የኢትዮጵያ የአካባቢ ጥበቃ ባለስልጣን
Ethiopian Environmental Protection Authority

BIOSAFETY

REGULATORY LEGAL FRAMEWORKS OF ETHIOPIA

2022
Addis Ababa

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መቅድም

የዘረ መል ምህንድስና ቴክኖሎጂ ከባዮ ቴክኖሎጂ ምርምር የቴክኖሎጂ ዘርፍ ውጤቶች አንዱ ሲሆን በዋናነት ለሰው ልጅ ጠቃሚ የሆኑ እፅዋትና እንስሳት የሚፈለገውን ጂን (ባህሪ የሚቆጣጠር የዘረመል ቅንጣት) በተፈጥሮ ከሌላቸው ከሌሎች ያልተዛመዱ ነፍሳት (እፅዋት፤ እንሰሳት፤ ባክቴሪያ፣ ፈንገስ፣ ወዘተ.) በማምጣት ከህዋሱ ዘረመል ጋር በማቀናጀት ዝርያን የማሻሻል ሂደት ነው።

በዚህም ዘዴ በርካታ ለምግብ እና ለአግሮ-ኢንዱስትሪ የሚውሉ ሰብሎች ላለፉት 25 ዓመታት በዓለም ላይ በተለያየ መልክ ተሻሽለው ለገበያ ቀርበው አገልግሎት ላይ ውለዋል። በሀገራችን ኢትዮጵያም የሰብል ምርታማነትንና ጥራትን በማሻሻል የምግብ ዋስትናችንን ለማረጋገጥና ኢኮኖሚያችንንም ለማሳደግ ጉልህ ሚና ይኖረዋል።

የዘረ-መል ምህንድስና ቴክኖሎጂ ጥቅም ላይ ሲውል ከታሰበለት ዓላማ ውጪ በሕብረተሰቡ እና በአካባቢ ላይ ያልተጠበቀ ጉዳት እንዳያደርስ ጥንቃቄ ማድረግ እንደሚያስፈልግ ይታመናል። ለዚህም ሀገራት እንደየሀገራቸው ብዝሀ ሕይወት እና ተፈጥሮ ሀብት ሁኔታ የራሳቸውን ህግ እና ደንብ የሚያወጡ ሲሆን በአለም አቀፍ ደረጃም ሀገራት የተስማሙባቸውን የተለያዩ ስምምነቶች መሰረት በማድረግ ቴክኖሎጂዎቹን ጥቅም ላይ እያዋሉ ይገኛሉ፡፡ ከእነዚህ መካከል አለም አቀፍ የስምምነት ማዕቀፎች መሀል Convention on Biological Diversity (CBD) ስምምነት እና Cartagena Protocol on Biosafety ተጠቃሾች ናቸው።

የብዝሃ ሕይወትን ለመጠበቅ የተደነገገው የብዝሐ ሕይወት ስምምነት እ.ኤ.አ በ1992 ዓ.ም የፀደቀ ሲሆን ሀገራችንም ስምምነቱን በአዋጅ ቁጥር 98/1986 አፅድቃ አባል ሆናለች፡፡ የስምምነቱ ዋና አላማ የብዝሀ ህይወት ጥበቃ፣ የብዝሀ ህይወትን በዘላቂነት መጠቀም እና ከጄኔቲክ (Genetic) ሀብቶች የሚገኙ ጥቅሞችን ፍትሀዊ እና እኩል በሆነ መንገድ መጋራትን የተመለከተ ነው።

የብዝሃ-ህይወት አለም አቀፍ ስምምነትን /Convention on Biological Diversity/ መነሻ በማድረግ የተዘጋጀው ሌላኛው አለም አቀፍ ስምምነት የካርታሂና የደህንነተ-ህይወት ፕሮቶኮል ነው። ይህ ፕሮቶኮል የልውጥ-ህያዋንና ውጤቶቻቸው ድንበር ዘለል ዝውውርን፣ ተዛማጅ የአገር ውስጥ አያያዝንና ሌሎች ድርጊቶችን የሚመለከት ሲሆን ዓላማው ልውጥ ሕያዋን ጉዳት ሳያደርሱ ለታሰበላቸው አላማ እንዲውሉና ጉዳት እንዳያደርሱ የሚጠበቅ

የህግ ማዕቀፍ ነው። በመሆኑም በሰው ጤና እንደዚሁም በማህበረሰቦች በጎ ሁኔታ ላይ የሚከተልን ጠንቅ ለመቋቋም፣ ብዝሀ-ህይወትን ለመንከባከብ እና ብዝሀ ህይወትን በዘላቂነት ለመጠቀም እንዲያስችል ሆኖ የተቀረፀ ነው። ሀገራችንም ፕሮቶኮሉን በአዋጅ ቁጥር 362/ 2003 አፅድቃ በመተግበር ላይ ትገኛለች።

የዓለማችን በርካታ ሀገራትም ይህን ለመተግበር የተስማሙ ሲሆን በተጨማሪም ሀገራት የራሳቸውን የደሕንነተ-ህይወት የሕግ ማዕቀፍ እንዲያዘጋጁና እንዲተገብሩ ታስቦ የተዘጋጀ አለም አቀፍ ስምምነት ነው።። ሀገራችን ኢትዮጵያም ሁለቱንም አለም አቀፍ ስምምነቶች የፈረመች ሲሆን ከእነዚህ ስምምነቶች በመነሳት በካርታጌና የደህንነተ ህይወት ፕሮቶኮል የተጣለባትን አለም አቀፍ ግዴታ ለማስፈፀም የሚያስችሉ የደሕንነተ-ሕይወት የህግ ማዕቀፍ (አዋጆች፣ ደንቦች እና መመሪያዎች) አዘጋጅታ ወደ ትግበራ ከገባች ዓመታቶችን አስቆጥራለች።

በዚህ ሰነድ የደህንነት ሕይወት (ማሻሻያ) አዋጅ ቁጥር 896/2007፣ የብሔራዊ ደህንነተ ሕይወት አማካሪ ኮሚቴ ለማቋቋም የወጣ ደንብ ቁጥር 411/2009 እና የተለያዩ መመሪያዎችን ማለትም ልውጥ ሕያዋንን በዝግ አጠቃቀም ለምርምር ወይም ለትምህርት ለማዋል የሚያስችል ልዩ ፈቃድ ለማግኘት፣ የጠንቅ ግምገማ፣ ሊደርስ የሚችል ጠንቅ መቋቋሚያ የአሰራር ሥርዓት፣ ለማጓጓዝና ለማከማቸት፣ በልውጥ ሕያዋን እንቅስቃሴዎች ላይ ለመሰማራት እና የተቋማት ደህንነተ-ሕይወት ኮሚቴ ለማደራጀት የወጡ መመሪያዎች ተካትተዋል።

የክቡር ዋና ዳይሬክተር መልእክት

አገራችን ከፍተኛ የብዝሀ-ህይወት እና የጀነቲክ ሀብት ክምችት የሚገኝባት ሀገር ከመሆኗ ጋር ተያይዞ እነዚህን ሀብቶች በአግባቡ እንድትጠቀም እና ባልታሰበ ምክንያት ጉዳት እንዳይደርስባቸው መደረግ ስላለበት ጥንቃቄ የሚደነግጉ የደሕንነተ-ሕይወት የህግ ማዕቀፎች በተለያዩ ጊዜያት መዘጋጀታቸው ይታወቃል።

ይሁን እንጂ የተዘጋጁት የደህንነተ-ህይወት የህግ ማዕቀፎች በአንድ ላይ ተሰባስበውና በመጽሀፍ መልክ ባለመዘጋጀታቸው በተቋም ደረጃም ይሁን በባለድርሻ አካላት ዘንድ በተፈለገው ሰዓትና ወቅት የህግ ማዕቀፎችን በቀላሉ ለማግኘት አስቸጋሪ በመሆኑ ባለስልጣን መ/ቤታችን የልውጥ-ህያው ዝውውርን ለመቆጣጠር የተዘጋጁ የተለያዩ የህግ ማዕቀፎችን ለተቋማችንና ለባለድርሻ አካላት በቀላሉ ተደራሽ እንዲሆኑ አንድ ላይ በማድረግ በመጽሀፍ መልክ አዘጋጅቷል።

በአጠቃላይ የሰነዱን ዓላማ በመገንዘብና በመተግበር በአካባቢና ብዝሀ-ህይወት ላይ ሊደርስ የሚችለውን ጠንቅ መቀነስ ወይም ወደ ኢምንትነት ማድረስ የባለስልጣን መ/ቤቱ፣ የተመራማሪዎች እና የሚመለከታቸው ባለድርሻ አካላት ወሳኝ ስራ መሆኑን በመረዳት በአካባቢ፣ በሰውና በእንስሳት ላይ ሊደርስ የሚችለውን ጉዳት መከላከል የሁላችንም ድርሻ መሆኑን በመገንዘብ የበኩላችሁን ሁሉ እንድትወጡ በዚህ አጋጣሚ ከአደራ ቄምር ጥሪዬን አቀርባለሁ።

ጌታሁን ጋረደው (ዶ/ር)

የአካባቢ ጥበቃ ባለስልጣን ዋና ዳይሬክተር

ነሀሴ፣ 2014 ዓ.ም፣ አዲስ አበባ

1 Biosafety Directives

መመሪያ ቁጥር 04/2010

ልውጥ ሕያዋንን በዝግ አጠቃቀም ለምርምር ወይም ለትምህርት ለማዋል የሚያስችል ልዩ ፍቃድ ለማግኘት የሚቀርቡ ማመልከቻዎች ይዘትን ለመወሰን የወጣ መመሪያ

ልውጥ ሕያዋንን በዝግ አጠቃቀም ለምርምር ወይም ለትምህርት ለማዋል የሚያስችል ልዩ ፍቃድ ለማግኘት የሚቀርብ የፈቃድ ጥያቄ ማመልከቻ ዋና ዋና ይዘትን መወሰን አስፈላጊ በመሆኑ፤

የአካባቢ፣ ደን እና የአየር ንብረት ለውጥ ሚኒስቴር ስለደሕንነት ሕይወት በወጣው አዋጅ ቁጥር 655/2001 (በአዋጅ ቁጥር 896/2007 እንደተሻሻለው) አንቀጽ 25 መሠረት ይህን መመሪያ አውጥቷል።

ክፍል አንድ
ጠቅላላ

1. **አጭር ርዕስ**

ይህ መመሪያ "ልውጥ ሕያዋንን በዝግ አጠቃቀም ለምርምር ወይም ለትምህርት ለማዋል የሚያስችል ልዩ ፍቃድ ለማግኘት የሚቀርብ የፈቃድ ጥያቄ ማመልከቻ ይዘት መወሰኛ መመሪያ ቁጥር 04/2010" ተብሎ ሊጠቀስ ይችላል።

2. **የተፈፃሚነት ወሰን**

ይህ መመሪያ ልውጥ ሕያዋንን በዝግ አጠቃቀም ለምርምር ወይም ለትምህርት ለማዋል በሚቀርቡ ማመልከቻዎች ላይ ተፈጻሚነት ይኖረዋል።

3. **አጠቃላይ መረጃዎች**

ልውጥ ሕያዋንን በዝግ አጠቃቀም ለምርምር ወይም ለትምህርት ለማዋል የሚቀርብ ማመልከቻ የሚከተሉትን አጠቃላይ መረጃዎች መያዝ ይኖርበታል፤

1/ የአመልካች ስምና አድራሻ እንዲሁም ከሚሰራበት መስሪያ ቤት ጋር ያለው ግንኙነት፤

2/ ኘሮጀክቱን ለማቀድና ለመተግበር፣ እንዲሁም ለቁጥጥር፣ ለክትትልና ለደኅንነት ኃላፊነት ያለባቸው ሠራተኞች ስምና የሰለጠኑባቸው መስኮች፣ እንዲሁም ሌሎች የብቃት መመስከርያዎች፣ በተለይም የኃላፊው ሳይንቲስት ስምና ብቃት የሚያሳይ መረጃ፤

3/ ተቋማዊ ብቃትን የሚገልጹ መረጃዎች፤ እንዲሁም ከደረጃ I-III የደህንነት መጠበቂያ ካቢኔቶች፣ አስፈላጊ ሆኖ ሲገኝ ከደረጃ I-IV የሆኑ የላቦራቶሪ ወይም

ግሪን ሀውስ ወይም የእንስሳት ማቋያ አገልግሎት መስጫ ሥፍራ ያለው መሆኑን የሚያሳይ መረጃ፤

4/ የአካባቢ ተጽኖ ግምገማ ለማካሄድ እና ሊመጡ የሚችሉ አደጋዎችን ለመቋቋም የሚያስችል የተዘረጋ ተቋማዊ ሥርዓት፣ ማለትም መደበኛ የአሰራር ሥርዓት፣ ተቋማዊ የደህንነተ ሕይወት ኮሚቴ እና የተመደበ የደህንነተ ሕይወት ባለሙያ መኖር የሚያሳይ መረጃ።

ክፍል ሁለት
የሰጪ፤ ተቀባይ እና የልውጥ ሕያው መረጃ

4. ሰጪ እና ተቀባይ (ወላጆች) ህያዋን ባህርያት

የሰጪ ሕያው፣ የተቀባይ እና ልውጥ ህያዉን በተመለከተ የሚከተሉት መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ ሰጪ የሆነው ሕያው ሳይንሳዊ ስም፣ የተሰጠው ከሆነም የተለምዶ ስም፤

2/ ተቀባይ የሆነው ልውጥ ሕያው ሳይንሳዊ ስም፣ የተሰጠው ከሆነም የተለምዶ ስም፤

3/ በክስተት ጥንቅሩ ውስጥ የተካተቱ አዲስ ዘረመሎች ምንጭ ከሆኑት ሕያዋን ሁሉ ጋራ የሚዛመዱ ዝርያዎች ሳይንሳዊ ስሞችና የተሰጣቸው ከሆነም የተለምዶ ስሞች፤

4/ ተቀባይ እና ሰጭ (ወላጆች) ሕያዋን ያላቸው የመመሳሰል ደረጃ፤

5/ ሰጪና ተቀባይ የሆኑት ዝሪያዎች (ወላጆች) መልካምድራዊ ሥርጭት፣ የተፈጥሮ መገኛ ቦታ ወይም የሚከሰትበት አካባቢ፣ አስፈላጊ ሆኖ ሲገኝ የበይዎች፣ ተበይዎች፣ ጥገኞች፣ ተወዳዳሪዎች፣ ተደጋጋፊዎች እና ተሸካሚዎች መረጃ።

5. የባህርይ ክስተትን የሚለውጡ ኑክሊይክ አሲዶች ባህሪያት

የኑክሊይክ አሲዱ ባህርያት በተመለከተ የሚከተሉት መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የኑክሊይክ አሲዱ ቅደም ተከተል፤

2/ ያለከሆነ የሚከስተው ባሕርይ ምንነት፤

3/ ያሉ ከሆነ ዘረመላዊ አመላካቾች፤

4/ ኑክሊይክ አሲዱ መኖር ወይም የአለመኖር ማወቅያ ዘዴዎች መግለጫ፤

5/ ኑክሊይክ አሲዱን ለመለየትና ለማወቅ በጥቅም ላይ የሚውሉ ዘዴዎች ለክነት፣

በአሃዝ የሚገለጽ አስተማማኝነት እና ለይነት።

6. **<u>የአድራሽ ባህርያት</u>**

የአድራሽ ባህርያት በተመለከተ እንደአስፈላጊነቱ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የአድራሹ ባሕሪይ እና ምንጭ፤

2/ ልውጥ ሕያዉን ለመሥራት ወደ ተቀባይ ዝርያ በተከተተው የክስተት ጥንቅር ውስጥ የነበሩ ባህርይ የማይከስቱ የዘረመል ቁራጮች ቅደም ተከተል።

7. **<u>የልውጥ ሕያዉ ባህርያት በተመለከተ</u>**

የልውጥ ሕያዉ ባህርያትን በተመለከተ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የሕያዉን የአለዋወጥ ሂደት የሚመለከቱ መረጃዎች፣

ሀ) ልውጥ ሕያውን ለመስራት ጥቅም ላይ የዋሉ ዘዴዎች፤

ለ) የተከተተው ንጥረ ነገር ለመሥራት እና ወደ ተቀባይ ሕያዉ ወይም ወደማንኛውም ኑክሊይክ አሲድ ወይም ፕሮቲን ቅደም ተከተል ውስጥ ለመክተት በጥቅም ላይ የዋሉ ዘዴዎች።

2/ ልውጥ ሕያዉን የሚመለከቱ መረጃዎች፣

ማመልከቻው ለታቀበ የመስክ ምርምር ከሆነ አመልካቹ የሚከተሉትን መረጃዎች ማቅረብ አለበት፤

ሀ) ሳይንሳዊና የተለምዶ ስሞችና የተለወጠበት ክንዋኔ፤

ለ) የልውጥ ሕያዉ አካላዊ ሁኔታ መግለጫ፣ በተለይም የተከሰቱና እንዳይከሰቱ የታገዱ ባህሪያት፤

ሐ) ለባህሪ ክስተት ለውጥ የዋለው ኑክሊይክ አሲድ ወደ ሌሎች ህያዋን የመተላለፍ ወይም ከሌሎች ህያዋን ጋር ለመለዋወጥ ያለው አቅም፤

መ) ለባህሪ ክስተት ለውጥ የዋለው ኑክሊይክ አሲድ እርጋታ ማረጋገጫና አስፈላጊ ሆኖ ሲገኝ እርጋታውን የሚወስኑ ምክንያቶች፤

ሠ) ይከሰታል ተብሎ የሚጠበቀው ባህሪይ ተግባር፤

ረ) ልውጥ ሕያዉ ተጠኖ ከአሁን በፊት ስለ መለቀቁ ወይም በጥቅም ላይ ስለመዋሉ የሚገልፅ መረጃ፤

ሰ) በሰው ወይም በእንስሳት ጤና፣ በብዝሃ ሕይወት እና በአካባቢ ላይ ሊደርሱ የሚችሉ ጠንቆች እና ምርምሩን ለማሳለጥ እነዚህን ጠንቆች ለመቀነስ የሚያስችሉ የአያያዝ ዘዴዎች፤

ሸ) በተፈጥሮአዊ ሥርዓተ ምህዳሮች ውስጥ ትውልድ የመተኪያ ጊዜ፣ ሩካባዊ እና ኢሩካባዊ የመራባት ኡደቶች፤

ቀ) ዘርን፣ ዱኬን፣ እስክሎሮሺያን ወይም ሌሎች አካላትን በመፍጠር የማይስማማው ወቅትን የማሳለፍ ችሎታውና ከወቅቶች ጋራ የመለዋወጡ ሁኔታ መረጃዎች፤

በ) አስፈላጊ ሆኖ ሲገኝ በሽታ የማስያዝ፣ የመመረዝ፣ የማጥቃት፣ አለርጂ የመቀስቀስ፣ በሽታን የማዛመት መረጃ፤

ተ) አስፈላጊ ሆኖ ሲገኝ አንቲባዮቲኮችን የመቋቋም አቅምና እነዚህ አንቲባዮቲኮች ሰዎች ወይም የቤት እንስሳት በበሽታ እንዳይያዙ ለመከላከያነት ወይም ለመድኃኒትነት ጥቅም ላይ መዋላቸው፤

ቸ) ልውጥነትን ወደ ሌሎች ሕያዋን የማጋባት ጠንቅ።

3/ በገበያ ላይ የሚገኝ rDNA ለትምህርትና ለምርምር አገልግሎት ጥቅም ላይ የሚውል ከሆነ አመልካቹ የሚከተሉትን መረጃዎች ማቅረብ አለበት፤

ሀ) በአቅረቢ ድርጅት የተሰጠውን የ rDNA መግለጫ የንግድ ስሙን ጨምሮ፤

ለ) የአቅረቢ ድርጅቱ (ቶቹ) ስም፤

ሐ) የrDNA በምርምር ፕሮጀክት ወይም በማስተማር ሂደት ውስጥ የሚሰጠው አገልግሎት፤

መ) የrDNA መደበኛ የአያየዝና አወጋገድ ስርአት፤

ሠ) ተቋሙ ለምርምር ወይም ለትምህርት አገልግሎት እንዲያውለው ፍቃድ የተሰጠው መሆኑን የሚያሰይ ሰነድ።

8. <u>የቆሻሻ አወጋገድ</u>

አመልካቹ በምርምር ሂደት ሊመነጩ የሚችሉ ቆሻሻዎችን በተመለከተ የሚከተሉትን መረጃዎች ማቅረብ አለበት፤

1/ የሚወጣው የቆሻሻ ዓይነት፤

2/ የሚጠበቀው የቆሻሻ መጠን፤

3/ ሊደርሱ የሚችሉ ጠንቆች፤

4/ የታቀዱ ቆሻሻ የማምከኛ መንገዶች ዝርዝር መግለጫ።

9. **<u>የድንገተኛ አደጋ መቋቋሚያ ዕቅድ</u>**

ለትምህርት ወይም ለምርምር ስራ የታሰቡ ልውጥ ሕያዋን ባልታሰበ ሁኔታ ወደ አካባቢ ቢለቀቁ ሊያስከትሉ የሚችሉትን የድንገተኛ አደጋ ለመቋቋሚያ የሚከተለው እቅድ መዘጋጀት ይኖርበታል፤

1/ የልውጥ ሕያዉ ያልታሰበ መዛመትን መቆጣጠር የሚያስችሉ ዘዴዎችና አሰራሮች፤

2/ ባልታሰበው መዛመት የተበከለውን አካባቢ የማምከኛ ወይም ልውጥ ሕያዉን የማስወገጃ ዘዴዎች፤

3/ ያልታሰበ መዛመት ባጋጠመ ጊዜ የተጋለጡ እፀዋትን፣ እንስሳትን እና አፈርን የማፅጃ ወይም የማስወገጃ ዘዴዎች፤

4/ ባልታሰበ መዛመት የተጠቃውን ቦታ ለይቶ መከለል የሚያስችሉ ዘዴዎች፤

5/ የሰውን ጤንነትና የአካባቢን ደህንነት ከድንገተኛ አደጋ ለመጠበቅ የሚያስችል ዕቅድ።

10. **<u>መመሪያው የሚፀናበት ጊዜ</u>**

ይህ መመሪያ ከ..ሚያዚያ..ቀን..2010..ዓ.ም ጀምሮ የፀና ይሆናል።

አዲስ አበባ ..ሚያዚያ 8..ቀን 2010 ዓ.ም

ዶ/ር ገመዱ ዳሌ
የአካባቢ የደንና የአየር ንብረት ለውጥ
ሚኒስቴር ሚኒስትር

Directive No.04./2018

DIRECTIVE ISSUIED TO ESTABLISH MAJOR CONTNTS OF AN APPLICATION FOR SPECIAL PERMIT TO ENGAGE IN THE TRANSACTIONS OF MODIFIED ORGANISMS FOR RESEARCH OR TEACHING

WHEREAS it is found necessary to determine the major contents of applications for research and/ or teaching involving modified organisms;

NOW THEREFORE, this directive is issued by the Ministry of Environment, Forest and Climate Change in accordance with Article 25 of the Biosafety Proclamation No. 655/2009 (as amended by Proclamation No. 896/2015):

PART ONE
GENERAL

1. Short Title

This directive may be cited as the "Directive to Determine Major Contents of Application for Special Permit for the Contained Use of Modified Organisms in Research or Teaching No.04/2018".

2. Scope of application

The directive shall be applied on any application related to modified organisms in contained use in research or teaching.

3. General Provisions

Application to seek a special permit for contained use shall accompany the following general information with the application:

1/ Name and address and institutional affiliation of the applicant;

2/ Information on personnel including name, training and other qualifications of persons responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and safety, in particular the name and qualifications of the responsible scientist;

3/ Information on institutional capacity to carry out the transactions availability of the necessary facilities such as biosafety class cabinet I-III, as required and biosafety level laboratory or greenhouse or animal facilities levels I-IV, as required;

4/ Information on institutional system to conduct risk assessment and manage potential risk, namely standard operating procedures, institutional biosafety committees and designated bio-safety officer.

