the Commission has begun an investigation in terms of section 16 of the International Trade Administration Act, 2002 (the ITA Act). The Commission will conduct its investigation in accordance with the relevant sections of the ITA Act, the World Trade Organisation Agreement on Implementation of Article VI of the GATT 1994 (the Anti-Dumping Agreement) and the Anti-Dumping Regulations of the International Trade Administration Commission of South Africa (ADR). Both the ITA Act and the ADR are available on the Commission's website (www.itac.org.za) or from the Trade Remedies section, on request.

In order to obtain the information it deems necessary for its investigation, the Commission will send non-confidential versions of the petition and questionnaires to all known importers and exporters, and known representative associations. The trade representatives of the exporting countries have also been notified. Importers and other interested parties are invited to contact the Commission as soon as possible in order to determine whether they have been listed and were furnished with the relevant documentation. If not, they should immediately ensure that they are sent copies. The questionnaire has to be completed and any other representations must be made within the time limit set out below.

CONFIDENTIAL INFORMATION

Please note that if any information is considered to be confidential then a non-confidential version of the information must be submitted for the public file, simultaneously with the confidential version. In submitting a non-confidential version the following rules are strictly applicable and parties must indicate:

- where confidential information has been omitted and the nature of such information; reasons for such confidentiality;
- a summary of the confidential information which permits a reasonable understanding of the substance of the confidential information; and
- in exceptional cases, where information is not susceptible to summary, reasons must be submitted to this effect.

This rule applies to all parties and to all correspondence with and submissions to the Commission, which unless indicated to be confidential and filed together with a non-confidential version, will be placed on the public file and be made available to other interested parties.

If a party considers that any document of another party, on which that party is submitting

representations, does not comply with the above rules and that such deficiency affects that party's ability to make meaningful representations, the details of the deficiency and the reasons why that party's rights are so affected must be submitted to the Commission in writing forthwith (and at the latest 14 days prior to the date on which that party's submission is due). Failure to do so timeously, will seriously hamper the proper administration of the investigation, and such party will not be able to subsequently claim an inability to make meaningful representations on the basis of the failure of such other party to meet the requirements.

ADDRESS

The response to the questionnaire and any information regarding this matter, and any arguments concerning the allegation of continuation or recurrence of dumping, and the continuation or recurrence of material injury must be submitted in writing to the following address:

Physical address
The Director: Trade Remedies II
International Trade Administration Commission
4th Floor
SABS Building, No. 1 Dr Lategan Road
GROENKLOOF
PRETORIA, SOUTH AFRICA

Postal address
The Director: Trade Remedies II
Private Bag X753
PRETORIA
0001
SOUTH AFRICA

PROCEDURES AND TIME LIMITS

All responses, including non-confidential copies of the responses, should be received by the Director: Trade Remedies II not later than 30 days from the date hereof, or from the date on which the letter accompanying the abovementioned questionnaire was received. The said letter shall be deemed to have been received seven days after the day of its dispatch.

Late submissions will not be accepted except with the prior written consent of the Commission. The Commission will give due consideration to written requests for an extension of *not more than 14 days on good cause shown* (properly motivated and substantiated), if received prior to the expiry of the original 30-day period. Merely citing insufficient time is not an acceptable reason for extension. Please note that the Commission will not consider requests for extension by Embassies on behalf of exporters.

The information submitted by any party may need to be verified by the Investigating Officers in order for the Commission to take such information into consideration. The Commission may verify the information at the premises of the party submitting the information, within a short period after the submission of the information to the Commission. Parties should therefore ensure that the information submitted will subsequently be available for verification. It is planned to do the verification of the

information submitted by the exporters within three to five weeks subsequent to submission of the information. This period will only be extended if it is not feasible for the Commission to do it within this time period or upon good cause shown, and with the prior written consent of the Commission, which should be requested at the time of the submission. It should be noted that unavailability of, or inconvenience to consultants will not be considered to be good cause. Parties should also ensure when they engage consultants that they will be available at the requisite times, to ensure compliance with the above time frames. Parties should also ensure that all the information requested in the applicable questionnaire is provided in the specified detail and format. The questionnaires are designed to ensure that the Commission is provided with all the information required to make a determination in accordance with the rules of Anti-Dumping Agreement. The Commission may therefore refuse to verify information that is incomplete or does not comply with the format in the questionnaire, unless the Commission has agreed in writing to a deviation from the required format. A failure to submit an adequate non-confidential version of the response that complies with the rules set out above under the heading "Confidential Information" will be regarded as an incomplete submission.

Parties that have not exported to the SACU area during the period of investigation must provide details of all their exports to other countries in the required format and detail.

Parties who experience difficulty in furnishing the information required, or submitting in the format required, are therefore urged to make written applications to the Commission at an early stage for permission to deviate from the questionnaire or provide the information in an alternative format that can satisfy the Commission's requirements. The Commission will give due consideration to such a request on good cause shown.

Any interested party may request an oral hearing at any stage of the investigation in accordance with Section 5 of the ADR, provided that the party indicates reasons for not relying on written submission only. The Commission may refuse an oral hearing if granting such hearing will unduly delay the finalisation of a determination. Parties requesting an oral hearing shall provide the Commission with a detailed agenda for, and a detailed version, including a non-confidential version, of the information to be discussed at the oral hearing at the time of the request. Oral representations will be limited to one hour for SACU manufacturers and exporters and thirty minutes for importers.

Note: If the required information and arguments are not received in a satisfactory form within the time limit specified above, or if verification of the information cannot take place, the Commission may disregard the information submitted and make a finding on the basis of the facts available to it.

Enquiries may be directed to the investigating officers, Mr E Tema at telephone (012) 428-7725, Ms K Machiu at telephone (012) 428-7728 and Mr J Boning at telephone (012) 428-7732 or at fax (012) 428-7736.

NOTICE 1053 OF 2004

INTERNATIONAL TRADE ADMINISTRATION COMMISSION

NOTICE OF INITIATION OF A SUNSET REVIEW OF THE ANTI-DUMPING DUTIES ON ACRYLIC BLANKETS ORIGINATING IN OR IMPORTED FROM THE PEOPLE'S REPUBLIC OF CHINA (PRC) AND TURKEY

In accordance with the provisions in Article 11.3 of the World Trade Organisation Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade, any definitive anti-dumping duty shall be terminated on a date not later than five years from its imposition, unless the authorities determine, in a review initiated before that date on their own initiative or upon a duly substantiated request made by or on behalf of the domestic industry within a reasonable period of time prior to that date, that the expiry of the duty would be likely to lead to continuation or recurrence of dumping and injury.

On 30 May 2003, the International Trade Administration Commission (the Commission) notified all interested parties, through Notice No. 1560 of Government Gazette No. 24893, that unless a request is made by or on behalf of the domestic industry for the duty to be reviewed prior to the expiry thereof, the anti-dumping duties on acrylic blankets originating in or imported from the PRC and Turkey, will expire on 18 June 2004. A duly completed application Review Questionnaire was submitted to the Commission on 2 June 2004.

THE APPLICANT

The application was lodged by Texfed, on behalf of Aranda Textiles (Pty) Ltd and Ahlesa Blankets (Pty) Ltd, being manufacturers of the subject product in the SACU. The applicant alleges that the expiry of the duty would be likely to lead to continuation or recurrence of dumping and injury. The applicant submitted sufficient evidence and established a *prima facie* case to enable the Commission to arrive at a reasonable conclusion that a review investigation should be initiated.