PART TWO
INFORMATION ON THE DONOR, RECIPIENT, THE MODIFIED ORGANISM

4. Characteristics of the parental organisms

The applicant subject to this directive shall provide the following information about the genetically modified organism:

1/ scientific name, and when available also common name of the donor of the transgene;

2/ scientific name, and when available also common name of the recipient organism;

3/ scientific names, and when available also common names, of species that are related to any of the organisms from which any of the transgenes in the expression cassette have been taken;

4/ degree of relatedness between transgene donor and recipient (between parental) organisms;

5/ description of the geographic distribution and of the natural habitats of the parental organisms; when applicable, their predators, preys, parasites, competitors, symbionts and hosts.

5. Characteristics of nucleic acids that affect trait expression

The applicant shall provide the following information with regard to characteristics of nucleic acids that affect trait expression:

1/ nucleic acid sequences;

2/ description of the trait that it expresses, if any;

3/ genetic markers, if any;

4/ description of identification and detection techniques;

5/ sensitivity, reliability (in quantitative terms) and specificity of the detection techniques.

6. Characteristics of the vector

The applicant shall provide the following information in regards to vectors, where it is applicable:

1/ nature and source of the vector;

2/ sequence of the non-coding genetic segments used to construct the expression cassette and to introduce it into the recepient organism to produce the modified organism.

7. **Characteristics of the modified organism**

The applicant shall provide the following detail information in regards to the modified organism:

1/ Information relating to the modification:

a) methods used for the modification;

b) methods used to construct and introduce the inserts into the recipient organism or into any nucleic acid or protein sequence.

2/ Information on the modified organism:

Where application is for confined field trial, the applicant shall provide information as to:

a) scientific and common names and transformation event;

b) description of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

c) potential for nucleic acids involved in trait expression being transferred to or exchanged with other organisms;

d) verification of the stability of the nucleic acids involved in trait expression and factors affecting their stability, if applicable;

e) expected function of the new trait;

f) history of previous genetic modification, releases or uses of the modified organism if available;

g) potential risks to human or animal health, biological diversity, the environment and ways to manage those risks to acceptable levels so as to facilitate the research;

h) generation time in natural ecosystems, sexual and asexual reproductive cycles;

i) information on survival, including seasonality and the ability to form seeds, spores, sclortia and other survival structures, as appropriate;

j) where applicable, pathogenicity, infectivity, toxicity, virulence, allergenicity, ability to be a carrier (vector) of pathogens;

k) where applicable, antibiotic resistance, and potential use of these antibiotics in humans or domestic animals for prophylaxis or therapy;

l) risk of passing modification to other organisms.

3/ For commercially available rDNA molecules intended for research and teaching purposes, the applicant shall provide the following information:

Ministry of Environment, Forest and Climate Change

a) the description of the rDNA molecules as provided by the provider companies including trade names;

b) the names of company (ies) that provide the rDNA molecules;

c) the specific purpose of the rDNA molecules in the research project or teaching activities;

d) SOP to handle the rDNA molecules and disposal after use;

e) a document explaining approval of the transaction for research or teaching transaction by the institution.

8. Waste treatment

The applicant shall provide the following information on potential wastes that generated during the particular research work:

1/ type of waste generated;

2/ expected amount of waste;

3/ possible risks;

4/ description of methods of treatment envisaged.

9. Emergency response plan

The following risk management plan shall be put in place in case of accidental or unintended release of the modified organisms destined for research or teaching:

1/ methods and procedures for controlling the modified organism in case of unexpected spread;

2/ methods for the decontamination of the areas or the eradication of the modified organism;

3/ methods for disposal or sanitation of plants, animals and soils that were exposed during the unexpected spread;

4/ methods for the isolation of the area affected by the unexpected spread;

5/ plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

10. Effective Date

This directive shall enter into force as of the 16/01 day of 2018.

Done at Addis Ababa, this 16 day of Jan 2018

Dr. Gemedo Dalle

MINISTER OF MINSTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

መመሪያቁጥር 05./2010

በልውጥ ሕያዋን ላይ ለሚደረግ የጠንቅ ግምገማ የሚያገለግሉ መስፈርቶችን ለመወሰን የወጣ መመሪያ

በልውጥ ሕያዋን ላይ የሚደረግ ማንኛውም እንቅስቃሴ በተገቢው የጠንቅ ግምገማ ሂደት ማለፍ ያለበት በመሆኑ፣

የልውጠ ሕያዋን የጠንቅ ግምገማ ለማድረግ ቁልፍ መስፈርቶችን መለየት አስፈላጊ በመሆኑ፣

የአካባቢ የደንና የአየር ንብረት ለውጥ ሚኒስቴር ስለደሕንነተ ሕይወት ባወጣው አዋጅ ቁጥር 655/2001 (በአዋጅ ቁጥር 896/2007 እንደተሻሻለው) አንቀጽ 25 መሠረት ይህን መመሪያ አውጥቷል።

ክፍልአንድ
ጠቅላላ

1. **አጭር ርዕስ**

   ይህ መመሪያ "በልውጥ ሕያዋን ላይ ለሚደረግ የጠንቅ ግምገማ የሚያገለግሉ ቁልፍ መስፈርቶችን መወሰኛ መመሪያ ቁጥር 05/2010" ተብሎ ሊጠቀስ ይችላል።

2. **የተፈፃሚነት ወሰን**

   ይህ መመሪያ ከግንዛቤ የመነጨ ስምምነት ወይም ልዩ ፈቃድ ገና ሳይሰጣቸው በልውጥ ሕያዋን ላይ ማንኛውም ዓይነት እንቅስቃሴ ለማካሄድ በሚቀርብ ጥያቄ ላይ ተፈፃሚ ይሆናል።

3. **አጠቃላይ መረጃዎች**

   የልውጥ ሕያዋን የጠንቅ ግምገማ መስፈርቶች፣

   1/ በልውጥ ሕያዋን ማንኛውንም ዓይነት እንቅስቃሴ ላይ የሚሰማራ ሰው በሰው ወይም በእንስሳት ጤንነት እንዲሁም በአካባቢ ሊኖር የሚችለውን ጉዳት ለመለየት አስቀድሞ የጠንቅ ግምገማ ማካሄድ አለበት፤

   2/ ለተጨነ ልቀትና ለዝግ አጠቃቀም እንቅስቃሴዎች የሚያስፈልገው የመረጃ መጠን ሊለያይ ይችላል፤

   3/ በውሳኔ አሰጣጥ ሂደት ሚኒስቴሩ የማህበራዊ እና ኢኮኖሚዊ ሁኔታዎችን ከግምት ሊያስገባ ይችላል።

ክፍል ሁለት

የልውጥ ሕያው መረጃ

4. **የልውጥ ሕያዉ ሰጪና ተቀባይ ወይም ወላጆች ባህርያት**

የልውጥ ሕያዉ ሰጪና ተቀባይ ወይም ወላጆች ባህርያት ለመወሰን የሚከተሉት ቁልፍ መረጃዎች መቅረብ ይኖርባቸዋል፤

1/ ምንጭ የሆነው ዘረመል ሳይንሳዊ ስም፣ የተሰጠው ከሆነም የተለምዶ ስም፤

2/ የሚዛመዷቸው ሌሎች ዝርያዎችና የዝምድናቸው ቅርበት፤

3/ በሰጪና በተቀባይ ወይም በወላጅ ሕያዋን መካከል ያለው ዝምድና ቅርበት፤

4/ የሚታወቁ ከሆነ ሰጪና ተቀባይ ሕያዋኑ የተሰበሰቡባቸው ቦታዎች፤

5/ እያንዳንዱ ወላጅ ሕያው የሚራባበት ዘዴ፣ /ሩካቤያዊ ወይም ኢ-ሩካቤያዊ/ የመራባት ዑደቱ የሚፈጀው ጊዜ፣ አንድ ትውልድ ለመተካት የሚፈጀው ጊዜ እና ወቅቶችን ለማሳለፍ እና በሕይወት ለመቆየት የሚጠቅሙባቸው ሂደቶች መረጃዎች፤

6/ ተቀባይ ወይም ሰጪ ሕያዋኑ ቀድሞ የተደረገ የልውጥ ሕያውነት ታሪክ መኖሩ እና በምን ዘዴ ልውጥ እንደሆኑ፤

7/ የትኩረት አካላዊ ወይም ዘረመላዊ ምልክቶች፤

8/ የሕያዋኑ ምንነት፣ መኖርና አለመኖራቸው ለይቶ የማወቂያ ቴክኒኮች እና የለኪነታቸው አስተማማኝነት፤

9/ የሕያዋኑ መልክ ዓምድራዊ ስርጭትና የተፈጥሮ የመኖሪያ አካባቢዎቻቸው፣ በዱዎቻቸው፣ ተበዱዎቻቸው፣ ጥገኛዎቻቸው፣ ተወዳዳሪዎቻቸው፣ ተደጋጋፍዎቻቸው እና ተሸካሚዎቻቸውን ጨምሮ፤

10/ የተፈጥሮ የመኖሪያ አካባቢዎቻቸው የአየር ንብረት፤

11/ ልውጥ ሕያዉ ሆን ተብሎ ወይም በአጋጣሚ ወደአካባቢ ቢለቀቅ በአካባቢው በሕይወት የመቆየትና የመዛመት አቅም፤

12/ የሕያዋኑ ዘረመል መረጋጋትና በመረጋጋቱ ላይ ተፅዕኖ የሚያሳድሩ ሁኔታዎች፤

13/ ሕያዋኑ በቀጥታም ሆነ በጎንዮሽ መንገድ ዘረመልን ለሌሎች ሕያዋን የማስተላለፍ ወይም ከሌሎች ሕያዋን ጋር ለመለዋወጥ ሊኖር የሚችል አጋጣሚ፤

14/ ሰውን ወይም እንስሳትን በሽታ የማስያዝ ባሕርይ ካላቸው፤

15/ በሽታ የሚያስይዙ ከሆነ የማጥቃትና የመመረዝ ችሎታቸው እና በሽታን የማስተላለፍያ መንገዶቻቸው፤

16/ የሚታወቁ የአለርጂ ወይም የመርዛማነት ባህርይ ያላቸው ህይወታዊ ውሁዶች ወይም ንጥረ ነገሮች ስለመኖር፤

17/ ለበሽታ አምጪነታቸው፣ ለአለርጂ ቀስቃሽነታቸው እና ለመርዛማነታቸው ህክምና ስለመኖር።

5. **<u>በጥቅም ላይ ስለዋሉ አድራሽ ከሳች፣ ከልካይ እና መለያ ዘረመሎች ባህርያት መረጃዎች</u>**

በጥቅም ላይ ስለዋሉ አድራሽ፣ ከሳች፣ ከልካይ እና መለያ ዘረመሎች ባህርያት የሚከተሉት ቁልፍ መረጃዎች መቅረብ ይኖርባቸዋል፤

1/ የአድራሹ የተፈጥሮ ባህሪይ እና ምንጭ፤

2/ የአድራሹ ዘረመላዊ ንድፍ፣ የተከተተው ባይተዋር ዘረመል፣ የባሕርይ መከሰትን ሊነኩ የሚችሉ ማንኛቸውም የኑክላይክ አሲድ ቅደም ተከተል፣ የመለያ ዘረመል፣ የከሳች ዘረመል፣ እና የከልካይ ዘረመል መኖር፤

3/ አድራሹ የባሕርይ ክስተት ሊነኩ የሚችሉ ሌሎች ዘረመሎችን አቀናጅቶ ለማንቀሳቀስና ለማስተላለፍ ያለው ችሎታና የአድራሹን መኖር ወይም አለመኖር የማወቂያ ዘዴዎች፤

4/ ቀድሞ የተደረገ የልውጥነት ታሪክ፣ ተቀባይ ወይም ሰጪ ሕያዋኑ ልውጥ ህያዋን የነበሩ ስለመሆናቸው ወይም በምን ዘዴ ልውጥ እንደሆኑ፤

5/ ሰውን ወይም እንስሳትን በሽታ የማስያዝ እና የማጥቃት አቅም ወይም አለርጂ የመቀስቀስ፣ ችሎታ፤

6/ የአድራሹ ተፈጥሮአዊ እና ተሸካሚዎች ወሰን፤

7/ የአድራሹ ተፈጥሮአዊ ተሸካሚዎች እና ተሸካሚ ሊሆኑ ይችላሉ ተብለው የሚገመቱ ዝርያዎች ተፈጥሮአዊ የመኖርያ አካባቢዎችና መልክዓምድራዊ ስርጭት፤

8/ የአድራሹ ወይም የአስገባቸው አዲስ ዘረመሎች በአካባቢ ላይ ሊኖራቸው የሚችል በጎ ያልሆነ ተጽዕኖ፤

9/ አደጋ ሊያስከትሉ የሚችሉ ተፅዕኖዎችን ለመከላከል የሚወሰዱ እርምጃዎች፤

10/ በአካባቢው በህይወት ለመቆየትና ለመራባት ወይም ዘረመላዊ ውህደቶችን በመፍጠር የባሕርይ ክስተት ላይ ተጽዕኖ ለመፍጠር የሚኖረው አጋጣሚ፤

11/ የተሸካሚው ዘረመላዊ እርጋታ፣ ለምሳሌ በከፍተኛ ፍጥነት የመቀያየር ባህርይ።

6. **<u>የልውጥ ሕያዉ ባህርያት</u>**

የልውጥ ሕያዉ ባህርያትን በተመለከተ የሚከተሉት ቁልፍ መረጃዎች መቅረብ ይኖርባቸዋል፤

1/ ልውጥ ሕያዉ እንዴት እንደተሰራ የሚያመለክት ዝርዝር መግለጫ፤

2/ የልውጥነቱ ተግባር፣ እያንዳንዱ የተከተተው አዲስ ዘረመል ተግባራትን ጨምሮ፤

3/ የክስተት ጥንቅሩን ለመሥራትና ወደተቀባይ ሕያዉ ለመክተት በጥቅም ላይ የዋሉ ዘዴዎች፤

4/ ወደተቀባይ ሕያዉ የተከተተው አዲስ ዘረመል ስለመዋሃዱ ወይም በክሮሞዞሙ ውጫዊ አካል ላይ የቀረ ስለመሆኑ፤

5/ ወደ ተሸካሚ ጂኖም እንዲገቡ የተደረጉ የባሕርይ ከሳች ልውጥ ዘረመሎች ቁጥር እና ቅርፆቻቸው፣ ለምሳሌ የኮፒ ብዛት እና በቅደም ተከተል መገጣጠም ወይም ሌላ አይነት መደጋገም፤

6/ ወደ ልውጥ ሕያዉ የገቡ አዲስ ዘረመሎች ውጤቶች፣ በተለይም በዚህ ምክንያት የተከሰተው ባህርይ፤ የክስተቱ መጠንና፣ መለኪያ ዘዴዎች፤

7/ እንዲገቡ የተደረጉት አዲስ ዘረመሎች የተከሰቱ ወይም ያልተከሰቱ የእርጋታ ሁኔታ፤

8/ ልውጥ ሕያዉ ልውጥ ካልሆኑት አቻዎቹ ጋር ሲነፃፀር የሕይወታዊ ሂደቶችና የዚህ ውጤት ንጥረነገሮች ልዩነቶች፤

9/ ወደሌሎች ሕያዋን በቀጥታም ሆነ በጎንዮሽ ሊኖር የሚችለው የዘረመሎች መተላለፍ አጋጣሚ፤

10/ እንዲለወጡ የተደረጉት የኑክለ ክ አሲድ ንጥረ ነገሮች ወይም እንዲገቡ የተደረጉት አዲስ ዘረመሎች በሕያዉ ውስጥ ከሚገኙ ቫይረሶች፣ ፕላዝሚዶች ወይም ባክቴሪያዎች ጋር ተቀናጅተው በሽታ አምጪ ደቂቅ አካላትን ሊፈጥሩ የሚችሉበት አጋጣሚ፤

11/ አለርጂ የመቀስቀስ፣ መርዛማነት፣ በሽታ የማምጣት ወይም ሌሎች ያልታሰቡ ተጽዕኖዎች፤

12/ ልውጥ ሕያዉ ከአካባቢ ጋር ባለዉ መስተጋብር ልውጥ ካልሆነው አቻው ጋር ሲነፃፀር፤

13/ ልውጥ ሕያዉ ልውጥ ካልሆነው አቻው ጋር ሲነጻጸር ለበሽታና ለተባይ ተጋላጭነት ሁኔታ፤

14/ የልውጥ ሕያዉ ቀደም ሲል በጥቅም ላይ የመዋል መረጃ፣ ለተጨነ ልቀት እንዲበቃ ቀደም ብለው የተደረጉት የሙከራ ውጤቶችን ጨምሮ።

7. <u>ከልውጥ ህያዉ ጋር የተያያዙ የሰውና የእንስሳት ጤና ደህንነትን የተመለከቱ መረጃዎች</u>

ከልውጥ ህያዉ ጋር የተያያዙ የሰውና የእንስሳት ጤና ደህንነትን የተመለከቱ የሚከተሉት ቁልፍ መረጃዎች መቅረብ ይኖርባቸዋል፤

1/ የመዛመት ችሎታ፤

2/ ልውጥ ሕያዉ ሰውን ወይም እንስሳትን በሽታ የሚያስይዝ ከሆነ ከዚህ ቀጥሎ የተመለከቱት መረጃዎች መቅረብ ይኖርባቸዋል፤

ሀ) የተከሰቱት በሽታዎችና የማስያዣ መንገዶች፣ የማጥቃት ኃይልን ጨምሮ፤

ለ) ተላላፊነት፤

ሐ) በሽታ ሊያስይዝ የሚችለው መጠን፤

መ) በሽታው የሚይዛቸው ዝርያዎች ብዛትና አዲስ ዝርያዎችንም የማስያዙ አጋጣሚ

ሠ) ከሰው ወይም ከእንስሳት ሰውነት ውጪ በህይወት የመቆየት አቅም፤

ረ) የበሽታው አስተላላፊ ህያዋንና ሌሎች አማራጭ የመተላለፊያ መንገዶች መኖር፤

ሰ) ሥነ ህይወታዊ እርጋታ፤

ሸ) አለርጂ የመቀስቀስ፣ የመርዛማነት፣ በሽታ የማስያዝ እና ሌሎች ተዕዕኖዎች፤

ቀ) ተገቢ የሆኑ ህክምና መኖር።

8. <u>ከልውጥ ህያዉ ጋር የተያያዙ አካባቢን የተመለከቱ መረጃዎች</u>

ከልውጥ ህያዉ ጋር የተያያዙ አካባቢን የተመለከቱ የሚከተሉት ቁልፍ መረጃዎች መቅረብ ይኖርባቸዋል፤

1/ ልውጥ ሕያዉ በአካባቢው በህይወት መቆየት፣ መራባት እና መሰራጨት ላይ ተዕዕኖ የሚያሳድሩ ሁኔታዎች፤

2/ ልውጥ ሕያዉ መኖሩን ለማወቅ፣ ምንነቱን ለመለየትና ክትትል ለማድረግ የሚያስችሉ ዘዴዎች ዝርዝር፤

3/ ዘረመሎች ከልውጥ ሕያዉ ወደ ሌሎች ህያዋን የሚደረጉ ልውውጦችን ለማወቅ የሚያስችሉ ዘዴዎች ዝርዝር፤

4/ የሚታወቁና የሚገመቱ ለልውጥ ሕያዉ የሚመቹ አካባቢዎች፤

5/ ባልተጠነ ልቀት ምክንያት ሊነኩ የሚችሉት ሥርአተ-ምህዳሮች መግለጫ፤

6/ ልውጥ ሕያዉ ባልተጠነ ልቀት ምክንያት ከሌሎች ህያዋን ጋር ወደአካባቢ ቢለቀቅ ሊኖረው የሚችለው መስተጋብር፤

7/ የታወቁ ወይም የሚገመቱ ልውጥ ሕያዉ በእፀዋት፣ በእንስሳት ወይም በደቂቅዘ-አካላት ላይ ሊያደርሳቸው የሚችሉ በሽታ የማስያዝ፣ የመመረዝ፣ የማጥቃት፣ በሽታ አስተላላፊ የመሆን፣ አለርጂ የመቀስቀስ፣ የመዛመት ወይም ሌሎች ተዕዕኖዎች፤

8/ በሕይወታዊ እና ሥነምድራዊ የንጥረ ነገሮች ዑደት የሚኖረው ሚና፤

9/ ያልተጠነ ልቀት ቢያጋጥም ቦታውን ከብክለት ለማጽዳት የሚያስችሉ ዘዴዎች ዝርዝር፤

10/ በግብርና ላይ ሊኖር የሚችል ተዕዕኖ።

9. <u>ማህበራዊና ኢኮኖሚያዊ ጉዳዮችን በተመለከተ</u>

በእንቅስቃሴው ምክንያት በዘላቂ ግብርና፣ በሥራ ዕድል ፈጠራ፣ በገበያ ዕድል፣ በአጠቃላይ የማህበረሰቦችን አኗኗር ማቀብና እና/ወይም ዕድገት ላይ ይመጣሉ.

ተብለው የሚገመቱ ማህበራዊ፣ ኢኮኖሚያዊ ተፅዕኖዎች የሚያሳዩ ቁልፍ መረጃዎች በትኩረት ውስጥ መካተት አለባቸው።

10. **የሚፀናበትጊዜ**

ይህ መመሪያ ከ ጥር 8 ቀን 2010 ዓ.ም. ጀምሮ የፀና ይሆናል።

አዲስ አበባ ጥር 8 ቀን 2010 ዓ.ም

ዶ/ር ገመዶ ዳሌ
የአካባቢ የደንና የአየር ንብረት ለውጥ
ሚኒስቴር ሚኒስትር

Directive No.05/2018

DIRECTIVE ISSUED TO PROVIDE RISK ASSESSMENT PARAMETERS FOR MODIFIED ORGANISMS

Whereas every transaction on modified organisms shall be preceded by an appropriate risk assessment,

Whereas it is essential to identify the key parameters that standardize a risk assessment procedure in the country;

Now, therefore, the Ministry of Environment, Forest and Climate Change has issued this directive in accordance with Article 25 of the Biosafety Proclamation No. 655/2009 (Amended by Proclamation No. 896/2015) as follows:

PART ONE
GENERAL PROVISIONS

1. Short Title

This directive may be cited as the "Directive on Risk Assessment Parameters for Modified Organisms No. 05/ 2018".

2. Scope of Application

This directive shall be applicable for any transaction of modified organism that has yet not been given an advance informed agreement or special permit by the ministry.

3. General Information

1/ any person who engages in any transaction of modified organisms shall carry out a risk assessment to evaluate possible harm to human or animal health and the environment prior to any activity;

2/ the extent of data or information required may vary depending on whether the transaction is for deliberate release or contained use;

3/ upon decision making, the Ministry shall take into account inclusion of socio-economic considerations.

PART TWO

4. Characteristics of Donor and Recipient or Parental Organisms

In relation to characteristics of donor and recipient or parental organisms, the following information shall be presented:

1/ scientific name, and when available also common name of the donor gene;

2/ species that are related to and degrees of relatedness;

3/ the degree of relatedness between the donor and recipient or parental organisms;

4/ all the sites from where the donor and recipient organisms were collected, if known;

5/ information on the type of reproduction (sexual/ asexual) of both parental organisms and the length of reproductive cycle and generation time, as well as the formation of resting and survival stages;

6/ history of prior genetic modification, whether and how the donor or recipient organisms were already modified;

7/ phenotypic and genetic markers of interest;

8/ the identification and detection techniques for the organisms, and the sensitivities of these techniques;

9/ geographic distribution and natural habitats of the organisms including information on natural predators, preys, parasites, competitors, symbionts and hosts;

10/ climatic characteristics of their original habitats;

11/ ability of the organisms to survive and colonize the environment to which the release of the modified organism is intended or may accidentally occur;

12/ genetic stability of the organisms, and factors affecting the stability;

13/ the potential of the organisms to transfer to or exchange genes with other organisms, either vertically or horizontally;

14/ pathogenicity to humans or animals, if any;

15/ if pathogenic, their virulence, infectivity, toxicity and modes of transmission;

16/ known allergenicity or toxicity of biochemical or metabolic products;

17/ availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

5. Characteristics of the Vector, Promoter, Terminator and Marker Genes

In relation to characteristics of the vector, promoter, terminator and marker genes, the following information shall be provided:

1/ nature and source of the vector;

2/ genetic map of the vector, position of the transgene inserted, other nucleic acid sequences that may affect the expression of traits, marker gene, promoter, terminator that affects trait expression;

3/ ability of the vector to mobilize and transfer other genes that affect trait expression by integration and methods for determining the presence of the vector;

4/ history of prior genetic modification, whether and how the donor or recipient organisms were modified;

5/ potential for human or animal pathogenicity and virulence or allergenicity in humans or animals;

6/ natural host range of vector;

7/ natural habitat and geographic distribution of natural and potential hosts of the vector;

8/ potential impacts of the vector or the inserted transgeneson the environment;

9/ measures for counteracting adverse impacts;

10/ potential to survive and multiply in the environment, or to form genetic recombinants that affect trait expression;

11/ genetic stability of vector, such as hypermutability.