THE PRODUCT

The product under investigation is blankets (excluding electric blankets), of acrylic fibres classified under tariff sub-heading 6301.40 and 6301.90 originating in or imported from the PRC and Turkey.

THE ALLEGATION OF THE CONTINUATION OR RECURRENCE OF DUMPING

The allegation of continuation or recurrence of dumping is based on the comparison between the normal value in Turkey and the export prices from the PRC and Turkey. The normal value for Turkey was based on a quote obtained from a Turkish trader. Turkey was nominated as the surrogate country for the PRC. The export prices were based on the

export statistics from the PRC and Turkey. On this basis, the Commission found that there was *prima facie* proof of the likely recurrence of dumping if the duties expire.

THE ALLEGATION OF THE CONTINUATION OR RECURRENCE OF MATERIAL INJURY

The applicant alleges and submitted sufficient evidence indicating that there was an increase in imports, price undercutting and that the prices of the imports in question will be suppressing its selling prices. The applicant's information indicated that it will experience a decline in sales volume, profit, output, market share, productivity, employment and a negative effect on cash flow and growth, if the duties expire. It was also indicated that the applicant's market share will decrease at the expense of a corresponding increase in the market share of the dumped goods. On this basis the Commission found that there was *prima facie* proof of the likely continuation and/or recurrence of material injury.

PERIOD OF INVESTIGATION

The period of investigation for purposes of determining the continuation or recurrence of dumping from the exporting countries of origin will be from 1 January 2003 to 31 December 2003. The period of investigation for purposes of determining continuation or recurrence of injury will be from 1 January 2000 to 31 December 2003. An estimate of what the situation will be, if the duties expire, will also be considered by the Commission.

PROCEDURAL FRAMEWORK

Having decided that there is sufficient evidence and a *prima facie* case to justify the initiation of an investigation, the Commission has begun an investigation in terms of section 16 of the International Trade Administration Act, 2002 (the ITA Act). The Commission will conduct its investigation in accordance with the relevant sections of the ITA Act, the World Trade Organisation Agreement on Implementation of Article VI of the GATT 1994 (the Anti-Dumping Agreement) and the Anti-Dumping Regulations of the International Trade Administration Commission of South Africa (ADR). Both the ITA Act and the ADR are available on the Commission's website (www.itac.org.za) or from the Trade Remedies section, on request.

In order to obtain the information it deems necessary for its investigation, the Commission will send non-confidential versions of the petition and questionnaires to all known importers and exporters, and known representative associations. The trade representatives of the exporting countries have also been notified. Importers and other interested parties are invited to contact the Commission as soon as possible in order to determine whether they have been listed and were furnished with the relevant documentation. If not, they should immediately ensure that they are sent copies. The questionnaire has to be completed and any other representations must be made within the time limit set out below.

CONFIDENTIAL INFORMATION

Please note that if any information is considered to be confidential then a non-confidential version of the information must be submitted for the public file, simultaneously with the confidential version. In submitting a non-confidential version the following rules are strictly applicable and parties must indicate:

- where confidential information has been omitted and the nature of such information;
- reasons for such confidentiality;
- a summary of the confidential information which permits a reasonable understanding of the substance of the confidential information; and
- in exceptional cases, where information is not susceptible to summary, reasons must be submitted to this effect.

This rule applies to all parties and to all correspondence with and submissions to the Commission, which unless indicated to be confidential and filed together with a non-confidential version, will be placed on the public file and be made available to other interested parties.

If a party considers that any document of another party, on which that party is submitting representations, does not comply with the above rules and that such deficiency affects that party's ability to make meaningful representations, the details of the deficiency and the reasons why that party's rights are so affected must be submitted to the Commission in writing forthwith (and at the latest 14 days prior to the date on which that party's submission is due). Failure to do so timeously, will seriously hamper the proper administration of the investigation, and such party will not be able to subsequently claim an inability to make meaningful representations on the basis of the failure of such other party to meet the requirements.

ADDRESS

The response to the questionnaire and any information regarding this matter, and any arguments concerning the allegation of continuation or recurrence of dumping, and the continuation or recurrence of material injury must be submitted in writing to the following address:

Physical address
The Director : Trade Remedies II
International Trade Administration Commission
4th Floor
SABS Building, No. 1 Dr Lategan Road
GROENKLOOF
PRETORIA, SOUTH AFRICA

Postal address
The Director: Trade Remedies II
Private Bag X753
PRETORIA
0001
SOUTH AFRICA

PROCEDURES AND TIME LIMITS

All responses, including non-confidential copies of the responses, should be received by the Director: Trade Remedies II not later than 30 days from the date hereof, or from the date on which the letter accompanying the abovementioned questionnaire was received. The said letter shall be deemed to have been received seven days after the day of its dispatch.

Late submissions will not be accepted except with the prior written consent of the Commission. The Commission will give due consideration to written requests for an extension of *not more than 14 days on good cause shown* (properly motivated and substantiated), if received prior to the expiry of the original 30-day period. Merely citing insufficient time is not an acceptable reason for extension. Please note that the Commission will not consider requests for extension by Embassies on behalf of exporters.

The information submitted by any party may need to be verified by the Investigating Officers in order for the Commission to take such information into consideration. The Commission may verify the information at the premises of the party submitting the information, within a short period after the submission of the information to the Commission. Parties should therefore ensure that the information submitted will subsequently be available for verification. It is planned to do the verification of the information submitted by the exporters within three to five weeks subsequent to submission of the information. This period will only be extended if it is not feasible for the Commission to do it within this time period or upon good cause shown, and with the prior written consent of the Commission, which should be requested at the time of the submission. It should be noted that unavailability of, or inconvenience to consultants will not be considered to be good cause. Parties should also ensure when they engage consultants that they will be available at the requisite times, to ensure compliance with the above time frames. Parties should also ensure that all the information requested in the applicable questionnaire is provided in the specified detail and format. The questionnaires are designed to ensure that the Commission is provided with all the information required to make a determination in accordance with the rules of Anti-Dumping Agreement. The Commission may therefore refuse to verify information that is incomplete or does not comply with the format in the questionnaire, unless the Commission has agreed in writing to a deviation from the required format. A failure to submit an adequate non-confidential version of the response that complies with the rules set out above under the heading "Confidential Information" will be regarded as an incomplete submission.

Parties that have not exported to the SACU area during the period of investigation must provide details of all their exports to other countries in the required format and detail.

Parties who experience difficulty in furnishing the information required, or submitting in the format required, are therefore urged to make written applications to the Commission at an early stage for permission to deviate from the questionnaire or provide the information in an alternative format that can satisfy the Commission's requirements. The Commission will

give due consideration to such a request on good cause shown.

Any interested party may request an oral hearing at any stage of the investigation in accordance with Section 5 of the ADR, provided that the party indicates reasons for not relying on written submission only. The Commission may refuse an oral hearing if granting such hearing will unduly delay the finalisation of a determination. Parties requesting an oral hearing shall provide the Commission with a detailed agenda for, and a detailed version, including a non-confidential version, of the information to be discussed at the oral hearing at the time of the request. Oral representations will be limited to one hour for SACU manufacturers and exporters and thirty minutes for importers.