6. <u>Characteristics of Modified Organism</u>

In relation to characteristics of modified organism, the following essential information shall be presented:

1/ the description of the modifications;

2/ the function of the modifications including that of each of the transgenes;

3/ the methods for constructing the expression cassette and for introducing it into the recipient organism;

4/ whether the introduced transgene has been integrated or is extra chromosomal;

5/ number of expression transgenes inserted in the host genome, and their structures, for example the copy number and whether in tandem or other types of repeats;

6/ products of the introduced transgenes, in prticular induced trait and levels of expression and methods for measuring expression;

7/ stability of the introduced transgenes that are expressed or not;

8/ biochemical and metabolic differences of the modified organism compared with its unmodified counterpart;

9/ probability of vertical or horizontal gene transfer to other species;

10/ probability of the inserted nucleic acids, transgenes generating pathogenic recombinants with endogenous viruses, plasmids or bacteria;

11/ allergenicities, toxicities, pathogenicities, and other unintended effects;

12/ autecology of the modified organism compared with that of its unmodified counterpart;

13/ susceptibility of the modified organism to diseases and pests compared with its unmodified counterpart;

14/ detailed information on past uses including results of all experiments leading to previous releases.

7. **Information on the Modified Organisms With Respect To Safety Considerations For Human And Animal Health**

In relation to information on modified organisms with respect to safety considerations for human and animal health, the following essential information shall be presented:

1/ capacity for colonization;

2/ if the modified organism is pathogenic to humans or animals the following information is required:

a) diseases caused and mechanism of pathogenicity, including virulence;
b) communicability;
c) infective dose;
d) host range and possibilities of using new hosts;
e) ability to survive outside of the human or animal host;
f) the existence of vectors or other means of transmission;
g) biological stability;
h) allergenicity, toxicity, pathogenicity and other impacts;
i) availability of appropriate therapies.

8. **Information on Modified Organisms with respect to Environmental considerations**

In relation to information on modified organisms with respect to environmental considerations, the following essential information shall be presented:

1/ factors affecting the survival, reproduction and spread of the modified organism in the environment;
2/ techniques for detection, identification and monitoring of the modified organism;
3/ techniques for detecting the transfer of genesfrom the modified organism;
4/ known and predicted habitats of the modified organism;
5/ description of the ecosystems which could be affected by accidental release;
6/ possible interactions of the modified organism with other organisms following its accidental release into the environment;
7/ known or predicted effects of the modified organism on plants or animals or microorganisms including infectivity, pathogenicity, toxicity, virulence, being a vector of pathogens, allergenicity, colonization or other impacts;
8/ possible involvement in biogeochemical cycles;
9/ methods for decontamination of the area in case of accidental release;
10/ possible impacts on agriculture.

9. **Socio-Economic Considerations**

Essential information related to anticipated socio-economic impacts such as on sustainable agriculture, employment, market opportunities and, in general, conserving and/or enhancing means of livelihood of the communities likely to be affected shall be considered.

10. **Effective Date**

This directive shall enter into force as of the 16/01 day of 2018

Done at Addis Ababa. 16 ...day of... Jan 2018

Dr. Gemedo Dalle

MINISTER OF MINSTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

መመሪያ ቁጥር.06/2010

ልውጥ ሕያዋን ላይ በሚደረጉ ማናቸውም እንቅስቃሴዎች በተያያዘ ሊደርስ የሚችል ጠንቅ መቋቋሚያ የአሰራር ሥርዓት መመሪያ

ከልውጥ ሕያዋን እንቅስቃሴዎች በተያያዘ ሊደርሱ የሚችሉትን ድንገተኛ አደጋዎችን ለመከላከል የሚያስችል የጠንቅ መቋቋም አሰራር ሥርዓት መዘርጋት በማስፈለጉ፣

የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ስለደሕንነት ሕይወት በወጣው አዋጅ ቁጥር 655/2001 (በአዋጅ ቁጥር 896/2007 እንደተሻሻለው) አንቀጽ 25 መሠረት ይህን መመሪያ አውጥቷል።

ክፍል አንድ
ጠቅላላ

1. አጭር ርዕስ

ይህ መመሪያ "ከልውጥ ሕያዋን እንቅስቃሴ ጋራ የተያያዘ ጠንቅን የመቋቋሚያ የአተገባበር ሥርዓት ለመዘርጋት የተዘጋጀ መመሪያ ቁጥር 06/2010" ተብሎ ሊጠቀስ ይችላል።

2. የተፈፃሚነት ወሰን

(1) ይህ መመሪያ ለተጨነ እና ላልተጨነ ልቀት፣ ልውጥ ሕያዋን ለመሥራት፣ ለማስተማሪያነት፣ ለምርምር፣ ከውጪ ለማስመጣት፣ ወደ ውጪ ለመላክ፣ በትራንዚት ለማስተላለፍ፣ በዝግ ሁኔታ ለማምረት፣ ለማከማቸት፣ ለማጓጓዝ፣ በጥሬ ዕቃነት ለማዋል እና በገበያ ላይ በማዋል ጊዜ ሊፈጥር በሚችለው ጠንቅ ላይ ተፈፃሚነት ይኖራዋል።

(2) በዚህ መመሪያ በሌላ ሁኔታ ካልተገለጸ በስተቀር ካልተጨነ ልቀት የሚመነጩ ጠንቆች ያሚከተሉትን ያጠቃልላል፣

ሀ/ በማከማቸት ወይም በማጓጓዝ ወቅት የሚንጠባጠቡ፣

ለ/ በሰዎች ስህተት የሚለቀቁ፣

ሐ/ ከአቅም በላይ በሆነ ምክንያት የሚለቀቁ

ክፍል ሁለት

3. ከማንኛውም እንቅስቃሴ የሚመነጩ ጠንቆችን የመቋቋሚያ ምላሽ

(1) ማንኛውንም ፍቃድ ጥያቄ ሲቀርብ ሚኒስቴሩ ፍቃድ ከመስጠቱ በፊት ጥያቄው የሚከተሉትን መረጃዎች ማካተቱትን ማረጋገጥ ይኖርበታል፡፡

ሀ/ ደህንነትን ለማረጋገጥ የሚወሰዱ እርምጃዎች መረጃ እና የአተገባበር ስልትን ያጠቃለለ የአደጋ መቋቋሚያ ጊዜ እቅድን ማዘጋጀት እና

ለ/ በእንቅስቃሴው ጉዳት ሊደርስበት የሚችል ሰው/ሰዎች ቢኖሩ መረጃ የሚያገኙበት ዕቅድ መዘጋጀቱን ማረጋገጥ ይኖርበታል፡፡

4. የድንገተኛ አደጋ መከላከል ግብረ ሃይል

(1) ማንኛውም የልውጥ ሕያው እንቅስቃሴ ሲደረግ የሚያጋጥም ድንገተኛ አደጋን ለመቋቋም እንዲቻል የአደጋ መከላከል ግብረ ሀይል ሚኒስቴሩ ይሰይማል፡፡

(2) ሚኔስቴሩ የድንገተኛ አደጋ መከላከል ግብረ ሀይል ሲቀመንበርን፣ ጸሐፊንና አባላትን የድንገተኛ አደጋን የመቋቋሚያ እርምጃ መውሰድ አቅም ካላቸው ተቋማት መካከል ይሰይማል፡፡

(3) የድንገተኛ አደጋ መከላከል ግብረ ሀይል ኃላፊነቶችና ተግባራት ከዚህ በታች የተዘረዘሩት ናቸው፤

ሀ/ ብሔራዊ የአደጋ መቋቋሚያ እቅድን ማዘጋጀት፣ ሲያስፈልግ መተግበርና በየጊዜው ማሻሻል፤

ለ/ ማንኛውም ከልውጥ ሕያው እንቅስቃሴ የሚደርስ ያልተጠነ ልቀት መከሰቱን ለመለየትና ለመዘገብ የሚያስችሉ ተገቢ ስርዓቶችን መዘርጋት፤

ሐ/ ከልውጥ ሕያዋን ያልተጠነ ልቀት ሊመጣ የሚችለውን በሰው ወይም በእንሰሳት ጤንነትና በአካባቢ የሚደርስ አደጋን ለመከላከል የሚያስችል ፈጣን የመቋቋሚያ ስልት ምንጊዜም ዝግጁ መሆኑን ማረጋገጥ፤

መ/ የልውጥ ሕያዋን ያልተጠነ ልቀት በሚያጋጥምበት ጊዜ በሰው ወይም በእንሰሳት ጤንነት እና በአካባቢ ጉዳት ሳይደርስ ለውጥ ሕያውን ለማስወገድ በቂ ዝግጅት ምንጊዜም መኖሩን ማረጋገጥ፤

ሠ/ ወጪዎችን ለማስመለስና ካሳን ለማስከፈል እንዲያግዝ የአደጋ መቋቋሚያ እርምጃ በሚወሰድበት ጊዜ የሚደርሱ ወጪዎችን በተሟላና በትክክለኛ መንገድ መመዝገባቸውን ማረጋገጥ፤

ረ/ ያልተጠኑ ልቀትን መቋቋም የሚያስችል የሰው ኃይል፣ ገንዘብና መሣሪያ ዝግጁ መሆኑን ማረጋገጥ፤

(4) የድንገተኛ አደጋ መከላከል ግብረ ሀይል በአገር አቀፍ ደረጃ የሚያጋጥም ማናቸውንም ልውጥ ሕያዋንን የሚመለከት አደጋ የመምራት እና ለመቋቋም የሚያግዙ ድርጅቶችና ግለሰቦችን የማስተባበር ኃላፊነት አለበት።

(5) የድንገተኛ አደጋ መከላከል ግብረ ሀይል የተሰጡትን ተግባራትና ኃላፊነቶች ለመወጣት እንደአስፈላጊነቱ በሚወስነው ሰዓትና ፍጥነት መገናኘት የሚችል ሲሆን ነገር ግን ከ6 ወር በላይ መብለጥ አይኖርበትም።

(6) በልውጥ ሕያዋን ያልተጠኑ ልቀት አማካኝነት ድንገተኛ አደጋ በሚደርስበት ጊዜ የድንገተኛ አደጋ መከላከል ግብረ ሀይል ኃላፊነት ከተሰጠው ሰው እና ሌሎች ጉዳዩ ከሚመለከታቸው ባለድርሻ አካላት ጋራ በቅርብ በመሥራት አደጋውን መቀነስ ወይም ሙሉ በሙሉ ማስወገድ ይኖርበታል።

(7) የዚህን መመሪያ አንቀፆች እንደተጠበቁ ሆነው የድንገተኛ አደጋ መከላከል ግብረ ሀይል የራሱን የአደጋ ጊዜ መቋቋሚያ የአሰራር ሥራዓቶችን ማውጣት ይችላል።

5. ፈቃድ የተሰጠው ሰው ኃላፊነቶች

(1) በልውጥ ሕያዋን እንቅስቃሴዎች ወቅት አደጋ ቢያጋጥም፣ ማንኛውም አመልካች ወይም ፈቃድ የተሰጠው ማንኛውም ሰው፣ አደጋው ባጋጠመ በሃያ አራት ሰዓት ውስጥ፣ ለአደጋ መቋቋሚያ ቡድኑ የሚከተሉትን መረጃዎች መስጠት ይጠበቅበታል፦

ሀ/ አደጋው የደረሰባቸው ሁኔታዎች፣

ለ/ አደጋው ሲከሰት የነበረው ልውጥ ሕያው ምንነትና መጠን፣

ሐ/ ማንኛውንም በብዝሀ ሕይወት ጥበቃና ዘላቂ አጠቃቀም እና በሰዎች ጤንነት ላይ ሊያደርስ የሚችለው አሉታዊ ተፅእኖ የሚገልፅ መረጃ፣

መ/ የተወሰዱ የማስተካከያ እርምጃዎች፣ እና

ሠ/ ሌሎች ማንኛውም ተያያዥ መረጃዎች።

6. በአመልካቹ መወሰድ የሚኖርባቸው የጠንቅ አያያዝ እርምጃዎች

(1) አመልካቹ ወይም ማንኛውም ፈቃድ የተሰጠው ግለሰብ አደጋዎች በሚደርሱበት ወቅት የሚከተሉትን የጠንቅ አያያዝ ተግባራትን ማከናወን ይጠበቅበታል፦

ሀ/ ለድንገተኛ አደጋ መከላከል ግብረ ሀይል ሪፖርት ማድረግ፣

ለ/ ለአካባቢው አመራር መረጃዎችን በመስጠት አካባቢው እንዲጠበቅ ማድረግ እና ለሕብረተሰቡ ግንዛቤ መስጠት፣

ሐ/ ቦታው ተለይቶ እንዲከለል አድርጎ በከፍተኛ ሁኔታ እንዲጠበቅ ማድረግ፣

መ/ አስፈላጊ ሆኖ ከተገኘ፣ አደጋው ከደረሰበት ቦታ ላይ ደረጃ በደረጃ ሰዎችንና እንሰሳትን ከቦታው እንዲለቁ ማድረግ፣

ሠ/ ከልውጥ ሕያዋኑ አደጋ መከሰት ጋር በተያያዘ በትርፍነት/ዝቃጭነት በቦታው ላይ የሚቀሩ ነገሮች ካሉ መሰብሰብና፣ አስፈላጊ ሆኖ ሲገኝም፣ ተገቢ በሆነ መንገድ እንዲወገዱ ማድረግ።

7. የሚፀናበት ጊዜ

ይህ መመሪያ ከ.ኖ.ም.. ፭..ቀን 2010 ዓ.ም ጀምሮ የፀና ይሆናል።

አዲስ አበባ.....ኖ.ም.፭.ቀን 2010 ዓ.ም

ዶ/ር ገመዶ ዳሌ
የአካባቢ የደንና የአየር ንብረት ለውጥ
ሚኒስቴር ሚኒስትር

DIRECTIVE NO.06/2018

DIRECTIVE TO ESTABLISH PROCEDURES FOR MANAGEMENT OF RISKS FROM ANY TRANSACTION INVOLVINGMODIFIED ORGANISMS

Whereas, it is essential to set a risk management procedure dealing with risks arising from any transaction involving modified organisms,

NOW THEREFORE, this directive is issued by the Ministry of Environment, Forest and Climate Change in accordance with Article 25 of the Biosafety Proclamation No. 655/2009 (as amended by Proclamation No. 896/2015):

PART ONE
GENERAL

1. Short Title

This directive may be cited as ''Directive Issued to Establish Procedures for the Management of Risks from any Transaction Involving Modified Organisms No.06/ 2018"

2. Scope of this Directive

(1) This Directive shall apply to manage any unforeseen risk arising from deliberate and unintentional release during making, use in teaching, research, import, export, transit, contained production, transport, storage, processing and putting in the market of any modified organisms.

(2) In this directive, unless the context otherwise requires, the Risk arising from unintentional release includes, *inter alia*;

a. Spillage from storage or transportation,

b. release out of Human error

c. Release out of force majeure.

PART TWO

3. Response Measures To Risks Arising From Any Transaction

(1) The ministry shall, before recommending an application for approval for any transaction, ensure that the application contains;

a. An emergency plan which includes information on safety measures and procedures to be adopted and,

b. Mechanisms through which the information shall be made available to the persons likely to be affected by the transaction.

4. Emergency Response Group

(1) The Minister shall establish an Emergency Response Group in order to respond to any emergency cases related to the transaction of modified organism.

(2) The Minister shall appoint the Chairperson, the Secretary and the members of the Emergency Response Group to comprise representatives of institutions capable of undertaking risk management measures.

(3) The duties and responsibilities of the Emergency Response Group shall be to:

a. Develop, implement when needed and keep updating a national risk management plan;

b. Develop appropriate systems for the detection and reporting of emergencies in any transaction involving modified organisms;

c. Ensure that there is a constant readiness to respond to any emergency of any modified organism to prevent damage to human and animal health, and the environment.

d. Ensure that there is a constant readiness for the disposal of modified organisms recovered after accidents without any harm to humans, animals or the environment;

e. Ensure that complete and accurate records of expenditures incurred in responding to emergencies are maintained to facilitate cost recovery and the payment of compensation;

f. Ensure prompt and efficient mobilization of manpower, financial resources and equipment to deal with any emergency;

(4) The Emergency Response Group shall be responsible to coordinate any accident at national level involving modified organisms and it shall direct the activities of institutions and individuals that may offer assistance.

(5) The Emergency Response Group shall meet at such times and with such frequency as may be necessary to fulfill its duties and responsibilities which, in any event, shall not be less than every six months.

(6) In cases of emergencies such as accidental release of modified organisms, the Emergency Response Group shall closely work with the authorized person and other relevant stakeholders to take rapid action to minimize or prevent possible risks

(7) Without prejudice to the provision of this article, the Emergency Response Group may adopt its own rules of procedures.

5. Duties of the Permit Holder

(1) Where there is an emergency related to transaction of modified organisms, the applicant or any person to whom approval was given shall, within twenty-four hours, inform the Emergency Response Group about the emergency providing the following information-

a. The circumstances of the accident,
b. The identity and quantity of the modified organism involved in the emergency,
c. Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health,
d. The mitigation measures taken, and
e. Any other relevant information.

6. Risk management measures to be taken by the applicant

(1) The applicant or any person to whom approval was given shall use the following Risk Management approaches in the event of emergency

a. Report to the Emergency Response Group.

b. Inform and involve the local leadership to take charge of the area and create awareness to the population.

c. Isolate the area and provide adequate security to cordon off the affected place, if needed.

d. When appropriate, evacuate humans and animals that are within reach by the exposure case by case.

e. In the event where there are residual materials arising from modified organisms, they have to be collected and, when applicable, be destroyed by appropriate means.

7. <u>Effective Date</u>

This directive shall enter into force as of the 16/01 day of 2018.

Done at Addis Ababa, this 16 day of Jan 2018.

Dr. Gemedo Dalle

MINISTER OF MINSTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

መመሪያ ቁጥር ዐ.ፖ /2010

ልውጥ ሕያዋንን ለማጓጓዝና ለማከማቸት መሟላት ስላለባቸው ጉዳዮች ለመወሰን የወጣ መመሪያ

ልውጥ ሕያዋን በሚጓጓዙበት እና በሚከማቹበት ወቅት ማሟላት የሚኖርባቸውን አስፈላጊ ሁኔታዎች መወሰን አስፈላጊ ሆኖ ስለተገኘ፤

የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ስለደሕንነት ሕይወት በወጣው አዋጅ ቁጥር 655/2001 (በአዋጅ ቁጥር 896/2007 እንደተሻሻለው) አንቀጽ 25 መሠረት ይህን መመሪያ አውጥቷል።

1. **አጭር ርዕስ**

ይህ መመሪያ "ልውጥ ሕያዋን ለማጓጓዝና ለማከማቸት መሟላት ስላለባቸው ግዴታዎችን ለመወሰን የወጣ መመሪያ ቁጥር ዐ.ፖ./2010" ተብሎ ሊጠቀስ ይችላል።

2. **የተፈፃሚነት ወሰን**

ይህ መመሪያ ማንኛውም በደህንነት ሕይወት ህግ ጥበቃ ስር ያለ ልውጥ ህያው በአየር ወይም በየብስ በማንኛውም ዓይነት መንገድ ከአንድ ቦታ ወደሌላ ቦታ ሲጓጓዝ ወይም እንቅስቃሴ ሲካሄድ ወይም ሲከማች ተፈጻሚ ይሆናል።

3. **ልውጥ ህያውን ከአንድ ቦታ ወደ ሌላ ቦታ ማጓጓዝ**

1/ ልውጥ ሕያዋንን በማጓጓዝ ሥራ መሰማራት የሚፈልግ ማንኛውም ሰው ከአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ወይም ሥልጣን ከተሰጠው ፈቃድ ሰጪ ባለሥልጣን የተሰጠ የማጓጓዝ ፈቃድ መያዝ አለበት።

2/ ልውጥ ሕያዋንን ለማጓጓዝ የተሰጠ ፈቃድ ፈቃዱ ከተሰጠበት ቀን ጀምሮ በየሁለት ዓመቱ መታደስ ይኖበታል።

3/ የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር የልውጥ ሕያዋንን ከቦታ ቦታ ዝውውር የሚከታተልበትና የሚቆጣጠርበት አሰራር የሚዘረጋ ሲሆን ሆኖም ልውጥ ሕያዋንን በአንድ ማከማቻ ውስጥ ከአንድ ቦታ ወደ ሌላ ቦታ ማንቀሳቀስን አያካትትም።

4/ ልውጥ ሕያዋንን ለማጓጓዝ ፈቃድ የተሰጠው ሰው በዚህ መመሪያ አንቀጽ 4 የተቀመጠውን አሟልቶ ካልተገኘ የተሰጠው ፈቃድ ሊሰረዝ ወይም ለተወሰነ ጊዜ ሊታገድ ይችላል።

5/ የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ልውጥ ሕያዋንን ከቦታ ወደ ቦታ ለማጓጓዝ ፈቃድ የሚሰጠው ማንም ሰው የልውጥ ሕያዋንን አያያዝን በሚመለከት በቂ ሥልጠና ያገኘ መሆኑን ያረጋግጣል፤ የልውጥ ሕያዋንን ከቦታ ወደ ቦታ የማጓጓዝ ሥልጠና ያገኘን ሰው መዝግቦ ይይዛል።

5/ ልውጥ ሕያው ከቦታ ወደ ቦታ የሚጓጓዙበት መስመር በተቻለ መጠን በሰው፣ እንስሳትና አካባቢ ላይ ሊደርስ የሚችልን ጉዳት ለመቀነስ እንዲያስችል አስቀድሞ ሊታቀድ ይገባዋል።

6/ ማንኛውም ልውጥ ሕያዋንን እንዲያጓጉዝ ፍቃድ የተሰጠው ሰው ያካሄደውን የልውጥ ሕያውን እንቅስቃሴ የሚኒስቴር መስሪያ ቤቱ በሚያወጣው የማሳወቂያ ፎርም መሠረት በየወሩ ማሳወቅ አለበት።

7/ ማንኛውም ልውጥ ሕያዋንን እንዲያጓጉዝ ፍቃድ የተሰጠው ሰው ያካሄደውን የልውጥ ሕያውን እንቅስቃሴ በየወሩ ካላሳወቀ የተሰጠው የማጓጓዣ ፍቃድ ሊታገድ ወይም ሊሰረዝ ይችላል።

8/ በማሳወቂያ ፎርም ውስጥ ሊካተቱ ከሚገባቸው መረጃዎች የሚከተሉት ይገኛሉ፤

ሀ) የሚጓጓዘው ጥቅል ባለቤት ሥምና አድራሻ፣ ልውጥ ሕያውን ለማጓጓዝ ኃላፊነት የወሰደው ሰው ሥምና የሚያጓጉዘው ድርጅት ሌላ ከሆነ የድርጅቱ ሥም፤