Note: If the required information and arguments are not received in a satisfactory form within the time limit specified above, or if verification of the information cannot take place, the Commission may disregard the information submitted and make a finding on the basis of the facts available to it.

Enquiries may be directed to the investigating officers, Mr TP Botha at telephone (012) 428-7722 and Mr K Modimokwane at (012) 428-7737.

NOTICE 1054 OF 2004

INTERNATIONAL TRADE ADMINISTRATION COMMISSION OF SOUTH AFRICA

NOTICE OF PRELIMINARY DETERMINATION OF AN INVESTIGATION INTO THE ALLEGED DUMPING OF ALUMINIUM OVERHEAD CABLE ORIGINATING IN OR IMPORTED FROM INDIA

The notice of initiation of this investigation was published in *Government Gazette* No. 25524 dated 10 October 2003 (Notice No. 2536 of 2003).

The Applicant alleged that aluminium overhead cable (the subject product), originating in or imported from India was being dumped into the Southern African Customs Union (SACU) market at export prices lower than the prices charged in the country of export thereby causing material injury and a threat of material injury to the domestic industry.

The investigation was initiated on a basis of alleged dumping, material injury and / or a threat of material injury, and causality.

Interested parties were notified of the initiation of the investigation and were sent questionnaires to complete.

On the information submitted, the Commission found that the subject product originating in or imported from India was not being dumped into the SACU.

The Commission subsequently made a preliminary determination to recommend that the investigation be terminated.

The detailed reasons for the Commission's decision are contained in the Commission's Report No. 61, which is available at the Commission's offices. All interested parties have the opportunity to respond and make representations, before the Commission makes its final determination.

CONFIDENTIAL INFORMATION

Please note that if any information is considered to be confidential then a non-confidential version of the information must be submitted for the public file, simultaneously with the confidential version. In submitting a non-confidential version the following rules are strictly applicable and parties must indicate:

- where confidential information has been omitted and the nature of such information;
- reasons for such confidentiality
- a summary of the confidential information which permits a reasonable understanding of the substance of the confidential information; and
- in exceptional cases, where information is not susceptible to summary, reasons must be submitted to this effect.

This rule applies to all parties and to all correspondence with and submissions to the Commission, which unless indicated to be confidential and filed together with a non-confidential version, will be placed on the public file and be made available to other interested parties.

If the above requirements regarding the submission of a non-confidential version of documents are not strictly adhered to, the Commission might disregard the information so submitted.

ADDRESS

The response to the preliminary report and any arguments concerning the allegation of dumping and the resulting material injury must be submitted in writing to the following address:

Physical address
The Director: Trade Remedies II
4th Floor, SABS Building
No. 1, Dr Lategan Road,
Groenkloof,
PRETORIA,
SOUTH AFRICA

Postal address
The Director: Trade Remedies II
Private Bag X753
PRETORIA
0001
SOUTH AFRICA

PROCEDURES AND TIME LIMITS

All responses, including non-confidential copies of the responses, should be received by the Director: Trade Remedies II not later than 14 days from the date hereof or from the date on which the report was made available.

Late submissions will not be accepted except with the prior written consent of the Commission. The Commission will give due consideration to written requests for an extension of not more than 14 days on good cause shown (properly motivated and substantiated), if received at least 7 days prior to the expiry of the original 14-day period. Merely citing insufficient time is not an acceptable reason for extension. Please note that the Commission will not consider requests for extension by Embassies on behalf of exporters.

Oral representations to the Commission by any interested party may also be made on written request to the Commission provided a party submits a detailed version of the information to be addressed at the oral hearing at the time of requesting such hearing. No request for an oral hearing will be considered more than 60 days after publication of this notice. Oral representations will be limited to one hour for SACU manufacturers and exporters and thirty minutes for importers.

If the required information and arguments are not received in a satisfactory form within the time limit specified above, the Commission may disregard the information submitted and final findings on the basis of the facts available to it.

Parties that have not responded or cooperated with the Commission in the preliminary phase of the investigation and/or have not provided responses to the Commission's questionnaires, must show good cause why the Commission should consider any such responses or submissions. The commission reserves its right to disregard responses or submissions received from parties that did not cooperate during the preliminary phase of the investigation.

Enquiries may be directed to Mr E Tema at telephone (012) 428-7725 Mr K Modimokwane at telephone (012) 428-7737 or at fax (012) 428-7736.

NOTICE 1055 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Eigenhaard Farm

NO.	NAME	ID NUMBER
1	Dlamini Alexina	5207020291080
2	Mbabazeni Million Qwabo	3201015387088
3	Nkosi Thabisile Witness	6004040318087
4	Nkosi Yephu Annania	5907085269083
5	Sibiya Lindi Memezele	4107090296089

Property description of the affected Land:	**Eigenhaard Farm**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1056 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Subdivision A of Kaffirsdrift Farm No. 116

NO.	NAME	ID NUMBER
1	Magagula Mlahleni	4309195314084
2	Shabalala Mbongiseni Jotham	6601085334083
3	Vundla Mhlaliseni Stanley	5811265596085
4	Vundla Zwelibana Isaac	5411105240083
5	Xaba Ndodayamacala	6807205670088

Property description of the affected Land:	**Subdivision A of Kaffirsdrift Farm No. 116**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1057 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Portion 13 and 9 of Makateeskop Farm No. 59

NO.	NAME	ID NUMBER
1	**Buthelezi Bhekokwakhe Z**	**5402185780080**
2	**Ngwenya Sibongile Agnes**	**4501290399081**

Property description of the affected Land:	**Portion 13 and 9 of Makateeskop No. 59**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1058 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Springfontein Farm

NO.	NAME	ID NUMBER
1	**Masondo Beatrice**	
2	**Masondo Kenneth**	
3	**Masondo Mbongiseni**	**6402265405086**
4	**Masondo Princess**	
5	**Msimango Getrude**	
6	**Zwane Enock**	**5310145388086**

Property description of the affected Land:	**Springfontein**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1059 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Portion 17 of Bergheim Farm No. 59

NO.	NAME	ID NUMBER
1	Nkosi Albert Mandlenkosi	4007155487086

Property description of the affected Land:	**Portion 17 of Bergheim Farm No. 59**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1060 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Portion 3 of Vredehof Farm No. 17

NO.	NAME	ID NUMBER
1	Ndaba Dumisani T	7604025767080

Property description of the affected Land:	**Portion 3 of Vredehof Farm No. 17**
Servitude:	
District:	**Uitrecht**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1061 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Subdivision D of Uitkomst Farm No. 36

NO.	NAME	ID NUMBER
1	**Dlamini Mthambo Willie**	**471102543804**

Property description of the affected Land:	**Subdivision D of Uitkomst Farm No. 36**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1062 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Subdivision A of Protest Farm No. 117

NO.	NAME	ID NUMBER
1	**Mabaso Mhlawuliseni Z**	**5908085685088**
2	**Masondo Mishack Thembinkosi**	**6808065296089**
3	**Ngozo Simeon Thembinkosi**	**5909245638082**
4	**Vundla Fana Jotham**	**4908195527080**
5	**Vundla Ntandokayise Betram**	**6910075745087**

Property description of the affected Land:	**Subdivision A of Protest Farm No. 117**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1063 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Rondekopje Farm

NO.	NAME	ID NUMBER
1	Dlamini Mndeni A	7105045496080

Property description of the affected Land:	**Rondekopje Farm**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1064 OF 2004

DEPARTMENT OF LAND AFFAIRS

APPLICATION IN TERMS OF THE LAND REFORM (LABOUR TENANTS) ACT, 1996

It is hereby given for general information that in terms of section 17(1) of the Land Reform (Labour Tenants) Act, 1996 (Act 3), the application for the acquisition of Land mentioned in the Schedule has been lodged with the Director-General.

SCHEDULE

Applicants List of Portion 1 of Sophiesdal Farm

NO.	NAME	ID NUMBER
1	Sangweni Sikhumba	5008195265085
2	Zondo Mbombela Ephraim	4107165427088

Property description of the affected Land:	**Portion 1 of Sophiesdal Farm**
Servitude:	
District:	**Paulpietersburg**
Province:	**Kwa- Zulu Natal**

Date:	***04 June, 2004***
Submitted by:	***Ms. Monica Nyembe***

NOTICE 1036 OF 2004

DEPARTMENT OF LABOUR

LABOUR RELATIONS ACT, 1995

REGISTRATION OF A TRADE UNION

I, Johannes Theodorus Crouse, Registrar of Labour Relations, hereby, in terms of section 109 (2) of the Labour Relations Act, 1995, give notice, that **UNITED ASSOCIATION OF SOUTH AFRICA (UASA)** has been registered as a trade union with effect from 1 June 2004.

Note: As the following trade unions are the registered trade unions which amalgamated to establish this trade union, their names have been removed from the register of trade unions:

(i) United Association of South Africa;

(ii) Pos- En Telkomvereniging van Suid-Afrika.

J. T. CROUSE

Registrar of Labour Relations

KENNISGEWING 1036 VAN 2004

DEPARTEMENT VAN ARBEID

WET OP ARBEIDSVERHOUDINGE, 1995

REGISTRASIE VAN 'N VAKBOND

Ek, Johannes Theodorus Crouse, Registrateur van Arbeidsverhoudinge, maak hierby ingevolge artikel 109 (2) van die Wet op Arbeidsverhoudinge, 1995, bekend dat **UNITED ASSOCIATION OF SOUTH AFRICA (UASA)** met ingang van 1 Junie 2004 as 'n vakbond geregistreer is.

Nota: Aangesien die volgende vakbonde die geregistreerde vakbonde is wat geamalgameer het om hierdie vakbond te stig, is hulle name geskrap uit die register van vakbonde:

(i) United Association of South Africa (UASA);

(ii) Pos- En Telkomvereniging van Suid-Afrika.

J. T. CROUSE

Registrateur van Arbeidsverhoudinge

(11 June 2004)/(11 Junie 2004)

NOTICE 1044 OF 2004

NATIONAL TREASURY

9,375% 2004 INTERNAL REGISTERED BONDS (R097); CERTIFICATE No. 369 FOR R97 000, ISSUED IN FAVOUR OF ELI SPILKIN (PROPRIETARY) LIMITED

Application having been made to the National Treasury for a duplicate of the abovementioned certificate, the original having been lost or mislaid, notice is hereby given that unless the original certificate is produced at the National Treasury, Private Bag X115, Pretoria, within four weeks from the date of publication of this notice, the duplicate as applied for, will be issued.

KENNISGEWING 1044 VAN 2004

NASIONALE TESOURIE

9,375% 2004 BINNELANDSE GEREGISTREERDE EFFEKTE (R097): SERTIFIKAAT 369 VIR R97 000, UITGEREIK TEN GUNSTE VAN ELI SPILKIN (PROPRIETARY) LIMITED

Aangesien daar by die Nasionale Tesourie aansoek gedoen is om 'n duplikaat van bovermelde sertifikaat wat verloop of verlê is, word hierby bekendgemaak dat tensy die oorspronklike sertifikaat binne vier weke na die datum van publikasie van hierdie kennisgewing by die Nasionale Tesourie, Privaatsak X115, Pretoria, ingelewer word, die verlangde duplikaat sertifikaat uitgereik sal word.

(11 June 2004)/(11 Junie 2004)

NOTICE 1045 OF 2004

NATIONAL TREASURY

9,25% 2004 INTERNAL REGISTERED BONDS (R093); CERTIFICATE No. 159 FOR R77 000, ISSUED IN FAVOUR OF ELI SPILKIN (PROPRIETARY) LIMITED

Application having been made to the National Treasury for a duplicate of the abovementioned certificate, the original having been lost or mislaid, notice is hereby given that unless the original certificate is produced at the National Treasury, Private Bag X115, Pretoria, within four weeks from the date of publication of this notice, the duplicate as applied for, will be issued.

KENNISGEWING 1045 VAN 2004

NASIONALE TESOURIE

9,25% 2004 BINNELANDSE GEREGISTREERDE EFFEKTE (R093): SERTIFIKAAT 159 VIR R77 000, UITGEREIK TEN GUNSTE VAN ELI SPILKIN (PROPRIETARY) LIMITED

Aangesien daar by die Nasionale Tesourie aansoek gedoen is om 'n duplikaat van bovermelde sertifikaat wat verloop of verlê is, word hierby bekendgemaak dat tensy die oorspronklike sertifikaat binne vier weke na die datum van publikasie van hierdie kennisgewing by die Nasionale Tesourie, Privaatsak X115, Pretoria, ingelewer word, die verlangde duplikaat sertifikaat uitgereik sal word.

(11 June 2004)/(11 Junie 2004)

NOTICE 1049 OF 2004

BANKS ACT, 1990 (ACT No. 94 OF 1990)

WITHDRAWAL OF CONSENT TO MAINTAIN A REPRESENTATIVE OFFICE OF A FOREIGN INSTITUTION IN THE REPUBLIC OF SOUTH AFRICA, IN TERMS OF SECTION 34 OF THE BANKS ACT, 1990 (ACT No. 94 OF 1990): NATIONAL BANK OF MALAWI

Notice is hereby given, for general information, that the consent granted to National Bank of Malawi, by the Registrar of Banks, to maintain a representative office of a foreign institution in the Republic of South Africa was withdrawn with effect from 30 April 2004.

(11 June 2004)

NOTICE 1050 OF 2004

BANKS ACT, No. 94 OF 1990

CONSENT IN TERMS OF SECTION 34 OF THE BANKS ACT, 1990, FOR A FOREIGN INSTITUTION TO ESTABLISH A REPRESENTATIVE OFFICE WITHIN THE REPUBLIC OF SOUTH AFRICA: ICICI BANK LIMITED

Notice is hereby given, for general information, in accordance with the provisions of section 30 of the Banks Act, 1990, that Icici Bank Limited, and institution that lawfully conducts business similar to the business of a bank in India, has been granted permission by the Registrar of Banks, in terms of section 34 of the Banks Act, 1990, to establish a representative office within the Republic of South Africa, with effect from 16 April 2004. The representative office referred to above is, however, not authorised to conduct the business of a bank in the Republic of South Africa.