ለ) የጥቅል፣ የማጓጓዣው መንገድ፣ የጉዞ መስመር፣ የተላከበትና የሚደርስበት ቀን መረጃ፤

ሐ) ልውጥ ሕያውን በተመለከተ የሰጪና የተቀባይ ሕያዋን የተለምዶና ሳይንሳዊ ስም እንዲሁም የልውጥ ህያው ዝርዝር መግለጫ፤

መ) የሚጓጓዘው ካልቸር መጠን ወይም የጥቅል ብዛት፤

ሠ) ልውጥ ሕያው መቼና በየትኛው ባለ ሥልጣን መሥሪያ ቤት ለዝግ አጠቃቀም ወይም ለተጨነ ልቀት እንደተፈቀደ የሚገልፅ መረጃ፤

ረ) የልውጥ ሕያው አያያዝ ደህንነት ጋር በተገናኘ መወሰድ ያለበት ቅድመ ጥንቃቄ፤

ሰ) እንዲያጓጉዝ የተፈቀደለት ሰው ሥም፣ ፊርማ እና ቀን።

9/ አስፈላጊ ሆኖ ሲገኝ ፍቃድ የሚሰጠው ወይም ማሳወቂያ ሪፖርት የሚቀበለው የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ወይም አግባብ ያለው ባለ ሥልጣን በዚህ አንቀጽ ንዑስ አንቀጽ (10) ከተገለጹት በተጨማሪ ሌሎች አስፈላጊ መረጃዎችን ሊጠይቅ ይችላል።

10/ የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር መመሪያዎችና ደንቦች መከበራቸውን ለማረጋገጥ የኢንስፔክሽን ሥራ ሊያካሂድ ይችላል፤ ለዚህም ይረዳው ዘንድ በቦታው ላይ በመገኘት ቁጥጥር የማካሄድ ሥልጣን ተሰጥቶታል።

11/ እንዲያንጉዝ ፈቃድ የተሰጠው ሰው ተቀባዩ ዕቃው ልውጥ ሕያው መሆኑን ወይም ልውጥ ህያው የያዘ መሆኑን መለየት በሚያስችለው ሁኔታ ምልክት መደረጉን ማረጋገጥ ይኖርበታል።

12/ የሚንገዘው ዕቃ በሚጠፋበት፣ በሚጎዳበት፣ ወይም ያለአቅጣጫው በሚንቀሳቀስበት ጊዜ የዕቃውን ባለቤት በቀላሉ ማግኘት እንዲቻል በዕቃው ላይ በሚደረገው ምልክት የባለቤቱ ስም፣ አድራሻና ሌሎች የመገናኛ ዝርዝሮች በግልፅ ማሳየት አለበት።

13/ በማንገዝ ወቅት በመጫንና በማውረድ፣ እንዲሁም በጉዞ ሊያጋጥም የሚችል መናወጥን መቋቋም የሚችል ጥራት ባለው ማሸጊያ ልውጥ ሕያው መታሸጉን ፍቃድ የተሰጠው አካል ማረጋገጥ ይኖበታል።

14/ ልውጥ ሕያው በየብስ በሚንገዝበት ጊዜ የመፍሰስ ወይም ሌላ አደጋ ቢያጋጥም ፈቃድ የተሰጠው አንገዥ የሚከተሉትን ተግባራት መፈፀም ይኖርበታል፤

ሀ) የተሸከርካሪውንና ጭነቱ የፈሰሰበትን አካባቢ የመከለል፤

ለ) አስፈላጊ ሆኖ ሲገኝ የአደጋ ጊዜ የእርዳታ አገልግሎት መጥራት ፤

ሐ) ሁኔታውን መገምገምና ተገቢውን እርምጃ መውሰድ፤

መ) ስለተፈጠረው አደጋ ወይም ስለአፈሳሰሱ ለአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር የማሳወቅ።

4. <u>ከልውጥ ሕያዋን መንገዝ ጋር መያያዝ ያለባቸው ሰነዶች</u>

1/ ከአንድ ቦታ ወደ ሌላ ቦታ ወይም ወደ አገር ውስጥ የሚገቡ ወይም ወደ ውጭ የሚላኩ ልውጥ ሕያዋን ሲንገዙ ከአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር የተሰጠ የማንገዣ ፈቃድ አብሮ መያያዝ አለበት፤ ይህም አግባብ ባለው ባለሥልጣን ወይም ተቆጣጣሪ ለሚደረግ ቁጥጥር በማንኛውም ጊዜ መቅረብ ይኖርበታል።

2/ በዚህ አንቀፅ ንዑስ አንቀጽ (1) የተመለከተው እንደተጠበቀ ሆኖ ፍቃድ የተሰጠው ሰው ቢያንስ የሚከተሉትን መረጃዎች የያዘ ሰነድ ሊኖረው ይገባል፤

ሀ) ጥቅሉ የሚደርስበት ቦታ ወይም ሀገር ስምና አድራሻ፤

ለ) የልውጥ ሕያው ሳይንሳዊና የተለምዶ ስሞችና የተለወጠበት ክንዋኔ፤

ሐ) የሚንገዘው ዕቃ ጠቅላላ መጠን ወይም የጥቅሎቹ ብዛት፤

መ) ዕቃውን ከሌሎች ዕቃዎች በትክክል መለየት የሚያስችል ተጨማሪ የአያያዝ መረጃ፤

ሠ) የዕቃው ላኪና ተቀባይ አድራሻዎች፣ የስልክ ቁጥርና ኢሜል፤

ረ) ባልተጠበቀ ልቀት ወይም በሌላ ድንገተኛ ሁኔታ የሚያጋጥም አደጋን ለመከላከል የሚያስችል የድርጊት ቅደም ተከተልን የያዘ መመሪያ።

5. <u>የልውጥ ሕያዋን አከመቻቸት መመሪያ</u>

1/ ልውጥ ሕያውን ለማከማቸት የሚውሉ አገልግሎት መስጫ ተቋማት በአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር መመዝገብ እና ፈቃድ ማግኘት ይኖርባቸዋል።

2/ አካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር የጤናን እና የሠራተኛ ጉዳይን ከሚመለከቱ ተቋማት ጋር በመመካከር ልውጥ ሕያዋን የሚከማቹባቸውን ቦታዎች ፈቃድ ይሰጣል፣ ይመዘግባል፤ ይህን ለማስፈፀም የሚከተሉትን ተግባራት ያከናውናል፤

ሀ) ልውጥ ሕያዋንን ለማከማቸት የሚያስፈልጉ ደረጃዎችን ያወጣል፤

ለ) ለማከማቻት ፈቃድና ምዝገባ የሚያስፈልጉ አሠራሮችና ቅድመ ሁኔታዎችን ያዘጋጃል፤

ሐ) ስለ ልውጥ ሕያዋን ደህንነት አያያዝ ለሠራተኞች በሚሰጥ ሥልጠና መሟላት ያለባቸውን አስፈላጊ ሁኔታዎች ይወስናል።

3/ በዚህ አንቀጽ ንዑስ አንቀጽ (1) እና (2) መሠረት ፈቃድ ሲሰጥና ምዝገባ ሲካሄድ ተቋማት በሰው ወይም በእንሳት ጤንነት ወይም በአካባቢ ላይ ጉዳት ቢያደርሱ የሚያካክስ በቂ የኢንሹራንስ ሽፋን መግባታቸውን አካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ሊጠይቅ ይችላል።

4/ ማንኛውም ልውጥ ሕያዋን ማከማቻ ተቋም ኃላፊ የሆነ ሰው ማከማቻው ለዚህ አገልግሎት ለማዋል ፈቃድ ለማግኘት ለአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ማመልከት አለበት።

5/ ማንኛውም ልውጥ ሕያውን ለማከማቸት የሚቀርብ ማመልከቻ የሚከተለውን ዝርዝር መረጃ መያዝ አለበት፤

ሀ) ለክምችት የታሰበው ልውጥ ሕያው የተሟላና ትክክለኛ ዝርዝር መግለጫ፣ እንዲሁም ሳይንሳዊና የተለምዶ ስሞችና የተለወጠበት ክንዋኔ፤

ለ) ለክምችት የሚውለው ልውጥ ሕያው መጠንና በክምችት ወይም በማቀነባበር ሂደት የሚቆይበት የጊዜ ገደብን የሚገልፅ ፅሁፍ፤

ሐ) የልውጥ ሕያው ማከማቻ ቦታ ስምና አድራሻ፤

መ) በማከማቻው ተቋም የሚተገበረው የአደጋ የመከላከልና ዝግጁነት እርምጃዎች መግለጫ።

6/ ማንኛውንም ልውጥ ሕያውን ለማከማቸት ማመልከቻ ሲቀርብ የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር የሚከተሉትን ለመወሰን የማከማቻ አካባቢውን እንዲፈተሽ ያደርጋል፤

ሀ) የተመለከተውን ልውጥ ሕያው ደህንነቱ በተጠበቀ ሁኔታ ለማከማቸት በቂ የአገልግሎት መስጫ ተቋም መኖሩን፤

ለ) የተሟላ ጥበቃ፣ ለይቶ ማቆያና አስፈላጊ የደህንነት መቆጣጠሪያ በአካባቢው መኖሩን፤

ሐ) ልውጥ ሕያዋንን አያያዝ በሚመለከት የባለሙያዎች ስልጠና መካሄዱን።

7/ አስፈላጊውን ቁጥጥር ካካሄደ በኋላ የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ከሚከተሉት መካከል አንዱን ይወስናል፤

ሀ) ልውጥ ሕያዋንን በማከማቻ የማቆየት ፈቃድ መስጠት፤

ለ) የማከማቻ አካባቢውን አጥጋቢ ለማድረግ ተጨማሪ ስራዎች የሚያስፈልጉ መሆናቸውን ማሳወቅ፤

ሐ) ጉዳትን ማስቀረት የማይቻል መስሎ ከታየ ፍቃድ መከልከል።

8/ በአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር የሚሰጠው ፈቃድ የሚከተሉትን መረጃዎች ማካተት ይኖርበታል፤

ሀ) ልውጥ ሕያው የሚከማችበት ቦታ ስምና አድራሻ፤

ለ) ለክምችት የታሰበው ልውጥ ሕያው የተሟላና ትክክለኛ ዝርዝር መግለጫ፣ ሳይንሳዊና የተለምዶ ስሞች እነዲሁም የተለወጠበት ክንዋኔ፤

ሐ) የክምችቱ መጠንና የሚቆይበት ጊዜ ገደብ፤

መ) የአደጋ መከላከያ እርምጃዎች።

9/ አካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ልውጥ ሕያውን ለማከማቸት ለአመልካቹ በሰጠው ፈቃድ የተዘረዘረ ማንኛውም ግዴታ በተገቢው መንገድ እየተሟላ ባልሆነበት በማንኛውም ጊዜ ስምምነቱን ሊሰርዝና ሥራውን ሊያስቆም ይችላል።

10/ በዚህ መመሪያ መሰረት ፈቃድ ከተሰጠ በኋላ በሰባት ቀን ውስጥ አካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ቅጂውን በብሔራዊው የደህንነተ ሕይወት የመረጃ ስርዓት ውስጥ ማስቀመጥ አለበት።

11/ ማንኛውም ልውጥ ሕያውን ለማከማችት አገልግሎት ላይ የሚውል ሥፍራ የተከማቹት ዕቃዎች የታሸጉ፣ ምንነታቸውን የሚገልፅ ጽሁፍ የተለጠፈባቸውና ተለይቶ የተቀመጡ መሆናቸውን ማረጋገጥ ይኖርበታል።

12/ ልውጥ ሕያው ማከማቻ ኃላፊ የሆነው ግለሰብ ከዚህ በታች የተዘረዘሩትን ተግባራት መፈፀም አለበት፤

ሀ) በክምችት ያለው ልውጥ ሕያው ያልተጤነ ልቀት ወይም መፍሰስ እንዳያጋጥም ኃላፊነት የተሰጠው ባለሙያ በየቀኑ ቁጥጥር ማድረግ ይኖርበታል።

ለ/ ያልተፈቀደለት ማንም ሰው ልውጥ ሕያው ወደተከማቸበት ቦታ አለመግባቱን ማረጋገጥ፤

ሐ) በክምችት ስለሚቆይ ማንኛውም ልውጥ ሕያው መረጃ መያዝና ተቆጣጣሪ ሲፈልገው ማቅረብ፤

መ) ያልተጤነ ልቀት ወይም ሌላ አደጋ ቢያጋጥም ለመቋቋም የሚያስችሉ የአሰራሮች ሁሌም ዝግጁ መሆናቸውን ማረጋገጥ፤

6. <u>መመሪያው የሚፀናበት ጊዜ</u>

ይህ መመሪያ ከ ጥቅምት ቀን 2010 ዓ.ም. ጀምሮ የፀና ይሆናል።

አዲስ አበባ ጥቅምት ቀን 2010 ዓ.ም

ዶ/ር ገመዶ ዳሌ

የአካባቢ የደንና የአየር ንብረት ለውጥ

ሚኒስቴር ሚኒስትር

Directive No. 07/2018

DIRECTIVE ISSUED TO DETERMINE THE REQUIREMENTS FOR TRANSPORT AND STORAGE OF MODIFIED ORGANISMS

WHEREAS it is become necessary to determine the requirements for the transport, and storage of modified organisms;

NOW THEREFORE, this directive is issued by the Ministry of Environment, Forest and Climate Change in accordance with Article 25 of the Biosafety Proclamation No. 655/2009 (as amended by Proclamation No. 896/2015):

1. Short Title

This Directive may be cited as the "Directive to Determine the Requirements for the Transport and Storage of Modified Organisms No07/2018".

2. Scope of Application

This Directive shall apply to the transportation or movement of any regulated modified organisms via air or land by any means from one place to another or storage of modified organism.

3. Transportation of Modified Organism

1/ Any person who engages in transportation of modified organisms shall obtain a transport authorization permit from the Ministry of Environment, Forest and Climate Change or from the designated competent authority.

2/ The transport authorization permit shall be renewed every two years from the date of its issuance.

3/ The Ministry of Environment, Forest and Climate Change Ministry of Environment, Forest and Climate Change shall establish a procedure for tracking and monitoring of modified organisms transported; provided, however, this does not include the transportation of modified organism within the same building.

4/ The transport authorization permit may be revoked or suspended when a permit holder fails to comply with the provisions of Article 4 of this Directive.

5/ The Ministry of Environment, Forest and Climate Change shall ensure that persons authorized to transport modified organisms receive adequate training on safe handling of modified organisms and shall register the personnel trained to undertake the transport.

6/ Any route for the consignment shall, where practicable, be planned carefully to minimize risks to human and animal health and the environment.

7/ Any person with the transport authorization permit shall notify and communicate the Ministry of Environment, Forest and Climate Change, on a monthly basis, of any transportation of modified organisms through a notification form to be developed by the Ministry.

8/ Failure to notify to the Ministry of Environment, Forest and Climate Change the transportation of modified organism on a monthly bases, may lead to cancelation or suspension of transport authorization permit.

9/ The notification form shall include, *inter alia*:

a) Name and address of the owner of the consignment of modified organism, person responsible for the transport of the modified organism and transporting institution if different;

b) Information concerning packaging means of transport, transport route and date of dispatch and delivery;

c) Information concerning the organism: Common and scientific name of the donor and recipient organisms and description of the modified organism;

d) Amount: such as the quantity of culture or number of packages to be transported;

e) Information concerning when and by which authority the genetically modified organism was approved or reported for contained use or deliberate release pursuant to relevant laws;

f) Precautions to be taken in connection with safe handling of the modified organism;

g) the name and signature of person permitted to transport and date.

10/ If necessary, the Ministry of Environment, Forest and Climate Change or the relevant competent authority responsible for granting approval or receiving notification may request further information in addition to those prescribed under sub-article (10) of this Article.

11/ The Ministry of Environment, Forest and Climate Change shall have the power to carry out inspection to ensure compliance with the conditions of permit and to this effect can execute spot inspection to ensure compliance with any requirement.

12/ The person secured authorization permit to transport shall ensure that the label is placed in a manner that enables other handlers know the material to be transported is modifies organism or contains modified organisms.

13/ The label shall clearly show the name, address and contact details of the owner of the consignment, so that the owner can be contacted should the container be lost, damaged or misdirected.

14/ While transporting, the authorized person shall ensure that the packaging of the modified organism is of adequate quality to withstand the shocks and loadings normally encountered during transport and subsequent handling.

15/ In the event of any spill or other accident during the transportation of any modified organism over land, it shall be the responsibility of the authorized person to:

a) secure the area around the vehicle and the spill;

b) when necessary calling emergency service;

c) assess the situation and react in an appropriate manner;

d) immediately notify to the Ministry of Environment, Forest and Climate Change of the nature of the spill or accident.

4. Documents Accompanying the Transport of Modified Organisms

1/ Modified organism that is moved from one place to another, imported, or exported shall be accompanied by a transport authorization permit issued by the Ministry of Environment, Forest and Climate Change, which shall, at all times, be available for inspection by any competent authority or an inspector.

2/ Without prejudice to the provision of sub-article (1) of this Article, while transporting, the authorized person shall, at least, hold documents bearing the following information:

a) Name and address of the destination of the consignment;

b) Scientific and common names of the modified organism and its transformation event;

c) Quantity or total number of package within the consignment;

d) Additional handling information necessary to ensure that the consignment will be segregated correctly;

e) The addresses of the consigner and consignee, contact telephone numbers, and e-mail;

f) An emergency procedure guide providing emergency measures that are to be employed in the event of any unintentional release or any other accident.

5. Procedures for Storage of Modified Organisms

1/ Facilities to be used for storing modified organisms shall be registered by the Ministry of Environment, Forest and Climate Change and obtain permit.

2/ The Ministry of Environment, Forest and Climate Change in consultation with the competent licensing agencies for health and labor affairs, shall undertake licensing and registration of premises for the storage of modified organisms and for this purpose shall establish:

a) standards pertaining to the storage of modified organisms;

b) procedures and requirements for the licensing and registration of storage;

c) requirements for the training of employees in the safe handling of modified organisms.

3/ In undertaking the licensing and registration of premises under sub-article (2) of this Article, the Ministry of Environment, Forest and Climate Change may require the premises to carry adequate insurance to cover liability for harm to human or animal health or the environment.

4/ The person in charge of any premise that is to be used for the storage of any modified organism shall apply to the Ministry of Environment, Forest and Climate Change to secure permit.

5/ Any application submitted to store a modified organism shall contain the following information:

a) a full and accurate description of the modified organism that is to be stored including scientific and common names and transformation event;

b) a statement of the quantity of the modified organism to be stored and the duration of the storage or processing;

c) the name and location of the place where the modified organism is to be stored;

d) a description of the risk management strategy and emergency measures that operate within the facility.

6/ Upon receipt of any application to store any modified organism, the Ministry of Environment, Forest and Climate Change shall inspect the premise to determine:

a) adequate facilities exist for the safe storage of the specified modified organism;

b) adequate security, segregation and safety measures exist at the premise;

c) employee training in the handling of modified organisms has been undertaken.

7/ Upon the completion of any inspection, the Ministry of Environment, Forest and Climate Change shall decide on one of the following:

a) issue permit for the storage of modified organisms;

b) specify conditions if some additional activities may make the premise satisfactory for storage;

c) refuse permit if it decides that a significant risk cannot be avoided.

8/ The permit issued by the Ministry of Environment, Forest and Climate Change shall contain information regarding:

a) the name and location of the place where the modified organism is to be stored;

b) full and accurate description of the modified organism that is to be stored including scientific and common names and the transformation event;

c) the quantity to be stored and the duration of the storage;

d) risk management measures.

9/ The Ministry of Environment, Forest and Climate Change may, at any time that it may consider appropriate, cancel the permit that has been issued, if any requirement contained therein is not strictly complied with and order the immediate cessation of the storage of the modified organism.

10/ Within seven days of issuing a permit under this Directive the Ministry of Environment, Forest and Climate Change shall keep its copy in the National Biosafety Clearing House.

11/ Any premise used for the storage of a modified organism shall ensure that all the stored material is packed, labeled and segregated.

12/ The person in charge of any premise used for the storage of any modified organism shall carry out the following activities:

a) ensure that a daily inspection of the modified organism stored in the premise is undertaken by a responsible person to check that no unintended release or leakage is occurring.

b) ensure that the entire modified organism in storage areas is secured against unauthorised access;

c) maintain data on any modified organism stored in the premise and ensure that the data are readily accessible to inspectors;

d) ensure that emergency procedures that are to be employed in the event of any unintended release or other accident are always ready;

6. Effective Date

This directive shall enter into force as of ..16/01...day of 2018

Done at Addis Ababa, this 16 day of Jan./2018

Dr. Gemedo Dalle

MINISTER OF MINSTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

መመሪያ ቁጥር ዐ፰/2010

በልውጥ ሕያዋን እንቅስቃሴዎች ላይ ለመሰማራት የሚቀርቡ ማመልከቻዎች ይዘትን ለመወሰን የወጣ መመሪያ

በልውጥ ሕያዋን እንቅስቃሴ ለመሰማራት የሚቀርቡ የፈቃድ ጥያቄ ማመልከቻዎችን ዋና ዋና ይዘት መወሰን አስፈላጊ በመሆኑ፤

የአካባቢ፣ የደን እና የአየር ንብረት ለውጥ ሚኒስቴር ስለደሕንነት ሕይወት በወጣው አዋጅ ቁጥር 655/2001 (በአዋጅ ቁጥር 896/2007 እንደተሻሻለው) አንቀጽ 25 መሠረት ይህን መመሪያ አውጥቷል።

ክፍል አንድ
ጠቅላላ

1. **አጭር ርዕስ**

ይህ መመሪያ "በልውጥ ሕያዋን የተጤነ ልቀት እንቅስቃሴዎች ለመሰማራት የሚቀርቡ ማመልከቻዎች ይዘት መወሰኛ መመሪያ ቁጥር ዐ፭/2010" ተብሎ ሊጠቀስ ይችላል።

2. **የተፈፃሚነት ወሰን**

ይህ መመሪያ ያለምንም ክልከላ ወደ አካባቢ በሚለቀቁ ማናቸውም ልውጥ ሕያዋን እንቅስቃሴ ላይ ለመሰማራት በሚቀርቡ ማመልከቻዎች ላይ ተፈጻሚነት ይኖረዋል።

3. **አጠቃላይ መረጃዎች**

በልውጥ ሕያዋን የተጤነ ልቀት እንቅስቃሴዎች ላይ ለመሰማራት የሚቀርብ ማመልከቻ የሚከተሉትን አጠቃላይ መረጃዎች መያዝ ይኖርበታል፤

1/ ስም፣ አድራሻ እና አመልካቹ የሚገኝበት ዝርዝር መረጃ፤

2/ ኘሮጀክቱን ለማቀድና ለመተግበር፣ እንዲሁም ለቁጥጥር፣ ለክትትል እና ለደኅንነት ኃላፊነት ያለባቸው ባለሙያዎች ስም፣ የሥልጠና መስኮች በተለይም የኃላፊው ሳይንቲስት ስም።

ክፍል ሁለት

የሰጪ ሕያው፣ የተቀባይ እና የልውጥ ሕያው መረጃ

4. የሰጪ ሕያው፣ የተቀባይ እና ልውጥ ህያዉ መረጃዎች

የሰጪ ሕያው፣ የተቀባይ እና ልውጥ ህያዉን በተመለከተ የሚከተሉት መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ ሰጪ የሆነው ሕያው ሳይንሳዊ ስም፣ የተሰጠው ከሆነም የተለምዶ ስም፤

2/ ተቀባይ የሆነው ልውጥ ሕያው ሳይንሳዊ ስም፣ የተሰጠው ከሆነም የተለምዶ ስም፤

3/ በክስተት ጥንቅሩ ውስጥ የተካተቱ ባይተዋር ዘረመሎች ምንጮች ከሆኑት ማናቸውም ሕያዋን ጋራ የሚዛመዱ ዝርያዎች ሳይንሳዊ ስሞችና የተሰጣቸው ከሆነም የተለምዶ ስሞች፤

4/ ተቀባይ እና ሰጪ (ወላጆች) ሕያዋን ያላቸው የመመሳሰል ደረጃ፤

5/ ሰጪ እና የተቀባይ (ወላጆች) ሕያዋን መልካአ ምድራዊ ሥርጭት፣ የተፈጥሮ መገኛ ቦታ ወይም የሚከሰትበት አካባቢ::

5. የባህርይ ክስተትን የሚለውጡ ኑክሊክ አሲዶች ባህርያት

የባህርይ ክስተትን የሚለውጡ ኑክላይክ አሲዶች ባህርያትን በተመለከተ የሚከተሉት መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የእያንዳንዱ ዘረመል ክስተት ጥንክር ዝርዝር መግለጫ፤