(11 June 2004)

BOARD NOTICES
RAADSKENNISGEWINGS

BOARD NOTICE 65 OF 2004

SOUTH AFRICAN COUNCIL FOR SOCIAL SERVICE PROFESSIONS

ELECTION OF SIX MEMBERS TO THE SOUTH AFRICAN COUNCIL FOR SOCIAL SERVICE PROFESSIONS IN TERMS OF SECTION 5(1)(a) OF THE SOCIAL SERVICE PROFESSIONS ACT, 1978 (ACT No. 110 OF 1978)

Under provision of regulation 15(14) of the Regulations relating to the election of members of the SA Council for Social Service Professions made under the Act and published as Government Notice No. R. 698 in Government Gazette No. 7525 of 3 April 1981, as amended by Government Notices No. R. 706 in Government Gazette No. 9662 of 29 March 1985, R. 947 in Government Gazette No. 13876 of 27 March 1992, R. 1655 in Government Gazette No. 16782 of 27 October 1995 and R. 1698 in Government Gazette No. 19644 of 31 December 1998, notice is herewith given for general information of the results of the election that took place on 28 May 2004:

Candidate	Number of votes
CARSTENS, Renate Catherine (10-11311)	387
CHAVULA, Dixie Matsiane (10-14807)	201
CLARKE-MCLEOD, Peter George (10-04451)	289
COLLINS, Kathleen Jane (Kathy) (10-00009)	444
DE JAGER, Mathilda Netta (Manette) (10-04798)	220
ERASMUS, Magaretha Cornelia (Corné) (10-03177)	285
GREEN Sulina, (10-01752)	351
KALIS, André Christiaan (10-112710)	377
KEMP, Rachel Jacoba (Mollie) 10-02031)	315
KINNEAR, Susanna Wilhelmina (10-01856)	185
MOHAPI, Boitumelo Joyce (10-01219)	240
NAUDé, Martin David Jacobus (10-10199)	87
OLIPHANT, Emmerentie (10-11461)	328
RAMMUTLA, Frans Makolobe 10-07490	287
ROESTENBURG, Willem Jan Horninge (Wim) (10-07690)	328
SHAPIRO, Nadya Lee (10-06245)	183
TOYIYA, Thembisile Kidwell	190

(10-13011)	
VAN DELFT Willem Friedemann (Wilfried) (10-00144)	438
WELMAN, Elna (10-01900)	202

J LOMBARD
Returning Officer

RAADSKENNISGEWING 65 VAN 2004

SUID-AFRIKAANSE RAAD VIR MAATSKAPLIKE DIENSBEROEPE

VERKIESING VAN SES LEDE VAN DIE SUID-AFRIKAANSE RAAD VIR MAATSKAPLIKE DIENSBEROEPE INGEVOLGE ARTIKEL 5(1)(a) VAN DIE WET OP MAATSKAPLIKE DIENSBEROEPE, 1978 (WET No. 110 VAN 1978)

Kragtens die bepalings van regulasie 15(14) van die Regulasies betreffende die verkiesing van lede van die SA Raad vir Maatskaplike Diensberoepe uitgevaardig kragtens die Wet en gepubliseer as Goewermentskennisgewing No. R. 698 in Staatskoerant No. 7525 van 3 April 1981, soos gewysig deur Goewermentskennisgewings No. R. 706 in Staatskoerant No. 9662 van 29 Maart 1985, R. 947 in Staatskoerant No. 13876 van 27 Maart 1992, R. 1655 in Staatskoerant No. 16782 van 27 Oktober 1995 en R. 1698 in Staatskoerant No. 19644 van 31 December 1998, word die uitslag van die verkiesing wat op 28 Mei 2004 plaasgevind het, hermee vir algemene inligting bekend gemaak:

Kandidaad	**Aantal stemme**
CARSTENS, Renate Catherine (10-11311)	387
CHAVULA, Dixie Matsiane (10-14807)	201
CLARKE-MCLEOD, Peter George (10-04451)	289
COLLINS, Kathleen Jane (Kathy) (10-00009)	444
DE JAGER, Mathilda Netta (Manette) (10-04798)	220
ERASMUS, Magaretha Cornelia (Corné) (10-03177)	285
GREEN Sulina, (10-01752)	351
KALIS, André Christiaan (10-112710)	377
KEMP, Rachel Jacoba (Mollie) 10-02031)	315
KINNEAR, Susanna Wilhelmina (10-01856)	185
MOHAPI, Boitumelo Joyce (10-01219)	240
NAUDé, Martin David Jacobus (10-10199)	87
OLIPHANT, Emmerentie (10-11461)	328
RAMMUTLA, Frans Makolobe 10-07490	287
ROESTENBURG, Willem Jan Horninge (Wim) (10-07690)	328
SHAPIRO, Nadya Lee (10-06245)	183

TOYIYA, Thembisile Kidwell (10-13011)	190
VAN DELFT Willem Friedemann (Wilfried) (10-00144)	438
WELMAN, Elna (10-01900)	202

J LOMBARD
Verkiesingsbeampte

BOARD NOTICE 67 OF 2004

The South African Council for the Project and Construction Management Professions

Recommended Scope of Services and Tariff of Fees for Persons Registered in terms of the Project and Construction Management Professions Act, 2000, (Act No. 48 of 2000)

The South African Council for the Project and Construction Management Professions has, under Section 34(2) of the Project and Construction Management Profession Act, 2000 (Act No. 48 of 2000) determined the guideline scope of services and tariff of fees in the Schedule.

Written comments and inputs are invited from Voluntary Associations and interested parties, which must be submitted to:

The Registrar
SACPCMP
P.O. Box 2376
HOUGHTON
2041

9 WELLINGTON ROAD
PARKTOWN
2193

TEL: 011 642 1150
FAX: 011 643 4632

THE COMMENTS SHOULD BE SUBMITTED BEFORE OR ON 30 JULY 2004

SCHEDULE

Guideline Scope of Services and Tariff of Fees for Registered Persons

Any amount mentioned in or fee calculated in terms of this Schedule is exclusive of Value Added Tax.

Index

*Words or expressions in **bold font** are defined in Clause 1.*

GENERAL PROVISIONS

1. DEFINITIONS

Where the words and phrases are highlighted in the text of this Tariff of Fees they shall bear the meaning assigned to them in clause 1 and where such words and phrases are not highlighted they shall bear the meaning consistent with the context:

(i) **"client"**, means any juristic person or organ of the State engaging a **construction project manager** for **services** on a **project;**

(ii) **"construction project manager"**, means any person registered in terms of Section 18 of **the Act**, or a legal person who employs such registered person, engaged by a **client** on a **project;**

(iii) **"construction project management"** means the management on behalf of a **client** of the entire process necessary for the procurement of the design and the construction of a project from briefing through to commissioning and occupation, taking into account the **client's** requirements in respect of aesthetics, quality, cost, time, etc.

(iv) **"contractor"** means any person or legal person under contract to a **client** to perform the **works** or part of it on a **project,** including a subcontractor under contract to such **contractor;**

(v) **"cost of the works"** means the total amount, exclusive of value added tax, certified or which would be certified for payment to **contractors** (irrespective of who actually carries out the works) in respect of the **works** in respect of which the **construction project manager** is performing a **construction project management** service, before deduction of liquidated damages or penalties;

(vi) **"normal services"** means the **services** set out in clause 3;

(vi) **"project"** means any total scheme envisaged by a **client,** including all the **works** and **services** concerned;

(vii) **"services"** means the services contemplated in clauses 3 and 4 on a **project** for which a **construction project manager** is engaged;

(viii) **"stage"** means a stage of **normal services** set out in clause 3;

(ix) **"the Act"** means the Project and Construction Management Professions Act, 2000 (Act No. 48 of 2000);

(x) **"total annual cost of employment"** means the total annual cost of employment as defined in clause 10(4);

(xi) **"works"** means the activities on a **project** for which **contractors** are under contract to the **client** to perform or is intended to be performed, including the supply of goods and equipment;.

2. SHORT TITLE

This Schedule is called the Guideline Scope of Services and Tariff of Fees for Registered **Construction Project Managers**, 2003.

GUIDELINE SCOPE OF SERVICES

3. NORMAL SERVICES

PROJECT STAGES

Project stage	Description
1	Project Initiation and briefing
2	Concept and viability
3	Design development
4	Tender documentation and procurement
5	Construction and contract administration
6	Contract Close out

Notes:
Refer to flowchart for typical project roll out process
Project stages or activities within stages may be overlapped in time, subject to approval by the **client**

	STAGE					
	1	2	3	4	5	6
Integration Management						
Consult with the client to establish the project scope, objectives, priorities, constraints, assumptions and strategies:	✓					
Review with client and update as necessary		✓	✓	✓	✓	
Manage the integration of the design, time programme and cost budget for the works, to form the basis of planning documents to be approved by the client:	✓	✓	✓			
Manage the execution of the project in accordance with the approved planning documents.		✓	✓	✓	✓	
Manage the control of all interrelated changes to the approved planning documents.		✓	✓	✓	✓	
Scope Management						

	STAGE					
	1	2	3	4	5	6
Break down the scope of the project into a manageable work breakdown structure encompassing professional services and construction:	✓	✓	✓	✓	✓	
Monitor the preparation of the design of the works through the duration of the project.		✓	✓	✓	✓	✓
Manage the acceptance by the client of the design.		✓	✓	✓	✓	✓
Manage the acceptance by the client of the construction of the works.					✓	✓
Establish and monitor the processes of controlling changes to the scope of the project, relevant to the stage	✓	✓	✓	✓	✓	
Time Management						
Develop a master time programme integrating the interdependencies of planning, design and construction:	✓	✓				
Review and update as necessary			✓	✓	✓	
Control changes to the master time programme to reflect actual project status.	✓	✓	✓	✓	✓	
Monitor that subordinate detailed time programmes are produced and maintained in conformity with the master time programme by the other project participants.		✓	✓	✓	✓	
Cost Management						
Establish responsibilities for information flow between the design team and the quantity surveyor.	✓	✓				
Monitor the preparation by the quantity surveyor of cost estimates and the cost budget for the project:	✓	✓	✓			
Establish a format for the cost budget in consultation with the quantity surveyor that meets the client's reporting requirements.	✓	✓	✓			
Establish and monitor the processes of controlling changes to the cost budget.		✓	✓	✓	✓	✓
Quality Management						
Establish the organisation structure and responsibilities for quality management in the provision of professional services.	✓	✓				
Establish the organisation structure and responsibilities for quality management in the construction of the works.				✓		
Monitor that all project participants meet their quality management obligations.	✓	✓	✓	✓	✓	✓

	STAGE					
	1	2	3	4	5	6
Human Resource Management						
Establish the roles, responsibilities and reporting relationships between the various participating organisations for the project.	✓	✓	✓	✓	✓	
Monitor that suitable key people are assigned by participating organisations to establish an adequate project team.	✓	✓	✓	✓	✓	✓
Promote the development of project team spirit to enhance project performance.	✓	✓	✓	✓	✓	✓
Communications Management						
Establish the communications structure and responsibilities for the project.	✓	✓	✓	✓	✓	✓
Monitor the information distribution and record keeping.	✓	✓	✓	✓	✓	✓
Collate information and prepare reports for submission to the client.	✓	✓	✓	✓	✓	✓
Manage the closing out of the project and submission to the client of required records.						✓
Risk Management						
Establish responsibilities for arranging project insurance and monitoring the timeous provision of proof of insurance:	✓	✓	✓	✓	✓	✓
Procurement Management						
Establish the procurement strategy and choice of contract systems for the project in consultation with the client:	✓	✓	✓			
Establish the client's requirements regarding potential consultants and methods of obtaining quotations, offers and tenders.	✓	✓				
Establish the client's requirements regarding potential contractors and methods of obtaining quotations, offers and tenders.			✓	✓		
Manage the processes of preparing proposal calls and tender documents, and calling for proposals and for tenders, in accordance with agreed procedures.	✓	✓	✓	✓		
Manage the evaluation of proposals and tenders, and facilitate their awards.	✓	✓	✓	✓	✓	
Appoint consultants and contractors on behalf of the client subject to prior written authorisation by the client	✓	✓	✓	✓	✓	
Act as agent of the client in the administration of contracts between the client and the consultants and/or contractors, in terms of such contracts	✓	✓	✓	✓	✓	✓

4. ADDITIONAL SERVICES

The following **services** are additional to the **normal services** provided by the **construction project manager**, and shall be performed by agreement between the **construction project manager** and the **client**. The agreement on scope of **services** and remuneration shall be in writing and should, if at all possible, be concluded before such services are rendered.

Additional services pertaining to all stages of the project

4.1 Appointment as agent in accordance with Regulation 4.(5) of the Construction Regulations 2003 under the Occupational Health and Safety Act, 1993 (Act 85 of 1993) to specifically ensure compliance with the Regulations on construction sites under its control.

4.2 Procuring of land and finance.

4.3 Procuring of tenants, tenant co-ordination and tenant installations.

4.4 Drafting of appointment contracts for other members of the professional team.

4.5 Project management services in relation to direct **contractors** engaged by the **client**, such as those engaged for furniture, fittings and equipment.

4.6 Mediation, arbitration and litigation proceedings and similar services. Such services will commence upon the notification of a dispute or the initiation of such proceedings.

4.7 All work arising out of failure of any consultant, contractor, supplier or other external party to perform its obligations.

4.8 Services required in respect of damage to or destruction of the **works**, insurance matters, postponement or cancellation of agreements.

4.9 Additional services resulting from changes by the **client** to previously issued instructions.

4.10 Construction management of various **contractors** engaged by the **client** in the event that more than one **contractor** is appointed.

4.11 Calculation and certification of professional fees applicable to other consultants engaged by the **client** for the **project**.

4.12 Any other services not specifically incorporated in this **Guideline Scope of Services and Tariff of Fees for Registered Persons**.

5. COMMISSIONS TERMINATED

5.1 Should a commission be terminated the fee for the **services** completed shall be calculated in accordance with the **Tariff of Fees** and the fee for services partially completed shall be determined *pro rata* to the complete **service**.

5.2 Should a commission be terminated by the **client** after the commencement of the commission then, in addition to the fee calculated in accordance with 5.1, a surcharge of 10 percent shall be payable on the difference between the full fee calculated in accordance with the **Tariff of Fees** for the **services** commissioned and the fee calculated in accordance with 5.1.

5.3 For purposes of 5.1 and 5.2, a commission shall be deemed to be terminated where the services are deferred or suspended for a period of more than 90 calendar days in the aggregate, unless otherwise agreed in writing by the parties.

6. APPLICATION OF TARIFF OF FEES

6. (1) The guideline tariff of fees contained in this Schedule applies in respect of the **services** set out in clause 3.

(2) The **client** should remunerate the **construction project manager**, for the **services** rendered, on the basis of clauses 6 to 9. In cases where the **client** and **construction project manager** have agreed that clauses 6 to 9 are not applicable, payment should be on the basis of clause 10 or as agreed according to clause 6(4).