2/ ኑክሊክ አሲዱ ምንም ለውጥ ሳይደረግበት ወደ ህያው መግባቱ፣ ወይም ልውጥ ከሆነም ኑክለይክ አሲዱን ለመለወጥ ሥራ ላይ የዋለው ዘዴ፤

3/ የኑክሊክ አሲዱ ቅደም ተከተል፣ በተለይም በዋናው ዘረመል፣ በፕሮሞተር፣ በተርሚኔተር ዘረ-መሎች፣ እና መምረጫ ዘረመላዊ ምልክት በመሳሰሉት፤

4/ የኒክሊክ አሲዲ የሚወክለው ባሕሪይ መገለጫ ዝርዝር መረጃ

5/ የባሕሪይ ምንነቱን ለመሥራት ሥራ ላይ የዋለው ዘዴ፤

6/ ዘረመላዊ ምልክቶች፤

7/ ዘረመሉ መኖር ወይም አለመኖሩን ማወቅያ እና መለያ ዘዴዎች መግለጫ፤

8/ ልውጥ ሕያዉን ለመለየትና ለማወቅ በጥቅም ላይ የሚውሉ ዘዴዎች በአህዝ የሚገለጽ ለኪነት እና አስተማማኝነት ደረጃ፣

9/ ወደ ልውጥ ሕያው የገባው ኑክላይክ አሲድ ወደ ሌሎች ሕያዋን የመተላለፍ ወይም ከሌሎች ሕያዋን ጋር የመቀያየር አቅም፤

10/ ኑክለይክ አሲዶች ሳይለወጡ የመቆየት አስተማማኝነት ማረጋገጫ እና ይህ አስተማማኝነት ላይ ተፅዕኖ የሚያደርጉ ነገሮች ዝርዝር።

6. <u>የአድራሽ ባህርያት</u>

የአድራሽ ባህርያት በተመለከተ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የአድራሹ ባሕሪ እና ምንጭ፤

2/ ልውጥ ሕያዉን ለመሥራት ወደ ተቀባይ ዝርያ በተከተተው የክስተት ጥንቅር ውስጥ የነበሩ ሆኖም ግን ባህሪን የማይከስቱ የዘረመል ክፋይ ቅደም ተከተል፤

7. <u>የልውጥ ሕያዉ ባህርያት በተመለከተ</u>

የልውጥ ሕያዉ ባህርያትን በተመለከተ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የሕያዉን የአለዋወጥ ሂደት የሚመለከቱ መረጃዎች፣

ሀ) ወደ ተቀባይ ሕያዉ ሌላ ባሕሪይ ሊከስት የሚችል የዘረመል ጥንቅር ለመክተት በጥቅም ላይ የዋለ ዘዴ፤

ለ) የተከተተውን የዘረመል ጥንቅር ቅጂ ብዛት፣

ሐ) የአድራሽ ባክቦን መኖር እና የኒዩክሊክ አሲድ ቅደም ተከተሉ፤

መ) የተለወጠ ወይም የተጨመረ ወይም የተወገደ ኑክሊክ አሲድ ቅደም ተከተል፤ልዩ ተግባሩ እና ቦታው ወይም ስፍራው በተለይም ጉዳት እንደሚያስከትል ከሚታወቅ የኑክሊክ አሲዱ ቅደም ተከተል አንፃር፤

2/ ልውጥ ሕያዉን የሚመለከቱ መረጃዎች፣

ሀ) የልውጥ ክስተት ልዩ መለያ ስያሜ፤

ለ) የልውጥ ሕያዉ አካላዊ ሁኔታ መግለጫ፣ በተለይም የሚከሰቱና የማይከሰቱ አዲስ ባህሪያት፣

ሐ) የባህርያት እርጋታ፣

መ) የገባለት አዲስ ዘረመል መከሰትና ክስተቱን ለመለካት የሚያስችሉ ዘዴዎችና ሰንሲቲቪቲ፣

ሠ) የተከሰተው ኘሮቲን ተግባር፣

ረ) ልውጥ ሕያዉን ለመለየትና ለማወቅ በጥቅም ላይ የሚውሉ ዘዴዎች በአህዝ የሚገለጽ ለኪነት እና አስተማማኝነት ደረጃ፣

ሰ) ልውጥ ሕያዉ ከአሁን በፊት ስለመለቀቁ ወይም በጥቅም ላይ ስለመዋሉ የሚገልፅ ታሪካዊ መረጃ፣

ሸ) በሰው ወይም በእንስሳት ጤና፣ በብዝሃ ሕይወት፣ በአካባቢ፣ ላይ ሊደርሱ የሚችሉ ጠንቆች፣

ቀ) በተፈጥሮአዊ ሥርዓተ ምህዳሮች ውስጥ የመራቢያ ጊዜ፣ ሩካባዊ እና ኢሩካባዊ የመራባት ኡደቶች፣

በ) ዘርን፣ ዱኬን፣ እስክሎሮሺያን ወይም ሌሎች አካላትን በመፍጠር ወቅቶችን የማሳለፍ ችሎታውና ከወቅቶች ጋራ የመለዋወጡ ሁኔታ መረጃዎች፣

ተ) በሽታ የማስያዝ፣ የመልከፍ፣ የመመረዝ፣ የማጥቃት፣ አለርጂ የመቀስቀስ፣ በሽታ የማዛመት አቅም፣ በሽታ እንዲያመጣ ወደ ሰው ወይም ወደ እንስሳት የሚያዛምቱት ሕያዋን ማንነት፣ በሽታ የሚንሆንባቸው ሕያዋን፣ የማይሳዱ ቫይረሶችን ወደ በሽታ አምጪነት የመለወጥ አቅም፣ ሌሎች ሕያዋንን የመውረር አቅም፣ ኑክላይክ አሲድ ወደ ሌሎች ዝርያዎች ህዋሳት ወይም ህብረ ህዋሳት የማስገባት አቅም፣

ቸ) አንቲባዮቲኮችን የመቋቋም አቅምና በእነዚህ አንቲባዮቲኮች ሰው ወይም የቤት እንስሳት በሽታ እንዳይያዙ ለመከላከል ወይም መድኃኒት ሆኖ የማገልገል ጠቃሚነት፣

ኀ) ልውጥ ሕያዉ በአካባቢያዊ ሂደቶች የሚጫወተው ሚና፣ ማለትም ኃይልን ወደ ምግብ ምርትነት በመለወጥ፣ ለዕፀዋት በሚያስፈልጉ ንጥረ ነገሮች ኡደት፣ በቁሳዊ አካል መበስበስ እና በሌሎች ተግባራት፣

ነ) ልውጥነትን ወደ ሌሎች ሕያዋን የማጋባት ጠንቅ፣

3/ በጤና ላይ ሊደርሱ የሚችሉ ተዕዕኖዎችን በተመለከተ፣

ሀ) ልውጥ ሕያዉ በሰው ወይም በእንስሳት ላይ በበሽታ አምጭነት፣ በአለርጂ ቀስቃሽነት ወይም ከሌሎች ተመሳሳይ ጉዳቶች አኳያ ያለው ተዕዕኖ ፣

ለ) ከሰጪና ከተቀባይ ወይም ልውጥ ካልሆኑት ወላጅ ሕያዋኑ ጋር ሲነፃፀር ልውጥ ሕያዉ በሰው ወይም በእንስሳት ላይ የሚያደርሳቸው መርዛማነት፣ የአለርጂ ቀስቃሽነት ወይም ሌሎች ተመሳሳይ ጉዳቶች፤

ሐ) ወደ አዳዲስ ቦታዎች የመዛመት አቅም፣

መ) ልውጥ ሕያዉ በሽታን የመከላከል አቅሙ በተሟላለት ሰው ወይም እንስሳ ላይ በሽታ የማስያዝ ወይም የመመረዝ ወይም አለርጂ የመቀስቀስ ተጽዕኖ የሚያስከትል ከሆነ የሚከተሉት መረጃዎች ያስፈልጋሉ፣

(1) ሊያደርስ የሚችላቸው በሽታዎች ወይም በሽታ የሚያስይዝባቸው መንገዶች፣ የመዛመትና የማጥቃት መጠን፤

(2) ተላላፊነት፤

(3) በሽታ ሊያስይዝ የሚችለው መጠን፤

(4) የተጠቂዎች ስፋትና መጠን፣ ወደ አዲስ ተጠቂዎች የመዛመት ሁኔታ፤

(5) ከሰዎች ወይም ከሌሎች ሕያዋን ውጪ የመቆየት አቅም፤

(6) አዛማች ሕያዋን ወይም ሌሎች የመዛመቻ መንገዶች፤

(7) ስነህይወታዊ እርጋታ፤

(8) ተገቢ ህክምና መኖር።

ክፍል ሦስት
ተቀባይ አካባቢ እና ልውጥ ሕያው ከተቀባይ አካባቢ ጋር ስለሚኖረው መስተጋብር

8. ስለተጤነ ልቀት መረጃዎች

ስለልቀቱ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የታቀደው የተጤነ ልቀት ሁኔታ፣ አስፈላጊነትና ይገኛል ተብሎ የታሰበው ውጤት፤

2/ ልቀቱ እንዲፈጸም የታቀደባቸው ቀናትና የሚቆይበት ጊዜ፤

3/ ልቀቱ የሚደረግበት ዘዴ፣

4/ የሚለቀቀው ልውጥ ሕያው መጠን፣

5/ ልቀት ከመካሄዱ በፊት የሚደረግ የመሬት ዝግጅት (የአስተራረስ አይነትና ዘዴ፣ የማዕድን ቁፋሮ፣ የመስኖ ልማት ወይም ሌሎች ድርጊቶች)፣

6/ ቀደም ሲል ከተደረገ የልውጥ ሕያዉ ልቀት የተገኙ ውጤቶች፣ በተለይም በተለያዩ መጠኖችና በተለያዩ ሥርዓተ መሕድሮች።

9. <u>በህይወት የመቆየት፣ መራባት፣ መዛመትና የባህርይ ክስተት</u>

በህይወት መቆየት፣ መራባት፣ መዛመትና የባህርይ ክስተት በተመለከተ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የልውጥ ሕያዉ በሕይወት መቆየትን፣ መራባትንና መዛመትን የሚወስኑ ሥነ ሕይወታዊ ባሕሪያት፤

2/ የልውጥ ሕያዉ ወይም የዘረመሉ በሕይወት መቆየትን፣ መራባትንና መዛመትን የሚወስኑ አካባቢያዊ ሁኔታዎች ላይ ተጽዕኖ ሊያደርሱ የሚችሉ የሚታወቁ ወይም የሚገመቱ (ነፋስ፣ ውሃ፣ አፈር፣ ሙቀት፣ አሲዳማነት፣ እንደ ፀረተባይ ያሉ በካዮች፣ ከባድ ብረት መሰል ማዕድናት፣ የጎንዮሽ የዘረመል ሽግግር እና የመሳሰሉ) የዘረመል ወይም የሌሎች ባዮኬሚካሎች ክስተት።

10. <u>ከአካባቢ ጋር ስለሚኖር መስተጋብር</u>

ከአካባቢ ጋር የሚኖር መስተጋብርን በተመለከተ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ ለልውጥ ሕያዉ ተስማሚ ይሆናሉ ተብለው የሚገመቱት የመኖሪያ አካባቢ (ምቹጌ) ዓይነቶች፤

2/ የተፈጥሮ ሥረዓተ-ምህዳር በሚመስሉ ሰው ሰራሽ ማሳደጊያ ክፍሎችና የመስተዋት ቤቶች በልውጥ ሕያዉ ባሕርያት ላይ የተደረጉ ሙከራዎች እና የተካሄዱ ሥረዓተ-ምህዳራዊ ተፅዕኖ ግምገማ፤

3/ የባሕርይ ማጋባት ችሎታው፣

ሀ) ከተጨነው ልቀት በኋላ በልውጥ ሕያዉ የተከተተው ዘረመል በተለቀቀበት ስነ-ምሕዳር ወደሚኖሩ ወደ ሌሎች ሕያዋን የመጋባት ዕድል፣

ለ) ከልቀት በኋላ በሥነ-ሕዳሮቹ ከሚገኙት ሕያዋን ወደ ልውጥ ሕያዉ የዘረመሎች መጋባት ዕድል፣

4/ ከተጨነው ልቀት በኋላ ሊኖር በሚችለው ግንኙት ምክንያት በልውጥ ሕያዉ ወይም በተዋጽአው ሊያጋጥም የሚችል ያልተጠበቀ ወይም የማይፈለግ የባህርይ ለውጥ፤

5/ የልውጥ ሕያዉ ዘረመላዊ እርጋታን ለማረጋገጥ የሚወሰዱ እርምጃዎች፣ ዘረመሎች ወደ ሌሎች ሕያዋን እንዳይተላለፉ ለማድረግ የሚያስችሉ ባሕሪያት፣ የእርጋታ እውንነት የሚረጋገጥባቸው ዘዴዎች፤

6/ የልውጥ ሕያዉ የመዛመቻ መንገዶች፣ የሚታወቁ ወይም የሚገመቱ ከአዛማች ሕያዋን ጋር የሚኖሩ ግኑኝነቶች፣ እነዚህም እንደ ነፋስ፣ ውኃ፣ ከትንፋሽ ጋር መግባት፣ ከምግብ ጋር መግባት፣ አካላዊ ንክኪነትና ወደ እንስሳት አካላት ሰርስሮ መግባትን ጨምሮ ሌሎች፤

7/ ልውጥ ሕያዉ ሊሰራጭባቸው ይችላሉ ተብለው የሚገመቱት ሥነምህዳሮች ዝርዝር መግለጫ::

11. <u>ሊደርሱ ይችላሉ ተብለው የሚገመቱ የአካባቢ ተፅዕኖዎች/ጠንቆች</u>

ሊደርሱ ይችላሉ ተብለው የሚገመቱ የአካባቢ ተጽዕኖዎችን በተመለከተ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ የልውጥ ሕያዉ በአካባቢው ውስጥ እጅግ በጣም የመባዛት አቅም፤

2/ ልውጥ ሕያዉ ልውጥ ካልሆኑት ወይም ከወላጅ ዝርያዎቹ ጋራ ሲነፃፀር ያለው የተወዳዳሪነት ብልጫ፤

3/ የልውጥ ሕያዉ ተጽዕኖ ዒላማ ሊሆኑ ይችላሉ ተብለው የተለዩ ዝርያዎች ዝርዝር መግለጫ፤

4/ በተለቀቀው ልውጥ ሕያው እና በዒላማነት በታሰቡት ዝርያዎች መካከል የሚኖረው ግኑኙነትና የሚጠበቀው ውጤት፤

5/ ተፅዕኖ ሊደርስባቸው የሚችሉ ነገር ግን በዒላማነት ያልታሰቡት ዝርያዎች ማንነትና ዝርዝር፤

6/ ከልቀት በኋላ ሊመጡ የሚችሉ ስነ ሕይወታዊ ለውጦች ወይም የዒላማ ወሰን፤

7/ በተወዳዳሪዎች፣ በተበይዎች፣ ተሸካሚዎች፣ በተደጋጋፊዎች፣ በበይዎች፣ በጥገኞች እና በበሽታ አምጪዎች ብዛት ላይ ሊደርሱ የሚችሉ የታወቁ ወይም የሚገመቱ ተፅዕኖዎች፤

8/ ልውጥ ሕያዉ በባዮጂኦኬሚካላዊ ዑደት ላይ የሚኖረው የሚታወቅ ወይም የሚገመት ሚና፤

9/ ሌሎች ወሳኝ የሚባሉ ከአካባቢ ጋር የሚኖሩ መስተጋብሮች።

12. **<u>የክትትል እና የቁጥጥር መንገዶች</u>**

የክትትል እና የቁጥጥር መንገድን በተመለከተ የሚከተሉት ዝርዝር መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ ልውጥ ሕያዉን መከታተያና የሚያስከትለውን ተፅዕኖ መገምገሚያ ዘዴዎች፤

2/ ልውጡን ሕያው ከሌሎች ሕያዋን ለመለየት ያለው የክትትል ዘዴ ተለይነት፣ ለኪነትና አስተማማኝነት ፤

3/ ወደ ልውጥ ሕያዉ ውስጥ የገባው አዲስ ዘረመል ወደ ሌሎች ሕያዋን መተላለፉን የማወቅያ ዘዴዎች፤

4/ ተገቢ ያልሆኑ የባሕርይ ክስተቶችንና መንስኤዎቻቸውን ማወቅያ መንገዶች።

<u>ክፍል አራት</u>
<u>ልውጥ ሕያውን ገበያ ላይ ለማዋል መቅረብ</u>
<u>ያለባቸው ተጨማሪ ዝርዝር መረጃዎች</u>

13. **<u>ልውጥ ሕያው ገበያ ላይ ለማዋል በሚቀርብ ማመልከቻ መቅረብ ያለባቸው ተጨማሪ መረጃዎች</u>**

ልውጥ ሕያውን ገበያ ላይ ለማዋል በሚቀርብ ማመልከቻ እንደአግባቡ የሚከተሉት ተጨማሪ መረጃዎችን በአመልካቹ መቅረብ አለባቸው፤

1/ የሸቀጡ ስምና በውስጡ የያዘው ልውጥ ሕያው ሳይንሳዊ ስም፣ የተለምዶ ስምና የተለወጠበት ክንዋኔ፤

2/ የልውጥ ህያዉ አምራችና አከፋፋይ ስሞችና አድራሻዎች፣ የስልክ ቁጥሮችንና ኢ-ሜይሎችን ጨምሮ፤

3/ በደኅንነተ ሕይወት ፕሮቶኮሉ የመረጃ ስርዓት ውስጥ ስለ ልውጥ ሕያዉ መረጃ ማግኘት የሚቻልበት መንገድ መግለጫ፤

4/ የሚሰጠው የአገልግሎት አይነት፤

5/ አከመቻቸቱንና አያያዙን በተመለከተ ግልጽ መግለጫ።

14. **ልውጥ ሕያው ያለበትን ሽቀጥ ለምግብነት ለገበያ ለማዋል በሚቀርብ ማመልከቻ መቅረብ ያለባቸው መረጃዎች**

ልውጥ ሕያው ያለበትን ሽቀጥ ለምግብነት ለገበያ ለማዋል በሚቀርብ ማመልከቻ እንደአግባቡ የሚከተሉት ተጨማሪ መረጃዎችን በአመልካቹ መቅረብ አለባቸው፤

1/ የወጥነት ጥናት ውጤት፤

2/ አገልግሎት ላይ ውሎ ከሆነ አንቲባዮቲክ የሚቋቋም ማርከር ጂን፤

3/ የአዲስ ፕሮቲኖች ባሕሪ ትንታኔ፣ አዲስ ፕሮቲን ከዚህ በፊት ለሰው ምግብነት አገልግሎት ላይ ውሎ ከሆነ የተያዘውን መረጃ፣ ወይም ከዚህ በፊት ለምግብነት አገልግሎት ላይ ከዋለው ንጥረ ነገር ጋር ያለው መመሳሰል፤

4/ በልውጥ ሕያው የተመረተው አዲስ ፕሮቲን መርዛማ የመሆን አጋጣሚ፤

5/ አዲሱ ፕሮቲን አለርጂ ለማስከተል ያለው አቅም፤

6/ የልውጥ ሕያው የምግብ ይዘት ትንታኔ እና ከልውጥ ሕያው የሚገኘው የምግብ ነክ ውጤት ይዘት ትንታኔ፤

7/ የምግብ ይዘት ለውጥ ተጽዕኖን ለመገምገም የሚያስችል መረጃ፤

8/ በእንስሳት ላይ የተደረገ የመኖ ጥናት መረጃ፤

9/ ምግቡ ገበያ ላይ ሲውል የሚሸጥበት ስያሜ።

15. **ልውጥ ሕያው ያለበትን ሽቀጥ ለእንስሳት መኖነት ለገበያ ለማዋል በሚቀርብ ማመልከቻ መቅረብ ያለባቸው መረጃዎች**

ልውጥ ሕያው ያለበትን ሽቀጥ ለእንስሳት መኖነት ለገበያ ለማዋል በሚቀርብ ማመልከቻ እንደአግባቡ የሚከተሉት ተጨማሪ መረጃዎች በአመልካቹ መቅረብ አለባቸው፤

1/ ለመርዛማነት እና ለፀረ-ሥነምግብ ባሕሪ መጋለጥን ጨምሮ ሕመምን ወይም አለርጂን በሰው ላይ የማስከተል እና በሰው ወይም በእንስሳት ላይ በጎ ያልሆነ ተጽዕኖ የማድረስ አቅም፤

2/ አዲሱ ምርት ከእንስሳት እዳሪ ጋር አብሮ የመውጣት አቅም እና የሚያስከትለው ተጽዕኖ፤

3/ አዲሱ እንስሳት መኖ ከሌላ ተመሳሳይ እንስሳት መኖ ጋር ሲነጻጸር የሥነ-ምግብ መረጃን ጨምሮ የተገኘ የይዘት ልዩነት መረጃ፤

4/ መኖው በተደጋጋሚ ለማግኘት ያላቸው አጋጣሚ፤

5/ ከውስጥ የሚፈጠር ወይም በአዲስ መልክ የሚከሰት የመርዛማነት መረጃ፤

6/ አለርጂ የማስከተል መረጃ፤

7/ በቤተሙከራ እንሰሳ ላይ የተካሄደ የምገባ ጥናት።

16. <u>ልውጥ ሕያው ያለበትን የታሸገ ጥቅል ለገበያ ለማዋል በሚቀርብ ማመልከቻ መቅረብ ያለባቸው መረጃዎች</u>

1/ ልውጥ ሕያው ያለበትን የታሸገ ጥቅል ለገበያ ለማዋል በሚቀርብ ማመልከቻ አመልካቹ የሚከተሉት መረጃዎች ጥቅሉ ላይ መለጠፍና ማሳየት አለበት፤

ሀ) የልውጥ ሕያውን ላኪ እና ተቀባይ የሆኑ ሰዎች ስልክና ኢሜል ጨምሮ ስም እና አድራሻ፤

ለ) በጥቅል እሽጉ ውስጥ የሚገኘው ሸቀጥ ልውጥ ሕያው ሲሆን "*ልውጥ ሕያው ያለበት*" የሚል መግለጫ በጥቅል ማሸጊያ ላይ በአማሪኛና በእንግሊዚኛ ቋንቋ ተጽፎ የተለጠፈበት።

2/ በጥቅል እሽጉ ውስጥ የሚገኘው ሸቀጥ ልውጥ ሕያው የሌለው ሲሆን "ልውጥ ሕያው የሌለበት" የሚል መግለጫ በጥቅል ማሸጊያ ላይ በአማሪኛና በእንግሊዚኛ ቋንቋ ተጽፎ ሊለጠፍበት ይቻላል።

17. <u>መመሪያው የሚፀናበት ጊዜ</u>

ይህ መመሪያ ከ...ኖቬ.8...ቀን..2010...ዓ.ም ጀምሮ የፀና ይሆናል።

አዲስ አበባ .....ኖቬ.8..ቀን 2010ዓ.ም

ዶ/ር ገመቺስ ዳሌ
የአካባቢ የደንና የአየር ንብረት ለውጥ
ሚኒስቴር ሚኒስትር

Directive No. 03--/2018

DIRECTIVE ISSUED TO DETERMINE THE CONTENT OF AN APPLICATION FOR UNDERTAKING DELIBERATE RELEASE OF MODIFIED ORGANISMS

Whereas it is important to determine the major contents of applications for deliberate release of modified organisms;

NOW THEREFORE, this directive is issued by the Ministry of Environment, Forest and Climate Change in accordance with Article 25 of the Biosafety Proclamation No. 655/2009 (as amended by Proclamation No. 896/2015):

PART ONE

GENERAL

1. Short Title

This directive may be cited as the "Directive to Determine the Content of an Application for Undertaking Transaction Involving Deliberate Release of Modified Organisms No. 03 /2018".

2. Scope of Application

This directive shall be applicable to an application submitted to engage in transaction for introduction into the environment of any modified organism for which no specific containment measures are used to limit their contact with the environment.