(3) The **client** shall reimburse the **construction project manager** for all expenses and costs incurred in terms of clause 11 in performing his **services**, irrespective of whether fees are charged in terms of clauses 6 to 9, as well as for all costs incurred on behalf, and with the approval, of the **client**.

(4) Should the tariff of fees contained in this Schedule be found to be inappropriate to any **project**, **works**, **services** or part thereof, the **client** and **construction project manager** may agree a fee deemed more appropriate. Contributing factors to be taken into account, although not limited to, may include all or any of the following:

(a) *Complexity:* Where the **works** call for the application of new, unusual or untried techniques or designs or application of complex **project** delivery, systems or processes or excessive complexity of the whole or part of the **works**.

(b) *Small projects:* Where projects are small in monetary value and the **tariff of fees** for normal projects does not compensate the **construction project manager** reasonably for the **services** to be rendered.

(c) ***Cost of the works:*** Where the **cost of the works** is abnormally low relative to the **services** required from the **construction project manager**.

(d) *Time duration:* Where the **works** are executed over an appreciably shorter or longer than normal or realistic time periods during any of the **stages** defined in clause 3, or where the **client** orders suspension of the **services** between

stages for periods in excess of 21 calendar days in the aggregate for any **stage**.

(e) *Level of responsibility, liability and risk:* Where unusually high demands in respect of these factors are expected to be carried by the **construction project manager**.

(5) Agreement on any adjustment of or special fees should be reached at the time of the engagement of the **construction project manager** or as soon after circumstances warrant such as practically possible, but should, if reasonably practicable, be concluded prior to the **construction project manager** rendering services which may be affected.

(6) Where at the instance and with the consent of the **client** the **works** are undertaken on separate non-contiguous sites, continuity is interrupted or are unusually fragmented or are constructed as separately documented phases or sections, the fee for ***normal services*** is:

(a) the sum of the fees calculated separately for each site, contract, phase or section as if they were separate **works**; or

(b) the fee agreed to between the **client** and the **construction project manager** and which fee lies between the fee calculated on the total **cost of the works** and the sum of the fees contemplated in clause 6(6)(a).

(7) The following fees may be claimed after each stage of **services** or monthly or as agreed between the **construction project manager** and the **client**:

(a) Percentage fees determined on the basis of the **cost of the works** prevailing at the time of the fee calculation and pro-rata to the completed **services**.

(b) Time based fees as specifically agreed on in writing by the **client,** applicable when the **services** were rendered.

(8) Disbursements as set out in clause 11 may be claimed monthly.

7. FEES FOR NORMAL SERVICES

7. (1) Construction project management services pertaining to building projects

The basic fee for **normal services** in the field of construction project management, pertaining to building projects, is calculated at the percentage mentioned against the ***cost of the works*** contained in following table:

Cost of the Works				
From	To	Primary Fee	Secondary Fee %	For value over
R0.00	R4,000,000.00	R0.00	5.90%	R0.00
R4,000,000.00	R8,000,000.00	R236,000.00	4.43%	R4,000,000.00
R8,000,000.00	R16,000,000.00	R413,000.00	3.85%	R8,000,000.00
R16,000,000.00	R32,000,000.00	R721,000.00	3.36%	R16,000,000.00

R32,000,000.00	R64,000,000.00	R1,258,000.00	2.93%	R32,000,000.00
R64,000,000.00	R128,000,000.00	R2,197,000.00	2.56%	R64,000,000.00
R128,000,000.00	R256,000,000.00	R3,836,000.00	2.24%	R128,000,000.00
R256,000,000.00	and above	R6,699,000.00	1.95%	R256,000,000.00

8. SERVICES PROVIDED PARTIALLY OR IN STAGES

8. (1) The following table shall be used for proportioning the basic fee for **normal services** over the various **stages** of the services:

Project stage	Description	Percentage of total fee
1	Project Initiation and briefing	10%
2	Concept and viability	10%
3	Design development	25%
4	Tender documentation and procurement	10%
5	Construction and contract administration	40%
6	Contract Close out	5%

9. FEES FOR ADDITIONAL SERVICES

9. The fees for additional services contemplated in clause 4 are to be agreed to between the **client** and the **construction project manager.**

10. TIME BASED FEES

10. (1) (a) Time based fees are all-inclusive fees, including allowances for overhead charges incurred by the **construction project manager** as part of normal business operations, including the cost of management, as well as payments to administrative, clerical and secretarial staff used to support professional and technical staff in general and not on a specific project only.

(b) Time based fees are calculated by multiplying the hourly rate contemplated in clause 11(3), which is applicable to the **construction project manager** or any other person employed by the **construction project manager**, with the actual time spent by such person in rendering the **services** required by the **client.**

(2) To determine the time based fee rates the persons concerned are divided into:-

(a) *Category A*, in respect of a private consulting practice in **construction project management**, shall mean a top practitioner whose expertise and relevant

experience is nationally or internationally recognized and who provides advice at a level of specialization where such advice is recognized as that of an expert.

(b) *Category B*, in respect of a private consulting practice in **construction project management**, shall mean a partner, a sole proprietor, a director, or a member who, jointly or severally with other partners, co-directors or co-members, bears the risks of the business, takes full responsibility for the liabilities of such practice, where level of expertise and relevant experience is commensurate with the position, performs work of a conceptual nature in **project management.**

(c) *Category C*, in respect of a private consulting practice in **construction project management**, shall mean all salaried professional staff with adequate expertise and relevant experience performing **project management** work and who carry the direct responsibility for one or more specific activities related to a project. A person referred to in Category B may also fall in this category if such person performs **project management** work at this level.

(d) *Category D*, in respect of a private consulting practice in **construction project management**, shall mean all other salaried technical staff with adequate expertise and relevant experience performing **project management** work with direction and control provided by any person contemplated in categories A, B or C.

(3) The time based fee rates and any applicable annual increase to rates are to be agreed to by the parties at the start of the commission, failing which applicable reasonable market related or gazetted rates shall be applied.

(4) For the purposes of clause 10(3), the **total annual cost of employment** of a person contemplated in clause 10(2) means the total amount borne by an employer in respect of the employment of such a person per year, calculated at the amounts applicable to such a person at the time of appointment of such staff to the project, including –

(a) Basic salary, or a nominal market related salary, excluding profit share and asset growth;

(b) Fringe benefits not reflected in the basic salary, including:

(i) normal annual bonus;
(ii) contribution to medical aid;
(iii) group life insurance premiums borne by the employer;
(iv) contribution to a pension or provident fund; and
(v) all other benefits or allowances payable in terms of a letter of appointment, including any transportation allowance or company vehicle benefit, telephone and/or computer allowances, etc; and

(c) Amounts payable in terms of a Act, including:

(i) contributions to the Compensation Fund in terms of the Compensation for Occupational Injuries and Diseases Act;
(ii) contributions to unemployment insurance in terms of the Unemployment Insurance Fund Act; and
(iii) recoverable levies to all spheres of government

11. EXPENSES AND COSTS

11. (1) For disbursements and for reasonable travelling and subsistence expenses additional payment shall be claimed over and above the fee payable under any other provision of this **Tariff of Fees.**

(2) Recoverable expenses include:

(a) Travelling expenses for the conveyance of the **construction project manager** or a member of the **construction project manager's** staff by means of:

(i) private motor transport, including any parking *charges*, toll fees and related expenses;
(ii) a scheduled air line or a train, bus, taxi or hired car; or
(iii) non-scheduled or privately owned air transport.