3. General information

The application for undertaking transactions involving deliberate release of modified organisms shall contain the following general information:

1/ name, address and contact details of applicant;

2/ name and field of studies of persons responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and safety, in particular the name of the responsible scientist.

PART TWO

INFORMATION ON DONOR, RECIPIENT AND THE MODIFIED ORGANISM

4. Description of the Donor, Recipient and the Modified Organisms

With regard to donor, recipient and modified organisms, the following information shall be presented by an applicant:

1/ scientific name, and when available also common name of the donor organism;

2/ scientific name, and when available also common name of the recipient modified organism;

3/ scientific names, and when available also common names, of species that are related to any of the organisms from which any of the trans-genes in the expression cassette have been taken;

4/ degree of relatedness between the donor and recipient (between parental) organisms;

5/ description of the geographic distribution and of the natural habitats of the donor and recipient (between parental) organisms; the environments where they occur.

5. Characteristics of nucleic acids that affect trait expression

With regard to characteristics of nucleic acids that affect trait expression the following information shall be presented by the applicant:

1/ description of each expression cassette;

2/ whether the nucleic acid that affects trait expression is introduced without change or has been modified; if modified, methods used to modify the nucleic acid composition;

3/ nucleic acid sequence of, inter alia, the target gene, promoter, terminator and selectable marker;

4/ description of the trait that it expresses

5/ methods used to construct the expression cassette;

6/ genetic markers;

7/ description of identification and detection techniques of the nucleic acids;

8/ quantitative expression of sensitivity, reliability and specificity of the identification and detection techniques;

9/ potential for nucleic acids involved in trait expression being transferred to or exchanged with other organisms;

10/ verification of the stability of the nucleic acids and factors affecting their stability.

6. Characteristics of the Vector

With regard to characteristics of the vector the following information shall be presented by the applicant:

1/ nature and source of the vector;

2/ sequence of the non-coding genetic segments used to construct the expression cassette and to introduce it into the recepient organism to produce the modified organism;

7. Characteristics of the Modified Organism

With regard to characteristics of the modified organism the following information shall be presented by the applicant:

1/ Information relating to the modification:

a) Methods used to introduce the inserts into the recipient organism;

b) Copy number of the insert;

c) Presence of any vector backbone including its sequence;

d) Sequence, functional identity and location of the altered or inserted or deleted nucleic acid with particular reference to any known harmful sequence;

2/ Information on the modified organism:

a) Unique identifier of the transformation event ;

b) Description of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or may no longer be expressed;

c) Stability of the traits;

d) Expression of the introduced new genetic material and methods and sensitivity of measurement;

e) Function of the expressed protein;

f) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques of the modified organism;

g) History of previous releases or uses of the modified organism;

h) Risks to human or animal health, biological diversity and the environment;

i) Generation time in natural ecosystems, sexual and asexual reproductive cycles;

j) Information on survival, including seasonality and the ability to form seeds, spores, sclortia and other survival structures;

k) Pathogenicity, infectivity, toxicity, virulence, allergenicity, ability to be a carrier (vector) of pathogens, identity of possible vectors to transimit it to humans or animals as a disease causing agent, host range, possible activation of latent viruses, ability to colonize other organisms, ability of nucleic acids or other molecules that affect trait expression to be introduced into the cells or tissues of other species;

l) Antibiotic resistance, and potential use of these antibiotics in humans or domestic animals for prophylaxis or therapy;

m) Involvement in environmental processes, primary production, nutrient cycling, decomposition of organic matter and other activities;

n) Risk of passing modification to other organisms;

3/ Considerations of impacts on health:

a) Toxic, allergenic, or other similar effects of the modified organism on humans or animals;

b) Comparison of the modified organism with the donor and recipient or unmodified parental organisms regarding pathogenicity, allergencity, or other similar effects in humans or animals;

c) Capacity for colonization;

d) If the organism is pathogenic or toxic or allergenic to immunocompetent humans or animal, the following information is required:

(1) diseases caused and mechanism of pathogenicity including invasiveness and virulence;

(2) communicability;

(3) infective dose;

(4) host range and possibility of alteration of hosts;

(5) possibility of survival outside of humans or other organisms;

(6) vectors or means of dissemination;

(7) biological stability;

(8) availability of appropriate therapies.

PART THREE
INFORMATION RELATING TO THE RECEIVING ENVIRONMENT AND INTERACTION BETWEEN THE MODIFIED ORGANISM AND THE RECEIVING ENVIRONMENT

8. Information on the Deliberate Release

With regards to the release the following information shall be presented by the applicant:

1/ description of the proposed deliberate release, including the purpose and foreseen outcome;

2/ planned dates and durations of the release;

3/ method to be used for the release;

4/ quantity of modified organism to be released;

5/ site preparation prior to release (type and method of cultivation, mining, irrigation, or other activities);

6/ information on, and results of, previous releases of the modified organism especially at different scales and in different ecosystems.

9. Survival, multiplication, dispersal and trait expression

With regard to survival, multiplication, dispersal and trait expression the following information shall be presented by the applicant:

1/ biological features which affect the survival, multiplication and dispersal of the modified organism;

2/ known or predicted environmental conditions which may affect the survival, multiplication and dispersal (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals, horizontal gene transfer and others) of the modified organism or of its genes or other biochemicals that affect trait expression.

10. Interactions with the environment

In relation to interaction with the invironment the following information shall be presented by the applicant:

1/ habitat types expected to be suitable for the modified organism;

2/ experiments carried out on the behaviour of the modified organism and an assessment of its ecological impact carried out in simulated natural environments, such as growth rooms and greenhouses;

3/ trait transfer capability:

a) possibility for post-release transfer of inserted genetic materials from the modified organism into organisms in the ecosystem;

b) possibility for post-release transfer of genetic material from organisms in the ecosystem to the released modified organism;

4/ likelihood of post-release interaction leading to the expression of unexpected or undesirable traits in the modified organism or in its products;

5/ measures employed to ensure and verify genetic stability; description of genetic traits which may prevent the transfer of genetic materials; methods used to verify stability;

6/ routes of biological dispersal of the modified organism, known or potential modes of interaction with the disseminating agents, including dispersal by wind, water, inhalation, ingestion, surface contact with or burrowing into animals, and others;

7/ description of ecosystem to which the modified organism could be disseminated.

11. Potential environmental impacts

In relation to potential environmental impact the following information shall be presented by the applicant:

1/ potential for excessive population increase of the modified organism in the environment;

2/ competitive advantage of the modified organism in relation to the unmodified or parental species;

3/ identification and description of the target species that are anticipated to be affected by the modified organism;

4/ anticipated mechanism and result of interaction between the released modified organism and the target species;

5/ identification and description of non-target species which may be affected;

6/ likelihood of post-release shifts in biological or in target range;

7/ known or predicted effects on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens;

8/ known or predicted involvement of the modified organism in biogeochemical processes;

9/ other potentially significant interactions with the environment.

12. Information on monitoring and monitoring techniques

With regard to monitoring and monitoring techniques the following information shall be presented by the applicant:

1/ methods for tracing the modified organism and for monitoring its effects;

2/ specificity, sensitivity and reliability of the monitoring techniques to identify the modified organism;

3/ techniques for detecting the transfer of the introduced transgene to other organisms;

4/ methods for detecting aberrant expression of traits and their causes.

PART FOUR
ADDITIONAL INFORMATION REQUIRED FOR PLACING ON A MARKET A COMMODITY CONSISTING OF A MODIFIED ORGANISM

13. Information required where the transaction relates to an application for placing a modified organism on a market

With regard to transaction relating to an application for placing a modified organism on a market, the following additional information, where relevant, shall be presented by the applicant:

1/ name of the commodity, the scientific and common names and the transformation event of the modified organism;

2/ names and addresses, including telephone numbers and e-mails, of the maker and the distributor of the modified organism;

3/ specification for accessing information on the modified organism in the Biosafety Clearing House of the Protocol;

4/ type of expected use;

5/ specific instructions for storage and handling.

14. Information required where the transaction relates to the placing of modified organism as food on the market

With regard to the transaction relating to the placing of modified organism as food on a market, the following additional information, where relevant, shall be presented by the applicant:

1/ equivalence studies;

2/ information on antibiotic resistance marker genes (if used);

3/ characterization of novel proteins or other novel substances which includes information about prior history of human consumption of the novel substances if any, or their similarity to substances previously consumed in food;

4/ the potential toxicity of novel proteins produced by the modified organisms;

5/ the potential allergenicity of novel proteins;

6/ compositional analysis of the modified organism as food or food derived from a modified organism;

7/ data to allow the nutritional impact of compositional changes in the food to be assessed;

8 data from animal feeding study;

9/ name the food will be marketed under.

15. **Information required where the transaction relates to the placing of the modified organism as feed on the market**

With regard to the transaction relating to the placing of the modified organism as feed on the market, the following additional information, where relevant, shall be provided by the applicant:

1/ the potential for adverse health effects to humans and livestock, including exposure to toxins and anti-nutritional factors, as well as irritation and allergenicity to humans;

2/ the potential to carry over of any novel product to manure and the potential impact of this to carry over;

3/ nutritional data which includes a comparison of the composition of the novel feed ingredient to that of the same feed ingredient derived from an appropriate counterpart;

4/ dietary exposure;

5/ toxicology data such as endogenous toxins or newly expressed material;

6/ allergenicity data;

7/ laboratory animal/livestock feeding trials.

16. **Information required where the transaction relates to the package containing the modified organism**

1/ With regard to the transaction relating to the package containing the modified organism, the applicant shall affix and show the following information on the package containing the modified organisms:

a) names and addresses including telephone number and e-mail of sender and reciever of the modified organisms;

b) the phrase "***contains modified organisms***" shall be written on the label in Amharic and English laguage whenever it is known that there is modified organism in the package.

2/ The phrase "*Contains no modified organisms*" may be written in Amharic and English on the label when the product is known to contain no modified organism.

17. **Effective Date**

This directive shall enter into force as of the 16/01 day of 2018

Dr. Gemedo Dalle

MINISTER OF MINSTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

መመሪያ ቁጥር 09/2011 **የተቋማት ደህንነተ ሕይወት ኮሚቴ ለማደራጀት የወጣ መመሪያ**	**DIRECTIVE NO. 09/2019** **A DIRECTIVE ISSUED TO ESTABLISH INSTITUIONAL BIOSAFETY COMMITTEES**
በልውጥ ሕያዋን ላይ ምርምር የሚያካሂዱ ተቋማት የምርምር ስራቸውን በሚያካሂዱበት ሂደት በስራ ላይ የሚገኙትን የደህንነተ ህይወት ህጎች እና የአሰረር ደረጃዎች እንዲያረጋግጡ በማስፈለጉ፤	WHEREAS institutions involved in the research of modified organisms are expected to ensure that their research is conducted in compliance with the applicable biosafety laws and standard operating procedures;
በልውጥ ሕያዋን ላይ ምርምር የሚያካሂዱ ተቋማት የምርምር ፈቃድ ማመልከቻ ለኮሚሽኑ ከማቅረባቸው በፊት በየተቋሙ ደህንነተ ሕይወት ኮሚቴ አስቀድሞ መገምገም በማስፈለጉ፤	WHEREAS it has become necessary for institutions conducting research involving modified organism to initially review applications by institutional biosafety committees before submitting to the Commission;
በልውጥ ሕያዋን ላይ ምርምር የሚያካሂዱ ተቋማት የምርምር ስራዎቻቸው በደህንነተ ሕይወት ህግጋት እና በፈቃድ ቅድመ ሁኔታዎች መሰረት እየተካሄዱ ስለመሆናቸው ለማረጋገጥ በየተቋማቱ የደህንነተ ህይወት ኮሚቴ ክትትልና ቁጥጥር ማድረግ አስፈላጊ መሆኑ ስለታመነበት፤	WHEREAS it has become necessary for institutions to undertake compliance and monitoring of researches involving modified organisms in line with the existing biosafety laws; and terms and conditions of approval;
የአካባቢ ደንና አየር ንብረት ለውጥ ኮሚሽን በደህንነተ ህይወት አዋጅ ቁጥር 655/2001 (በአዋጅ ቁጥር 896/2007 እንደተሻሻለው) አንቀጽ 25 መሰረት ይህን መመሪያ አውጥቷል።	THEREFORE, this directive is issued by the Environment forest and climate change commission in accordance with Article 25 of Proclamation No. 655/2009 (as amended by Proclamation No 896/2015).

1) ስያሜ

ይህ መመሪያ "የተቋማት ደህንነተ ሕይወት ኮሚቴ ለማደራጀት የወጣ መመሪያ ቁጥር 06/2011 ተብሎ ሊጠቀስ ይችላል።

2) የተፈጻሚነት ወሰን

ይህ መመሪያ በማንኛውም በልውጥ ሕያዋን ምርምር ስራ ላይ የተሰማራ ተቋም ላይ ተፈጻሚ ይሆናል።

3) የተቋማት ደህንነተ ሕይወት ማደራጀት

1/ ማንኛውም በልውጥ ሕያዋን ላይ ምርምር የሚያካሂድ ነባር ተቋም የሚያከናውናቸው የምርምር ስራዎች ከደህንነተ ህይወት ህግጋትና የአሰራር ደረጃዎች ጋር መጣጣማቸውን የሚያረጋገጥ ተቋማዊ ደህንነተ ህይወት ኮሚቴ ይህ መመሪያ በስራ ላይ ከዋለበት ቀን ጀምሮ ባሉት ስድስት ወራት ውስጥ ማደራጀት አለበት።

2/ ይህ መመሪያ በስራ ላይ ከዋለ በኃላ የሚቋቋም ማንኛውም በልውጥ ሕያዋን ምርምር ላይ የሚሰማራ ተቋም ከተቋቋመበት ቀን ጀምሮ ባለው ስምንት ወራት ውስጥ ተቋማዊ ደህንነተ ህይወት ኮሚቴ ማደራጀት አለበት።

3/ ማንኛውም በልውጥ ሕያዋን ምርምር ላይ የሚሰማራ ተቋም የተደራጀውን ተቋማዊ ደህንነተ ሕይወት ኮሚቴ ለኮሚሽኑ ወዲያውኑ ማሳወቅ አለበት።

1. Designation

This directive may be cited as "Directive Number 6/2019" issued to establish institutional biosafety committees.

2. Scope of application

This directive shall apply to any institution engaged in researches involving modified organisms.

3. Establishment of institutional biosafety committee

1/ Any existing institution, which undertakes research on modified organisms, shall establish institutional biosafety committee within six months from the date of entry into force of this directive to ensure the research activities are in line with the Biosafety laws and standard operating procedures.

2/ New research institutions that are established to conduct researches on modified organisms after the entry into force of this directive shall establish institutional biosafety committee within eight months from the date of their establishment.

3/ Any institution that is engaged in the research of modified organisms shall immediately notify the commission the institutional biosafety committee that is established under the institution.

4) የኮሚቴ አባላት ስብጥር

1/ ተቋማዊ ደህንነተ ሕይወት ኮሚቴ ቢያንስ ስድስት አባላት ይኖሩታል።

2/ ተቋማዊ ደህንነተ ሕይወት ኮሚቴ ከዚህ በታች የተዘረዘሩት የአባላት ስብጥር ይኖሩታል፡-

ሀ) የተቋሙ ዋና ኃላፊ ወይንም በኃላፊው የሚመደብ ሰው፣

ለ) ቢያንስ አንድ ሞለክዩላር ባዮሎጂስት እና አንድ የስነ-ምህዳር ባለሙያ (ኢኮሎጂስት)፣

ሐ) እንደ አስፈላጊነቱ ከአባላቱ አንዱ የሰው፣ የእንስሳት ወይም የዕጽዋት ጤና ባለሙያ፣

መ) የደሕንነተ ሕይወት ተጠሪ እና

ሠ) እንደአስፈላጊነቱ ተጨማሪ ባለሙያ ሊካተት ይችላል።

3/ የጥቅም ግጭት በሚከሰትበት በማንኛውም ጊዜ ሁሉም የኮሚቴው አባላት ኃላፊነት ለሰጣቸው ባለሥልጣን የማሳወቅ ግዴታ ይኖርባቸዋል።

4/ በዚህ አንቀጽ ንዑስ አንቀጽ (2) የተመለከተው እንደተጠበቀ ሆኖ የኮሚቴው አባላት በተቋሙ የሚከናወኑ ማንኛውንም የልውጥ ሕያዋን ምርምር በአግባቡ ለመገምገምና ለመከታተል የሚያበቃቸው የሳይንስና ቴክኖሎጂ ዕውቀትና ክህሎት ሊኖራቸው ይገባል።

5) የተቋማዊ ደሕንነተ ሕይወት ኮሚቴ ሰብሳቢ

1/ የኮሚቴው ሰብሳቢ በተቋሙ ኃላፊ መሰየም ይኖርበታል።

2/ የኮሚቴው ሰብሳቢ በልውጠ ሕያዋን የሳይንሳዊ ምርምር ሥራዎች በቂ ዕውቀትና

4) Composition

1/ Institutional biosafety committee shall have at least six members.

2/ Institutional biosafety committee shall be composed of the following members:

a) head of the institution or a person assigned by the head of the institution;
b) at least one molecular biologist and one ecologist;
c) a member with qualifications on human, animal or crop health as appropriate;
d) biosafety focal person and
e) any co-opted expert when necessary.

3/ Whenever conflict of interest arises, members of the committee shall have the obligation to notify to their appointing authority.

4/ Notwithstanding Sub –Article (2) of this Article, the committee members shall possess scientific and technological knowledge and expertise sufficient to enable them to properly evaluate and monitor any work involving modified organisms conducted by the institution.

5) Chairperson of the Institutional biosafety committee

1/ The Chairperson of the committee shall be designated by the head of the institution.

2/ The Chairperson shall have adequate knowledge and experience in scientific research pertaining to modified organisms.

ልምድ ያለው መሆን አለበት።

6) የኮሚቴ አባላት አሰያየም

1/ የኮሚቴ አባላት በሚመለከተው የምርምር ተቋም መሰየም አለባቸው።

2/ የኮሚቴው አባላት የአገልግሎት ዘመን አምስት ዓመት ሲሆን እንደአስፈላጊነቱ ለሁለተኛ የአገልግሎት ዘመን ሊመረጡ ይችላሉ።

7) የኮሚቴ አባላት ለውጥ

1/ ማንኛውንም የተቋማዊ የደህንነተ ሕይወት ኮሚቴ አባላት ላይ ለውጥ ሲደረግ ተቋሙ በሁለት ሳምንት ጊዜ ውስጥ ለኮሚሽኑ ማሳወቅ ይኖርበታል።

2/ ለኮሚሽኑ የአባለት ለውጥ ስለመደረጉ የሚላከው ማሳወቂያ የተከለሰ የአባለት ዝርዝር፣አድራሻ እና የአዳዲስ አባላት ሙሉ መረጃ መያዝ ይኖርበታል።

3/ ከዚህ በታች የተዘረዘሩት የተቋማዊ የደህንነተ ሕይወት ኮሚቴ አባላት ላይ ለውጥ ለማድረግ ምክንያት ሊሆኑ ይችላሉ:

ሀ/ የአባለት በሞት መለየት፣

ለ/ የሙያ ስነምግባር ጥሰት፣

ሐ/ በጤና ምክንያት፣

መ/ ከስራ በመልቀቅ፣

8. የተቋማዊ የደህንነተ ሕይወት ኮሚቴ ኃላፊነት

የተቋማዊ የደህንነተ ሕይወት ኮሚቴ ኃላፊነት ከዚህ በታች የተዘረዘሩትን የሚያጠቃልል ሲሆን በእነዚህ ብቻ የተወሰነ አይሆንም:-

6) **Appointment of members of the committee**

1/ Members of the committee shall be appointed by the respective research institution.

2/ The term of office of the members of the institutional biosafety committee shall be five years with a possibility of serving for a second term as appropriate.

7) **Changes in membership**

1/ If any change is made in the membership of the Institutional biosafety committee, the institution shall within two weeks notify such change to the commission.

2/ The notification that will be made to the commission shall contain the revised list of members, contact details and background information of the newly appointed members.

3/ The following can be possible causes to make changes in the membership of the institutional biosafety committee membership:-

a. death of a member,
b. breach of professional code of conduct,
c. unsound health conditions,
d. resignation from service.

ሀ) የደህንነተ ሕይወት ማመልከቻ የተሟላና አስፈላጊውን መረጃ መያዙን ያረጋግጣል፤

ለ) የተዘጋጀው የጠንቅ ግምገማ፣ የጠንቅ አያያዝ እና የአደጋ ጊዜ እቅድ በበቂ ሁኔታ መዘጋጀቱን ያረጋግጣል፤

ሐ) የቀረበውን ማመልከቻ በቅድመ ሁኔታ ወይም ያለ ቅድመ ሁኔታ ማጽደቅ እና ውድቅ ማድረግ ፤ አስፈላጊ ሆኖ ሲገኝ ተጨማሪ መረጃ እንዲቀርብ ይጠይቃል፤

መ) የቀረበለትን ማመልከቻ በስልሳ ቀናት ውስጥ ገምግሞ ምላሽ ይሰጣል፤

ሠ) በስራ ላይ የዋሉ የደህንነተ ሕይወት ህጎችን፣ በውሳኔ ጊዜ የተሰጡ ቅድመ ሁኔታዎች፣ ጋይድላየኖች እና ደረጃዎችን መሰረት በማድረግ በልውጥ ህያዋን ምርምር ላይ ወቅታዊ ክትትልና ቁጥጥር ያደርጋል፤

ረ) በየወቅቱ በቤተ ሙከራ፣ በመስክ እና በሌሎች የልውጠ ህያዋን የምርምር መስሪያዎች ላይ ክትትል ያደርጋል፤ አስፈላጊው ማስተካከያ ሲያስፈልግ ለምርምሩ መሪ ተመራማሪ፤ ለስራው ክፍል ኃላፊና ለተቋሙ ኃላፊ የማስተካከያ ምክረ ሀሳብ ይሰጣል፤

ሰ) ከፍተኛ የአሰራር ጥሰት ሲከሰት ለተቋሙ ሀላፊ ሪፖርት ያደርጋል ፤የተቋሙ ሀላፊም ይህንኑ ለኮሚሽኑ ሪፖርት ማድረግ ይኖርበታል፤

ሸ) ልውጥ ህያዋንን በተመለከተ ወቅታዊና አግባብነት ያለው መረጃ ለሚመለከታቸው ባለድርሻ አካላት ያሰራጫል፤

8) Responsibilities of the Institutional biosafety committee

The responsibilities of the institutional biosafety committee include, but are not limited to the following:

a. check the information provided in a biosafety application form is correct and complete;
b. appraise and ensure that the proposed risk assessment, risk management and emergency plans are sufficient;
c. approve or reject an application with or without conditions or request additional information when necessary;
d. review applications within sixty days from date of receipt;
e. regularly review, monitor and inspect experiments involving modified organisms for compliance as per existing biosafety laws, guidelines and terms and conditions of approval ;
f. ensure timely and periodic inspection of laboratory and other facilities, and provide recommendations to principal Investigators, departments and heads of institution for corrective measures;
g. report to the head of the institution in the event of severe non-compliance, which the head of the institution shall report the same to the commission;
h. distribute new and relevant biosafety

ቀ) የልውጥ ህያዋን ምርምር ስራዎች አገሪቷ ባወጣቻቸው የደህንነተ ህይወት ህጎችና የአሰራር መመሪያዎች እና ደረጃዎች መሰረት መከናወናቸውን ያረጋግጣል፤

በ) የምርምር ሰራተኞች ምርምር ለማካሄድ በቂ እና በሙያው የሰለጠነ የሰው ኃይል መኖሩን ያረጋግጣል፤

ተ) ጉልህ የህግ ጥሰት ዘገባ ለተቋሙ ኃላፊ ያቀርባል፤

9. ዘገባ

የደህንነተ ሕይወት ኮሚቴ በየስድስት ወሩ ወይም ኮሚሽኑ በጠየቀ ጊዜ ከዚህ በታች የተመለከቱትን ጉዳዮች የያዘ ዘገባ ለኮሚሽኑ ያቀርባል፡-

ሀ/ የኮሚቴው አባላት እና የሙያ ብቃት፤

ለ/ በኮሚቴው የጸደቀ ምርምር፤

ሐ/ በዚህ መመሪያ በአንቀጽ 8 መሰረት የተዘረዘሩ የኮሚቴው ተግባራት፤

መ/ የምርምር ተቋሙን የልውጠ ህያዋን አያያዝ አቅም የሰው ሀይልና መሰረተ ልማት፤

ሠ/ ተጋላጭነት እና አደጋዎች ላይ የቀረቡ የመፍትሄ ሀሳቦች፤

10. ተቋማዊ የደህንነተ ሕይወት ኮሚቴ ስብሰባ

ሀ) ኮሜቴው አስፈላጊ በሆነ ጊዜ ስብሰባ ያካሂዳል። ሆኖም ኮሚቴው ቢያንስ በዓመት ሁለት ጊዜ መሰብሰብ ይኖርበታል።

ለ) የኮሚቴው ማንኛውም ስብሰባ የሚካሄደው

information related to research on modified organisms to the concerned stakeholders;

i. ensure research is conducted inconsistent with applicable biosafety laws , guidelines and standards ;

j. ensure the research staff has adequate training and expertise to perform research;

k. report to the head of the institution of any significant non-compliance;

9. Reporting

An institutional biosafety committee shall every six months or when requested by the commission submit the following report to the commission :

a) members of the committee and their competence;

b) research approved by the committee;

c) functions of the committee as per Article 8 of this Directive;

d) information about the capacity of the research institution in managing modified organisms ,human resources and the infrastructure;

e) reports of recommendation on incidents of exposure and accidents;

10. Meetings of the Institutional biosafety committee

a) The Institutional biosafety committee shall meet as required. However the committee shall meet at least twice a year.

b) The quorum for any meetings of the committee shall constitute two third of the

ሁለት ሶስተኛው የኮሚቴው አባላት ተሚልተው ሲገኝ ነው።

ሐ)የኮሚቴው አብዛኛው አባላት የሚስማሙበት ሀሳብ የኮሚቴው ውሳኔ ሆኖ ይጸናል።

11. አስቸኳይ ስብሰባዎች

የኮሚቴው ሰባሳቢ አስቸኳይ ጉዳዮች ሲያጋጥሙ ኮሚቴውን ድንገተኛ ስብሰባ ሊጠራ ይችላል።

12. ለግምገማ መቅረብ ያለባቸው ሰነዶች

የኮሚቴ ስብሰባዎች ከመካሄዳቸው አስቀድሞ ውይይት የሚደረግባቸው ሰነዶች ቅጂ ለኮሚቴ አባላት ሊደርስ ይገባል።

13. የተቋማዊ ደህንነተ ህይወት ኮሚቴ ስብሰባዎች ቃለ ጉባኤ

1/ የኮሜቴው ቃለ ጉባኤ የሚከተሉትን መረጃዎች መያዝ ይኖርበታል:-

ሀ/ በስብሰባው የተገኙ የኮሚቴው አባላት፣ ተጋባዥ ባለሙያዎች ፣ ወይም ሌሎች ተሳታፊዎች ዝርዝር እና

ለ/ ስብሰባው ስለተካሄደበት አጀንዳ እና የተላለፉ ውሳኔውችን።

14. የኮሚቴው መዛግብት

የደህንነተ ህይወት ኮሚቴ ከዚህ በታች የተዘረዘሩትን መዛግብት መያዝ ይኖርበታል:-

ሀ/ የኮሚቴው ስብሰባዎች ቃለ-ጉባዔ፣

ለ/ በኮሚቴው የፀደቁ ፕሮክቶች እና ተያያዥ፣ ጉዳዮች መረጃ እና

ሐ/ ሌሎች አግባብነት ያላቸው ሰነዶች።

members.

c) Decision shall be made by a majority vote.

11. Emergency meetings

The Chairperson may call an emergency meeting of the institutional biosafety committee to address any urgent issues.

12. Documents to be reviewed

Members of the committee shall in advance receive copies of documents to be reviewed in meetings of the committee.

13. Minutes of institutional biosafety committee meetings

1/ Minutes of institutional biosafety committee meetings shall contain the following information:

a) attendance of members of the committee, invited experts or any participants;

b) agenda and decisions of the meeting;

14. Records of the committee

An Institutional biosafety committee shall maintain the following records:-

a) minutes of committee meetings and

b) Information about projects approved by the committee and other related matters;

c) Other relevant documents.

15. Confidentiality

1/ All members of the committee shall maintain confidentially of Intellectual Property or business information requested by the applicant or organization or institute to remain confidential and consented by the committee.

15. ሚስጥራዊነት

1/ ሁሉም የኮሚቴው አባላት በአመልካቹ ወይም በተቋሙ በሚስጥር እንዲጠበቅ የተጠየቀና ኮሚቴው የተስማማበት የአእምሮአዊ ንብረት ወይም የንግድ መረጃ በሚስጥር መጠበቅ ይኖርባቸዋል።

2/ ሁሉም የኮሚቴ አባላት በኮሚቴው ስብሰባ ወቅት በአባላት ወይም በተጋባዥ ባለሙያዎች የተነሱ ወይም በፅሁፍ የቀረቡ ሰነዶችን ሚስጥራዊነት የመጠበቅ ግዴታ አለባቸው።

16. የዋናው ተመራማሪ ሀላፊነቶች

1/ ዋናው ተመራማሪ ከዚህ በታች የተዘረዘሩት ሀላፊነቶች ይኖሩታል፡-

ሀ/ በልውጠህያዋን ላይ የሚካሄዱ ምርምሮች የደህንነተ ህይወት ህጎች፣ የአሰራር መመሪያዎች፣ ደረጃዎች እና በውሳኔ ወቅት የተመለከቱ ቅድመ-ሁኔታዎችን ይተገብራል፤

ለ/ የኮሚቴው አባላት በደህንነተ ህይወት ህጎች፣ አሰራር መመሪያዎች እና ደረጃዎች ላይ ቅድመ ስልጠና እና ማነቃቂያ ስልጠና ማግኘታቸውን ያረጋግጣል፤

ሐ/ በዝግ የመስክ ወይም የቤተ ሙከራ ምርምር ውስጥ ለሚሰሩ ሰራተኞች የአሰራር ስርዓትና የደህንነት መረጃ ያቀርባል፤

መ/ አስፈላጊ የደህንነት ቅድመ ጥንቃቄዎች በዝግ የመስክ ወይም የቤተ ሙከራ ምርምር ስለመወሰዳቸው ያረጋግጣል፤

2/ Members of the committee shall have the obligation to maintain the confidential nature of the opinions expressed by other members or invited experts during discussions in the meetings or provided in written form.

16. Roles of the principal investigator

1/ The Principal Investigator shall have the following responsibilities:-

a) implement biosafety laws, guidelines, standards and terms and conditions of approval in conducting any research involving modified organism;
b) ensure members of the committee receive initial refresher training on biosafety laws, guidelines and standards;
c) provide protocols and safety information to staffs working in containment or confinement facilities;
d) ensure that necessary safety precautions in containment or confinement facilities are maintained.
e) ensure proper handling and disposal of waste;
f) ensure laboratory and other research facilities maintain safety certifications;
g) notify in advance the institutional biosafety committee of any significant changes in experimental protocol or location of the research;
h) provide other relevant information to the

ሠ/ ተገቢ የቆሻሻ አያያዝና አወጋገድ መኖሩን ያረጋግጣል፤

ረ/ ላቦራቶሪዎች እና ሌሎች የምርምር መሳርያዎች የደህንነት ማረጋገጫ የምስክር ወረቀት መያዛቸውን ያረጋግጣል፣

ሰ/ ማንኛውም ጉልህ የምርምር አሰራርና ቦታ ለውጥ ለኮሚቴው ያሳውቃል፤

ሸ/ ለኮሚቴው ሌሎች ተገቢ መረጃ እንደ አስፈላጊነቱ ያቀርባል፤

ቀ/ ሰራተኞችን ለአደጋ ተጋላጭ የሚያደረጉ ሁኔታዎችን ለመከላከልና ለመቆጣጠር የሚያስችሉ በቂ ስልጠና መውሰዳቸውን ያረጋግጣል፤

17. የኮሚቴ አባላት ስልጠና

ሁሉም የኮሚቴው አባላት በደህንነቱ ህይወት ህጎች፤ አሰራር መመሪያዎች እና ደረጃዎች ላይ ቅድመ ስልጠና እና ማነቃቂያ ስልጠና ማግኘት አለባቸው።

18. መመሪያውን ስለማሻሻል

ኮሚሽኑ ይህን መመሪያ እንደ አስፈላጊነቱ በማንኛውም ጊዜ ሊያሻሽል ይችላል::

instructional biosafety committee as necessary.

17. **Training of members of the Institutional biosafety committee**

All members of the institutional biosafety committee shall receive initial and refresher training on biosafety laws, guidelines and standards.

18. **Amendment of the directive**

The Commission may modify this directive at any time as appropriate.

19. መመሪያው የሚፀናበት ጊዜ ይህ መመሪያ ከ.....ማርች 11.....ቀን 2011 ዓ.ም ጀምሮ የፀና ይሆናል። አዲስ አበባ.....ማርች 11.....ቀን 2011 ዓ.ም ፕሮፌሰር ፈቃዱ በየነ የአከባቢ ደንና አየር ንብረት ለውጥ ኮሚሽን ኮሚሽነር	**19.Effective Date** This directive shall enter into force as of the------- 20th of March day of 2019 **Done at Addis Ababa, this 20th of March day of 2019.** **Prof. Fikadu Beyene** **Environment, Forest and Climate Change Commission Commissioner**

የአከባቢ፣ የደንና የአየር ንብረት ለውጥ ኮሚሽን
Environment, Forest & Climate Change Commission

APPLICATION FOR CONFINED FIELD TRIALS TO TEST GM PRODUCT FOR ….TRAITS IN ETHIOPIA

GENERAL REQUIREMENTS FOR THE APPLICATIONS FOR CONFINED FIELD TRIALS (CFT)

1.0 Name and Contact Address of Applicant	
Name of the Institute/Organization , Tel: (+251)- Fax: (+251) - P.O. Box:	
1. 1 Date of Submission:	
1.2 Name of applicant Name of Principal Investigator: Email: Name of Trial Manager Collaborating Investigators:	1.3 Name of Institutional Biosafety Committee (IBC)

1.4 Institution of applicant	1.5 Registration Status in Ethiopia
1.6 Affiliating institution (s)	
Institution: Role: Address: P.O. Box Contact person: Telephone: Fax E-mail**:**	

1.6.1 Address of applicant's institution			
1.6.2 Telephone	1.6.3 Facsimile /email	1.6.4 Telephone	1.6.5 Facsimile/email

2.0 Nature and purpose of contained use (confined field trial (CFT))

2.1 Brief Description of Proposed contained use (CFT) activity
2.2 Purpose of contained use (CFT) - character of the activity that will be carried out by applicant (e.g. research, laboratory control, manufacture)
2.3 If the contained use (CFT) work is successful, indicate whether a general release of the GMO is planned
2.4 Total period of contained use (CFT) and date of its expected starting-up

3.0 Risk assessment

3.1 Summary of the risk assessment for the genes and species of GMO involved.
3.2 Description of potential risks associated with the transformed organism, transformation genes or gene elements.
Toxicity and Allergenicity of the Transformed Trait(s)
3.3 Description of potential risks associated with the activities to be undertaken

4.0 Location where contained use activities are to be undertaken

4.1 Contained Use Facility: Laboratory and growth chambers

4.1.1 Facility Location	4.1.2 Approval No. or reference	4.1.3 Number of other contained use activities currently approved within the same facility

4.1.4.Biosafety level assigned to facility during approval (Level 1, or level 2, or level 3 or level 4)
4.1.5.Code of practice of a workplace (Indicate type)
4.1.6.Emergency Response Plan in the event of an accident
4.1.7 Characteristics of the workplace (Tick as appropriate)

4.1.7.1 Microbiological laboratory	4.1.7.2 Pilot plant
4.1.7.3 Production facilities	4.1.7.4 Glasshouse/growth room
4.1.7.5 Animal breeding facility	4.1.7.6 Other (Specify)

4.1.8 Species and amount of used organism and the used genetic modifications including nominally mentioned validated methods for detection of occurrence of genetically modified organisms.
Waste management plan

4.2 Contained Use/CFT Facility:

4.2.1 Facility Location	4.2.2 Approval No. or reference	4.2.3 Number of other activities currently approved within the same facility

4.2.4 Experimental design
4.2.5. Nature and type of data to be collected
4.2.6 Arrangements for transporting the GMO to the greenhouse (CFT)
4.2.7 Proposed herbicide/pesticide use, if any

4.2.7.1 Name of the pesticide /herbicide	4.2.7.2 Active ingredient	4.2.7.3 Total area to be sprayed (m^2 /hectarage)

4.2.8 Provide work schedule (post approval) of key activities including but not limited to:		
4.2.8.1 Dates of movement of material	4.2.8.2 Planting (anticipated)	4.2.8.3 Harvest/Sampling (anticipated)

4.2.9 Describe your plan for recording the quantities of seed planted/GMO used and accounting for any excess
4.2.10 Describe the disposition plan, including how and where any excess, or non-planted seed/GMO will be disposed of or stored.
4.2.11 State whether plants will be allowed to set seed or to reproduce

4.2.12 Indicate whether any harvested plant material will be retained from the trial	4.2.12.1 If yes, Type (e.g. seed, leaves, etc.)
4.2.12.2 Quantity to be retained	4.2.12.3 Purpose of retaining material

4.2.13 For harvested plant material, describe the following if applicable:	
4.2.13.1 The storage method	4.2.13.2 Storage location
4.2.13.3 Person in the institution responsible for the storage of the material	
4.2.13.3.1 Name	4.2.13.3.2 Telephone

5.0. Nature and identity of genetically modified organism

5.1 Name of GMO		
5.2 Modified trait(s) Identification		
☐ Herbicide Tolerance ☐ Male sterility/restoration ☐ Insect Resistance ☐ Nutritional change ☐ Drought Tolerance	☐ Modified Oil Composition ☐ Virus Resistance ☐ Stress Tolerance ☐ Fungal Resistance	☐ Pharmaceutical ☐ Genetic Research ☐ Generation of mutants ☐ Other (Specify)
5.3 Modified Trait(s) Describe each specific new trait associated with this GMO.		
5.4 Describe Mode of action of traits (gene product, metabolic pathways).		
5.5. Description of the Vector		
5.5.1 Is the vector naturally pathogenic?	5.5.2 Is the vector disarmed?	5.5.3 If yes, how was the vector disarmed?
5.6 Method of introduction of the insert		
5.7. Method for detection of genetically modified organism		
5.8. Amount of genetically modified organism to be used (volume of the culture, number of plants or animals)		
5.8 Information on whether the genetically modified organism has already been approved in some other country and for what purpose.		

6.0 Nature and purpose of the contained use activities

6.1 In case of import or export of the genetically modified organism intended for contained use	
6.1.1 The country of origin or destination, as appropriate	6.1.2 Importer or exporter, as appropriate
6.1.3 Maximum amount of genetically modified organism to be imported or exported	6.1.4 Means of transportation
6.1.5 Means of packaging and labelling	
6.2 Measures to protect human health and the environment and biological diversity	
6.3 Frequency and the manner of carrying out control of the occurrence of genetically modified organism inside and outside of the contained space	
6.4 Description of waste management plan	

7.0 Containment measures

7.1 Plan of training of employees prior to the commencement of the use of genetically modified organisms, and the plan of their refresher training

8.0 Declaration of correctness of information

I certify that the above information is true to the best of my knowledge.

Principal Investigator

Name _____
Signature _____
Date _____

Collaborator(s)

Name _____
Signature _____
Date _____

Institutional Biosafety Committee (IBC) Review

This application has been reviewed by IBC
Name of IBC: _____
Name of Chairperson: _____
Signature _____
Date _____

REFERENCES

Annex 1: Collaborating Institutions: Roles and responsibilities

Organization	Expertise	Roles and Responsibilities

APPLICATION FOR UNDERTAKING DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISM IN ETHIOPIA

EXECUTIVE SUMMARY

PART ONE: GENERAL

1. General Information

1(1). Name, Address and Contact Details of Applicant	
Date of Submission:	

1(2). Name and field of studies of persons responsible for planning and carrying out the implementation of the Project, including those responsible for monitoring and safety, in particular the name of the responsible scientist.

Responsible Scientist

PART TWO:

INFORMATION ON DONOR RECIPIENT AND THE MODIFIED ORGANISM

2. Description of the Donor. Recipient and the Modified Organisms

With regard to donor, recipient and modified organisms, the following information shall be presented by an applicant:

2(1). Scientific name, and when available also common name of the donor organism;

2(2). Scientific name, and when available also common name of the recipient modified organism;

2(3). Scientific names, and when available also common names, of species that are related to any of the organisms from which any of the trans-genes in the expression cassette have been taken;

2(4). Degree of relatedness between the donor and recipient (between parental) organisms;

2(5). Description of the geographic distribution and of the natural habitats of the donor and recipient (between parental) organisms; the environments where they occur.

3. Characteristics of nucleic acids that affect trait expression

3(1). Description of each expression cassette;

32). Whether the nucleic acid that affects trait expression is introduced without change or has been modified;

3(3). Nucleic acid sequence of, inter alia, the target gene, promoter, terminator and selectable marker;

34). Description of the trait that it expresses

3(5). Methods used to construct the expression cassette;

3(6). Genetic markers;

3(7). Description of identification and detection techniques of the nucleic acids;

3(8). Quantitative expression of sensitivity, reliability and specificity of the identification and detection techniques;

3(9). Potential for nucleic acids involved in trait expression being transferred to or exchanged with other organisms;

3(10). Verification of the stability of the nucleic acids and factors affecting their stability

4. Characteristics of the Vector: 6(1). Nature and source of the vector;

5. Characteristics of the Modified Organism

5(1). Information relating to the modification:

5(2).Information on the modified organism:

1. Unique identifier of the transformation event;
2. Description of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or may no longer be expressed;
3. Stability of the traits;
4. Expression of the introduced new genetic material and methods and sensitivity of measurement
5. Function of the expressed protein;
6. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques of the modified organism;
7. History of previous releases or uses of the modified organism;
8. Risks to human or animal health, biological diversity and the environment;
9. Generation time in natural ecosystems, sexual and asexual reproductive cycles;
10. Information on survival, including seasonality and the ability to form seeds, spores, sclerotia and other survival structures;
11. Pathogenicity, infectivity, toxicity, virulence, allergenicity, ability to be a carrier (vector) of pathogens,
12. identity of possible vectors to transmit it to humans or animals as a disease causing agent, host range, possible activation of latent viruses, ability to colonize other organisms, ability of nucleic acids or other molecules that affect trait expression to be introduced into the cells or tissues of other species;

5(3). Considerations of impacts on health:

PART THREE

INFORMATION RELATING TO THE RECEIVING ENVIRONMENT AND INTERACTION BETWEEN THE MODIFIED ORGANISM AND THE RECEIVING ENVIRONMENT

6. Information on the Deliberate Release

6(1). Description of the proposed deliberate release, including the purpose and foreseen outcome;

6(2). Planned dates and durations of the release;

6(3). Method to be used for the release;

6(4). Quantity of modified organism to be released;

6(5). Site preparation prior to release (type and method of cultivation, mining, irrigation, or other activities);

6(6). Information on, and results of, previous releases of the modified organism especially at different scales and in different ecosystems.

7. Survival, multiplication, dispersal and trait expression

7(1). Biological features which affect the survival, multiplication and dispersal of the modified organism;

7(2). Known or predicted environmental conditions which may affect the survival, multiplication and dispersal (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals, horizontal gene transfer and others) of the modified organism or of its genes or other biochemicals that affect trait expression)

8. Interactions with the environment

8(1).Habitat types expected to be suitable for the modified organism;

8(2).Experiments carried out on the behavior of the modified organism and an assessment of its ecological impact carried out in simulated natural environments,

8(3).Trait transfer capability:

8(4). Likelihood of post-release interaction leading to the expression of unexpected or undesirable traits in the modified organism or in its products;

8(5). Measures employed to ensure and verify genetic stability; description of genetic traits which may prevent the transfer of genetic materials; methods used to verify stability;

8(6). Routes of biological dispersal of the modified organism, known or potential modes of interaction with the disseminating agents,

8(7). Description of ecosystem to which the modified organism could be disseminated.

9. Potential environmental impacts

9(1). Potential for excessive population increase of the modified organism in the environment;

9(2). Competitive advantage of the modified organism in relation to the unmodified or parental species;

9(3). Identification and description of the target species that are anticipated to be affected by the modified organism;

9(4). Anticipated mechanism and result of interaction between the released modified organism and the target species;

9(5). Identification and description of non-target species which may be affected;

9(6). Likelihood of post-release shifts in biological or in target range;

9(7). Known or predicted effects on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens;

9(8). Known or predicted involvement of the modified organism in bio-geochemical processes;

9(9). Other potentially significant interactions with the environment.

10. Information on monitoring and monitoring techniques

10(1). Specificity, sensitivity and reliability of the monitoring techniques to identify the modified organism;

10(2). Techniques for detecting the transfer of the introduced transgene to other organisms;

10(3). Methods for detecting aberrant expression of traits and their causes.

PART FOUR

ADDITIONAL INFORMATION REQUIRED FOR PLACING ON A MARKET A COMMODITY CONSISTING OF A MODIFIED ORGANISM

11. Information required where the transaction relates to an application for placing a modified organism on a market

11(1). Name of the commodity, the scientific and common names and the transformation event of the modified organism;

11(2). Names and addresses, including telephone numbers and e-mails, of the maker and the distributor of the modified organism;

11(3). Specification for accessing information on the modified organism in the Biosafety Clearing House of the Protocol;

11(4). Type of expected use;

11(5). Specific instructions for storage and handling.

12 Information required where the transaction relates to the placing of modified organism as food on the market

12(1). Equivalence studies;

12(2). Information on antibiotic resistance marker genes (if used);

12(3). Characterization of novel proteins or other novel substances (which includes information about prior history of human consumption of the novel substances if any, or their similarity to substances previously consumed in food;

12(4). The potential toxicity of novel proteins produced by the modified organisms;

12(5). The potential allergenicity of novel proteins;

12(6). Compositional analysis of the modified organism as food or food derived from a modified organism;

12(7). Data to allow the nutritional impact of compositional changes in the food to be assessed;

14(8). Data from animal feeding study;

12(9). Name the food will be marketed under.

13. Information required where the transaction relates to the placing of the modified organism as feed on the market

13(1). The potential for adverse health effects to humans and livestock,

13(2). The potential to carry over of any novel product to manure and the potential impact of this to carry over;

13(3). Nutritional data which includes a comparison of the composition

13(4). Dietary exposure;

13(5). Toxicology data such as endogenous toxins or newly expressed material;

13(6). Allergenicity data

13(7). Laboratory animal/livestock feeding trials

14. Socio-Economic Considerations

Declaration of the Applicant

I Certify that the above information is true to the best of my knowledge

Name_____

Signature_____

Date_____

Collaborator(s)

Name_____

Signature_____

Date_____

Institutional Biosafety Committee (IBC) Review

This application has been reviewed by IBC

Name of IBC: _____

Name of Chairperson: _____

Signature _____

Date _____

REFERENCES

2. Biosafety Proclamations

የኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ

ፌዴራል ነጋሪት ጋዜጣ

FEDERAL NEGARIT GAZETA

OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

አሥራአምስተኛ ዓመት ቁጥር ፷፫ አዲስ አበባ ጳጉሜ ፬ ቀን ፪ሺ፩ ዓ.ም	በኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ የሕዝብ ተወካዮች ምክር ቤት ጠባቂነት የወጣ	15th Year No. 63 ADDIS ABABA 9th September, 2009

አዋጅ ቁጥር ፮፻፶፭/፪ሺ፩

ስለደህንነት ሕይወት የወጣ አዋጅ

በኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ሕገ መንግሥት አንቀጽ ፵፬ እና አንቀጽ ፺፪ የተደነገገው የአካባቢ ደህንነት መብት የሰውና የእንስሳት ጤናን፣ የአካባቢ ደህንነትን፣ ባጠቃላዩም የአገሪቷን ማህበራዊና ኢኮኖሚያዊ ሁኔታዎችን ከልውጥ ሕያዋን ሊከሰል ከሚችል ጠንቅ መጠበቅን አስፈላጊ ስለሚያደርገው፤

በኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ሕገ መንግሥት አንቀጽ ፶፭/፩/ መሠረት የሚከተለው ታውጇል።

፩. አጭር ርዕስ

ይህ አዋጅ "የደህንነት ሕይወት አዋጅ ቁጥር ፮፻፶፭/፪ሺ፩" ተብሎ ሊጠቀስ ይችላል።

፪. ትርጓሜ

የቃሉ አግባብ ሌላ ትርጉም ካላሰጠው በስተቀር በዚህ አዋጅ ውስጥ፡-

፩/ "ልውጥ ሕያው" ማለት ሰው ሰራሽ የሆነ ወይም ከሌላ ሕያው የተወሰደ ይሁን ከቅ ሪት የተወሰደ ወይም እንደአዲስ የተቀመመ ባይተዋር ዘረመል ወይም ሌላ ንጥረ ነገር ስለተከተተበት የዘረመሎች ይዘቱ ወይም የባሕርዩ ክስተት የተለወጠበት ሕያው ነው፤

PROCLAMATION NO. 655/2009

A PROCLAMATION ON BIOSAFETY

WHEREAS, the environmental rights provided under Articles 44 and 92 of the Constitution of the Federal Democratic Republic of Ethiopia require that human and animal health, environmental wellbeing and, in general, the socio-economic conditions of the country be protected from risks that may arise from modified organisms;

NOW, THEREFORE, in accordance with Article 55(1) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follows:

1. Short Title

This Proclamation may be cited as the "Biosafety Proclamation No.655./2009".