(b) Travelling time on the basis of the rate set out in clause 10, for all time spent in travelling by the **construction project manager** or members of his staff shall be as follows:

(i) when fees are paid on a time basis, all hours spent on travelling are reimbursable.
(ii) when fees are paid on a percentage basis, reimbursement for travelling time shall be for all time spent in travelling minus the first hour per return journey.

(c) Accommodation and subsistence expenses incurred by the **construction project manager** or a member of his staff;

(d) Agreed costs of typing, production, copying and binding of contract documents, pre-qualification documents, feasibility reports, preliminary design reports, final reports and manuals, excluding general correspondence, minor reports, contractual reports, progress reports, etc.

(e) Expenses on special reproductions, copying, printing, artwork, binding and photography, etc. requested by the **client.**

(f) Alternatively, a lump sum or percentage of the total fees payable to the **construction project manager** may be determined and agreed between the **construction project manager** and the **client** to cater for all or any of the above.

SACPCMP
TYPICAL PROJECT ROLL OUT PROCESS
STAGE 1
PROJECT INITIATION & BRIEFING
STAGE 2
CONCEPT & VIABILITY
STAGE 3
DESIGN DEVELOPMENT
STAGE 4
TENDER DOCUMENTATION & PROCUREMENT
STAGE 5
CONSTRUCTION DOCUMENTATION & CONTRACT ADMINISTRATION
STAGE 6
CONTRACT CLOSE OUT
APPOINT PROJECT MANAGER
ESTABLISH CLIENT VISION
SOURCE FUNDING FOR STAGE 1
APPOINT CORE TEAM
ESTABLISH PRELIMINARY BRIEF ON SCOPE OBJECTIVES & STRATEGIES
ESTABLISH PROCUREMENT STRATEGY
SECURE SITE FOR DEVELOPMENT
PREPARE ENVIRONMENTAL IMPACT ASSESSMENT BRIEFING
MARKET RESEARCH
IDENTIFY LAND REZONING REQUIREMENTS
IDENTIFY END USERS
IDENTIFY END USER REQUIREMENTS
SPACE PLANNING REQUIREMENTS
EIA SCOPING
EIA STUDY
INDICATIVE REVENUE SCHEMES
PREPARE ORDER OF MAGNITUDE COSTS
ESTABLISH INITIAL PHASING & STAGING OF PROJECT
IDENTIFY PROJECT FUNDING SOURCES
ORDER OF MAGNITUDE COMPLIANCE WITH STRATEGY & OBJECTIVES
ENVIRONMENTAL MANAGEMENT PLAN
LAND REZONING PROCESS
PROJECT INITIATION & BRIEFING REPORT
PROCEED TO STAGE 2
CLIENT APPROVAL TO PROCEED TO STAGE 2
SECURE STAGE 2 FUNDING
FINALISE PROJECT BRIEF
APPOINT BALANCE OF PROF TEAM
PREPARE ARCH CONCEPT
PREPARE MECHANICAL/ ELECTRICAL & OTHER SERVICES CONCEPT
PREPARE STRUCTURAL CONCEPT
PREPARE INDICATIVE PROJECT PROGRAMME
OTHER SPECIALIST STUDIES
GEOTECHNICAL INVESTIGATION
CADASTRAL/ TOPOGRAPHICAL SURVEY
PROJECTED RETURNS
INDICATIVE CAPITAL COST
INITIAL PROJECT VIABILITY
REFINE CONCEPT
FINALISE PROJECT VIABILITY
CONCEPT & VIABILITY REPORT
PROCEED TO PHASE 3
CLIENT APPROVAL TO PROCEED TO STAGE 3
SECURE FUNDING FOR REMAINDER OF PROJECT
PREPARE / SUBMIT & APPROVAL OF SDP
PREPARE ARCH PLANS/SECTIONS/ ELEVATIONS
PREPARE MECHANICAL/ ELECTRICAL & OTHER SERVICES SCHEMES
PREPARE STRUCTURAL/ CIVIL SCHEME
REFINE ESTIMATE
TECHNICAL CO-ORDINATION
VALUE ENGINEERING
PREPARE FINAL PROJECT BUDGET & COST PLAN
FINALISE PROJECT TIME PROGRAMME
COLLATE REPORT ON DESIGN PROGRAMME & BUDGET
SUBMIT BUILDING PLANS
APPROVAL OF BUILDING PLANS
PROCEED TO STAGE 4
CLIENT APPROVAL TO PROCEED TO STAGE 4
IDENTIFY TENDER PACKAGES
PREPARE PROCUREMENT SCHEDULE
PREPARE TENDER DRAWINGS
PREPARE TENDER SPECIFICATIONS
PREPARE & ISSUE TENDER DOCUMENTS
TENDER ADJUDICATION
PROCEED TO STAGE 5
CLIENT APPROVAL TO PROCEED TO STAGE 5
PREPARE CONSTRUCTION DOCUMENTATION
AWARD CONSTRUCTION CONTRACTS
MOBILISE CONTRACTORS
CONSTRUCTION ADMINISTRATION
COMMISSIONING & SNAGGING
PREPARE AS-BUILT DWGS & MAINTENANCE MANUALS & GUARANTEES
PRACTICAL COMPLETION OF CONSTRUCTION
TRANSFER RISK & CARE OF THE WORKS TO OWNER
END LIABILITY OCCUPATION
PREPARE COMPLETE OUTSTANDING CONSTRUCTION WORK LIST
PREPARE LIST OF PATENT DEFECTS
RECTIFICATION OF DEFECTS
PREPARE FINAL ACCOUNTS
FINAL COMPLETION
LATENT DEFECTS LIABILITY PERIOD
12/9/03

Dog ate your Gazette?
... read it online

www.SA Gazettes.co.za

A new information Portal keeping you up to date with news, legislation, the Parliamentary programme and which is the largest pool of SA Gazette information available on the Web.

- Easily accessible through the www!
  - Government Gazettes - from January 1994
  - Compilations of all Indexes pertaining to the past week's Government Gazettes
  - All Provincial Gazettes - from September 1995
  - Parliamentary Bills - as of January 1999
- Available in full-text, with keyword searching
- Sabinet Online scans, formats, edits and organize information for you. Diagrams and forms included as images.
- No stacks of printed gazettes - all on computer. Think of the storage space you save.
- Offers Bill Tracker - complementing the SA Gazettes products.

For easy electronic access to full-text gazette info, subscribe to the SA Gazettes from Sabinet Online. Please visit us at www.sagazettes.co.za

Sabinet Online

Tel: (012) 643-9500, Fax: (012) 663-3543, Toll free: 0800 11 8595, e-mail: corporate@sabinet.co.za, www: http://corporate.sabinet.co.za

Looking for out of print issues of Government and Provincial Gazettes

We can provide photocopies

Contact

The National Library of South Africa,
Pretoria Campus
PO Box 397
0001 PRETORIA

Physical address

C/o Andries and Vermeulen Streets
Entrance in Andries Street

Contact details

Tel: (012) 321-8931
Fax: (012) 325-5984
E-mail: infodesk@nlsa.ac.za

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531