2. Definitions

In this Proclamation, unless the context otherwise requires:

1/ "modified organism" means any biological entity which has been artificially synthesized, or in which the genetic material or the expression of any of its traits has been changed by the introduction of any foreign gene or any other chemical whether taken from another organism, from a fossil organism or artificially synthesized;

ያንዱ ዋጋ
Unit Price

ነጋሪት ጋዜጣ ፖ.ሣ.ቁ. ፹ሺ፩
Negarit G. P.O.Box 80001

፪/ "እንቅስቃሴ" ማለት ልውጥ ሕያውን መሥራት ወይም ለትምህርት፣ ለምርምር፣ ለምርት፣ ወደ አገር ውስጥ ለማስገባት፣ ወደ ውጪ ለመላክ፣ በትራንዚት ለማስተላለፍ፣ ለተጨነ ልቀት፣ በዝግ ለማምረት፣ ለማጓጓዝ፣ ለገበያ ለማቅረብ፣ ለሰው ወይም ለእንስሳ በመድኃኒትነት ለመጠቀም፣ ለምግብነት፣ ለመኖነት ወይም ለፋብሪካ ጥሬ ዕቃነት ማዋል ነው፤

2/ "transaction" means any making or use of any modified organism in teaching, production, import, export, transit, release, contained production, transport, placing on the market, or use as pharmaceutical, as food, as feed or for processing;

፫/ "መሥራት" ማለት በዘመናዊ ጥበበ ሕይወት ልውጥ ሕያው እንዲገኝ ማድረግ ነው፤

3/ "making" means the development of a modified organism through modern biotechnology;

፬/ "ዝግ አጠቃቀም" ማለት በሰው ወይም በእንሰሳት ጤና ወይም በአካባቢ ላይ የሚከተል ያልታቀደ ተፅዕኖን ለመከላከል በቁሳዊና በንጥረ ነገራዊ ከለላ ታጥረውና በባለሥልጣኑ በወጣው በተገቢው መመሪያ ከተፈቀደው ስፋት ባልበለጠ ቦታ ተወስነው ልውጥ ሕያዋን እንዲሰሩ፣ እንዲያድጉ፣ እንዲከማቹ፣ እንዲወገዱ ወይም ትምህርት-ንና ምርምርን ጨምሮ በሆነ ሌላ መንገድ በጥቅም ላይ እንዲውሉ ማድረግ ነው፤

4/ "contained use" means any operation in which modified organisms are produced, grown, stored, destroyed or used in some other way including for teaching and research isolated by physical and chemical barriers in space not exceeding the requirement stated in the appropriate directive issued by the Authority with a view to effectively preventing their contact with, and their unintended impact on, human, animals and the external environment;

፭/ "የተጨነ ልቀት" ማለት ከግንዛቤ በመነጨ ስምምነት መሠረት ልውጥ ሕያውን ለንግድ፣ ለምግብ፣ ለእርዳታ ምግብ፣ አካባቢን ለማዕዳት፣ ለማስተማሪያነት፣ ለምርምር፣ ለመስተዋት ቤት፣ ለውሃ ውስጥ አርባታ፣ ለእንስሳት መኖ፣ ለሰው ወይም ለእንስሳት ህክምና ወይም ለሌላ ጥቅም በመዋል ወደ አካባቢ እንዲዳረስ ማድረግ ነው፤

5/ "deliberate release" means any introduction into the environment of a modified organism based on an advance informed agreement and includes, inter alia, any use in commerce, food, aid food, remediation, teaching, research, greenhouses, aqua-culture, animal feed or other inputs for animals, medicines for humans or animals, or disposal;

፮/ "ከግንዛቤ የመነጨ ስምምነት" ማለት በዚህ አዋጅ መሠረት እንድ እንቅስቃሴ እንዲ ተገበር ከባለሥልጣኑ የሚሰጥ የአምንታ ጽሑፍ ነው፤

6/ "advance informed agreement" means a written consent granted by the Authority for the undertaking of a transaction in accordance with this Proclamation;

፯/ "ለገበያ ማቅረብ" ማለት ልውጥ ሕያውን ለተጨነ ልቀት ለማዋል ከግንዛቤ የመነጨ ስምምነትን ከተቀበለ በኋላ በእርዳታ ምግብነት መስጠትን ጨምሮ ለሶስተኛ ወገን በሽያጭ፣ በስጦታ ወይም በሌላ መንገድ ማስተላለፍ ነው፤

7/ "placing on the market" means obtaining an advance informed agreement for deliberate release and making available to third parties a modified organism for any use by selling, giving away or in any other way, and includes giving as aid food;

፰/ "ማህበራዊና ኢኮኖሚያዊ ተፅዕኖ" ማለት ከማንኛውም እንቅስቃሴ በቀጥታ ወይም በተዘዋዋሪ መንገድ የአገር ኢኮኖሚን ጨምሮ በማሕበረሰቦች ማህበራዊ ወይም ባሕላዊ ሁኔታዎች፣ የኑሮ መሠረት፣ ነባር ዕውቀት ወይም ጥበብ ላይ የሚደርስ አሉታዊ ውጤት ነው፤

8/ "socio-economic impact" means any direct or indirect adverse effect that results from a transaction on the social or cultural conditions, the livelihood or indigenous knowledge systems or technologies of a local community, including on the economy of the country;

፱/ "ጠንቅ" ማለት ከየትኛውም እንቅስቃሴ በቀጥታ ወይም በተዘዋዋሪ መንገድ፣ በአጭር፣ በመካከለኛ ወይም በረጅም ጊዜ በሰው ወይም በእንስሳ ጤና፣ በብዝሐ ሕይወት፣ በአካባቢ፣ በማህበረሰቦች ማህበራዊ፣ ኢኮኖሚያዊ ወይም ባህላዊ ሁኔታ፣ ወይም በአገሪቷ ኢኮኖሚ፣ ላይ ሊከተል የሚችል አደጋ ነው፤

9/ "risk" means direct or indirect, short, medium or long-term danger that may befall human or animal health, biological diversity, the environment, socio-economic or cultural conditions of local communities or the economic condition of the country from any transaction;

፲/ "ፕሮቶኮል" ማለት በአዋጅ ቁጥር ፫፻፷፪/፲፱፻፺፭ የፀደቀው የብዝሐ ሕይወት ኮንቬንሽን የካርታጌና የደሕንነተ ሕይወት ፕሮቶኮል ነው፤

10/ "Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity ratified by Proclamation No. 362/2003;

፲፩/ "ሥልጣን ያለው ብሔራዊ መሥሪያ ቤት" ማለት በፕሮቶኮሉ ከአንቀጽ ፯ እስከ ፲፪ የተዘረዘሩትን ተግባራት እንዲያስፈፅም ልውጥ ሕያው ወደ ኢትዮጵያ ከሚላክበት አገር መንግሥት ሥልጣን የተሰጠው ተቋም ነው፤

11/ "competent national authority" means the institution of a country of export of any modified organism designated by the government of that exporting country to carry out the functions stipulated under Articles 7 to 12 of the Protocol;

፲፪/ "ባለሥልጣን" ማለት በአዋጅ ቁጥር ፬፻፺፮/፲፱፻፺፯ የተቋቋመው የኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ የአካባቢ ጥበቃ ባለሥልጣን ነው፤

12/ "Authority" means the Environmental Protection Authority of the Federal Democratic Republic of Ethiopia established pursuant to Proclamation No. 295/2002;

፲፫/ "ሥልጣን የተሰጠው ፈቃድ ሰጪ መሥሪያ ቤት" ማለት የንግድ ወይም የሥራ ፈቃድ እንዲሰጥ በህግ ሥልጣን የተሰጠው ማንኛውም የመንግሥት አካል ነው፤

13/ "competent licensing agency" means any organ of government empowered by law to issue a business license or a work permit;

፲፬/ "ተቆጣጣሪ" ማለት ይህ አዋጅና በአዋጁ መሠረት የወጡ ደንቦችና መመሪያዎች መከበራቸውን ለማረጋገጥ የፍተሻና ሌላ የቁጥጥር እርምጃ እንዲወስድ ባለሥልጣኑ በሚያወጣው መመሪያ መሠረት የተሾመ ሰው ነው፤

14/ "inspector" means a person appointed pursuant the directives issued by the Authority to undertake examination and any other control measures to ensure compliance with this Proclamation and with regulations and directives issued hereunder;

፲፭/ "ብሔራዊ የደህንነተ ሕይወት የመረጃ ሥርዓት" ማለት በፕሮቶኮሉ አንቀፅ ፳ መሠረት ስለልውጥ ህያዋን የሚዘግቡ ሳይንሳዊ፣ ጥበባዊ፣ አካባቢያዊና ሕግ ነክ መረጃዎችንና የልውጥ ህያዋን አያያዝን በሚመለከት የልምድ ልውውጥ ለማስገኘት በባለሥልጣኑ የተዘረጋ ሥርዓት ነው፤

15/ "national biosafety clearing-house" means a system of acquisition and management of, and access to, information established by the Authority based on Article 20 of the Protocol in order to facilitate the exchange of scientific, technical, environmental and legal information and experience with modified organisms;

፲፮/ "ክልል" ማለት በኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ሕገ መንግሥት አንቀጽ ፵፯ የተመለከተው ማንኛውም ክልል ሲሆን የአዲስ አበባ እና የድሬዳዋ የከተማ አስተዳደሮችን ይጨምራል፤

16/ "region" means any regional state referred to in Article 47 of the Constitution of the Federal Democratic Republic of Ethiopia and includes the Addis Ababa and Dire Dawa city administrations;

፲፯/ "አመልካች" ማለት የሚጠይቀውን እንቅስቃሴ ለማካሄድ ከግንዛቤ የመነጨ ስምምነት እንዲሰጠው ለባለሥልጣኑ ያመለከተ ሰው ነው፤

17/ "applicant" means any person who submits an application to the Authority seeking an advance informed agreement to engage in a transaction;

፲፰/ "ፈቃድ የተሰጠው ሰው" ማለት ከግንዛቤ የመነጨ ስምምነት ከባለሥልጣኑ የተሰጠው ሰው ነው፤

18/ "authorized person" means any person who has been given an advance informed agreement by the Authority;

፲፱/ "ሰው" ማለት የተፈጥሮ ሰው ወይም በሕግ የሰውነት መብት የተሰጠው አካል ነው፤

19/ "person" means a natural or juridical person;

፳/ ማንኛውም በወንድ ጾታ የተገለጸው አነጋገር ሴትንም ይጨምራል።

20/ any expression in the masculine gender includes the feminine.

፫. የተፈጻሚነት ወሰን

3. Scope of Application

፩/ የዚህ አንቀጽ ንዑስ አንቀጽ /፪/ እና /፫/ ድንጋጌዎች እንደተጠበቁ ሆኖ ይህ አዋጅ በማንኛውም እንቅስቃሴ ላይ ተፈፃሚ ይሆናል።

1/ Without prejudice to the provisions of sub-article (2) and (3) of this Article, this Proclamation shall apply to any transaction.

፪/ ኢትዮጵያ ያፀደቀችው እስከሆነ ድረስ ለሰው ሕክምና የሚሆንን፣ በኢትዮጵያ ግዛት በትራንዚት የሚያልፍን ወይም ጎጂ ተፅዕኖ የማምጣት እድል የለውም የተባለን ልውጥ ሕያው የሚመለከት ዓለም ዓቀፍ ስምምነት በኢትዮጵያ ተፈጻሚ ይሆናል።

2/ Any treaty, provided that it has been ratified by Ethiopia, on the regulation of modified organism that is to be used as a pharmaceutical for humans, that is to transit through Ethiopian territory or that has been declared to have no adverse effect shall be applied throughout the territory of Ethiopia.

፫/ ባለሥልጣኑ በዚህ አንቀጽ ንዑስ አንቀጽ /፪/ የተጠቀሱት እንቅስቃሴዎችን የሚመለከት መረጃ በዚህ አዋጅ አንቀጽ ፲፫ መሠረት በተቋቋመው ብሔራዊ የደሕንነተ ሕይወት የመረጃ ሥርዓት ማስገባት አለበት።

3/ The Authority shall place information regarding the transactions referred to under sub-article (2) of this Article on the National Biosafety Clearing House established under Article 13 of this Proclamation.

፬. የአዋጁ ዓላማ

4. Objective of the Proclamation

የአዋጁ ዓላማ በሰውና በእንስሳት ጤና፣ በብዝሐ ሕይወት፣ በአካባቢ፣ በማኅበረሰቦችና በአጠቃላዩም በሀገር ላይ ከልውጥ ሕያዋን ሊደረስ የሚችለውን አሉታዊ ተፅዕኖ ማስቀረት ወይም ቢያንስ እስከ ኢምንታዊነት ደረጃ ድረስ ማሳነስ ነው።

The objective of this Proclamation is to protect human and animal health, biological diversity and in general, the environment , local communities and the country at large by preventing or at least managing down to levels of insignificance the adverse effects of modified organisms.

፭. ከግንዛቤ የመነጨ ስምምነት

5. Advance Informed Agreement

፩/ የዚህ አዋጅ አንቀጽ ፫ ድንጋጌዎች እንደተጠበቁ ሆነው ከግንዛቤ የመነጨ ስምምነትን ያላገኘ ሰው በማንኛውም እንቅስቃሴ ለመሰማራት አይፈቀድለትም።

1/ Without prejudice to the provisions of Article 3 of this Proclamation, no person shall engage in any transaction without obtaining an advance informed agreement.

፪/ በማንኛውም እንቅስቃሴ ለመሰማራት የሚፈልግ ሰው በዚህ አዋጅና በአዋጁ መሠረት በሚወጡት ደንቦችና መመሪያዎች መሠረት የተዘጋጀ ማመልከቻ ለባለሥልጣኑ ማቅረብ አለበት።

፫/ ባለሥልጣኑ ከግንዛቤ የመነጨ ስምምነት ለመስጠት እንዲቻለው አመልካቹ በዚህ አዋጅ የተመለከቱ ግዴታዎችን ለማሟላት በቂ ዋስትና እንዲያቀርብ መጠየቅ ይችላል።

፮. የአመልካች ግዴታ

፩/ አመልካቹ የጠንቅ ግምገማውን በዚህ አዋጅ መሠረት በሚወጡ ደንቦችና መመሪያዎች መሠረት ብቃት ባለው ባለሙያ ማካሄድና ዘገባ ማዘጋጀት፣ ዘገባውንም ባለሥልጣኑ ያስፈልጋሉ ካላቸው ከሌሎች ሰነዶች ጋር ለባለሥልጣኑ ማቅረብ አለበት።

፪/ የጠንቅ ግምገማ ዘገባው ከዝርዝር ሙያዊ ትንታኔው በተጨማሪ ማንም ሊረዳው በሚችል ቋንቋ የትንታኔውን ይዘት ባጭሩ ከያዘ መግለጫ ጋር መቅረብ አለበት።

፫/ የጠንቅ ግምገማ የማካሄጃና ዘገባ የማዘጋጃ ወጪ በአመልካቹ መሸፈን አለበት።

፯. ምንነትን መለየትና ጽፎ መለጠፍ

፩/ በዚህ አዋጅ መሠረት በሚወጡ አግባብነት ባላቸው ደንቦችና መመሪያዎች መሠረት የልውጥ ሕያዉን ምንነት በአማርኛና በእንግሊዘኛ ቋንቋዎች የሚገልፅ ዕሁፍ በልውጥ ሕያው ጥቅል ላይ ባልተለጠፈበት ልውጥ ህያው ከቤተ ሙከራ ዝግ ሁኔታ ውጪ ማንኛውም እንቅስቃሴ መካሄድ የለበትም።

፪/ "በዘረመላዊ ምሕንድስና የተለወጠ ሕያው ይገኝበት ይሆናል" የሚል ወይም ተመሳሳይ ግልጽ ያልሆነ ጽሁፍ በጥቅሉ ላይ መለጠፍ የተከለከለ ነው።

፫/ በልውጥ ሕያዋን ጥቅል ውስጥ የሚገኘውን ማንኛውንም ልውጥ ሕያዉ ምንነት በተለጠፈበት ጽሁፍ ላይ ሳይገልጹ መተው የተከለከለ ነው።

፬/ ማንኛውም ሰው በጥቅሉ ውስጥ ምንም ዓይነት ልውጥ ሕያው የማይገኝበት መሆኑን ካረጋገጠ "ልውጥ ሕያው የለበትም" የሚል ጽሁፍ ሊለጥፍበት ይችላል።

2/ Any person who intends to engage in any transaction shall submit to the Authority an application prepared in accordance with this Proclamation and regulations and directives to be issued pursuant to this Proclamation.

3/ The Authority may, as a condition for giving any advance informed agreement, require the applicant to furnish a guarantee which shall be sufficient to meet his obligations under this Proclamation.

6. Responsibility of Applicant

1/ The applicant shall use a qualified expert to undertake a risk assessment and prepare the report in accordance with regulations and directives issued pursuant to this Proclamation and submit the same to the Authority together with any other documents determined as necessary by the Authority.

2/ Besides a detailed technical analysis, a risk assessment report shall include a brief statement summarizing the report in non-technical terms.

3/ The cost of carrying out a risk assessment and writing a risk assessment report shall be borne by the applicant.

7. Identification and Labeling

1/ No transaction shall be carried out outside of the contained conditions of a laboratory unless the package of the modified organism has been labeled in both Amharic and English in accordance with the relevant regulations and directives issued pursuant to this Proclamation.

2/ It is prohibited to write "may contain modified organisms" or any equivalent unspecific statement on a label.

3/ It is prohibited to leave out any modified organism that is in the package of a modified organism unwritten on the label.

4/ Any person is entitled to write the words "contains no modified organism" when the product in a package is known to be free from modified organisms.

፰. ልውጥ ሕያው ወደ አገር ውስጥ ማስገባት

፩/ ከግንዛቤ የመነጨ ስምምነት ሳይዙ ልውጥ ሕያውን ወደ አገር ውስጥ ማስገባት የተከለከለ ነው።

፪/ ልውጥ ሕያውን ወደ አገር ውስጥ ለማስገባት ከግንዛቤ የመነጨ ስምምነት እንዲሰጥ ከሚቀርበው ማመልከቻ ጋራ የሚያያዘው መረጃ ትክክለኛና የተሟላ ስለመሆኑ የላኪው አገር ሥልጣን ያለው ብሔራዊ መሥሪያ ቤት ሙሉ ኃላፊነት መውሰዱን የመሥሪያ ቤቱ ኃላፊ በፊርማው ያረጋገጠበት መሆን አለበት።

፱. መሥራትና ሌሎች ዝግ አጠቃቀሞች

፩/ ልውጥ ሕያውን የሚሰራ ሰው የሚጠቀም-ባቸው ወላጅ ሕያዋንን ባሕርያት፣ ምርምሩ የሚካሄድበትን ቦታና የአካባቢውን ሁኔታ በመገምገም በቅድመ ጥንቃቄ መርሕ ተመ-ስርቶ በሳይንሳዊነቱ ተቀባይነት ያለውንና በአካባቢ ላይ ጠንቅ የማያስከትልን አሠራር በመከተል ሊከሰት የሚችል ጠንቅን ወደ ኢምንታዊነት ደረጃ መቀነስ አለበት።

፪/ በዝግ የአጠቃቀም ሁኔታ በልውጥ ሕያው ተጠቃሚ የሆነ ሰው ባልተጤነ ልቀት ምክንያት የሚከተለውን ጨምሮ ማንኛው-ምንም አደጋ ለማስቀረት አስፈላጊ የሆኑ የደህንነት ጥንቃቄዎች መወሰዳቸውን ማረጋገጥ እና የተሰራውን ልውጥ ሕያው ወይም የዋለበትን አገልግሎት እንዲሁም ማንኛውንም ያልታሰበ ክስተት በመዝገብ መያዝ አለበት።

፫/ ዝግ አጠቃቀም በዚህ አዋጅ መሠረት በሚወጡ ደንቦችና መመሪያዎች መሠረት ለዚሁ ተግባር ማካሄጃ በባለሥልጣኑ ተመዝግቦ ፈቃድ በተሰጠው ቦታ ብቻ መካሄድ አለበት።

፲. በትራንዚት ማሳለፍ

፩/ ልውጥ ሕያውን በኢትዮጵያ ግዛት በኩል በትራንዚት ለማሳለፍ የሚፈልግ ሰው ይህንኑ ለባለሥልጣኑ በቅድሚያ ማሳወቅ አለበት።

፪/ ባለሥልጣኑ በኢትዮጵያ ግዛት በኩል በትራንዚት ቢያልፍ አደገኛ ሆኖ የሚያገኘውን ልውጥ ሕያው በፕሮቶኮሉ የመረጃ ሥርዓት እንዲገለፅ ማድረግ አለበት።

8. Importation of Modified Organisms

1/ Importation of any modified organism without obtaining an advance informed agreement is prohibited.

2/ An application for an advance informed agreement for the importation of a modified organism shall be accompanied by a statement signed by the head of the competent national authority of the country of export to the effect that the competent national authority takes full responsibility for the completeness and accuracy of the information provided.

9. Making and other forms of Contained Use

1/ Any person who makes a modified organism shall take into account the characteristics of the parental organisms used, the research site and the surrounding environment, and apply scientifically acceptable and environmentally sound practices based on the precautionary principle in order to minimize possible risks to insignificant level.

2/ Any person that uses a modified organism under contained conditions shall ensure that the necessary safety precautions, including measures to limit the detrimental effects of any unintentional release, are taken and shall keep records of all the making or use of the modified organism and of any unforeseen event encountered.

3/ Any contained use shall take place only in a facility registered by the Authority for such use in accordance with regulations and directives issued pursuant to this Proclamation.

10. Transit

1/ A person who wishes to carry out any transit of a modified organism through the territory of Ethiopia shall notify the authority before that transit takes place.

2/ The Authority shall place any modified organism that it deems dangerous to transit through the territory of Ethiopia in the Biosafety Clearing-House of the Protocol.

፲፩. የሕዝብ ተሳትፎ

፩/ ባለሥልጣኑ የጠንቅ ግምገማ ዘገባ እንደደረሰው ዘገባውን በሕዝብ ማስታወቂያ አውታሮች በኩል ለባለድርሻዎች በማሰራጨት ከአንድ ወር ላልበለጠ ጊዜ አስተያየቶችን መሰብሰብ አለበት።

፪/ ከግንዛቤ የመነጨ ስምምነት ስለመስጠት ወይም ስላለመስጠት የሚቀርቡ አስተያየቶች ባለሥልጣኑ በወሰነው የጊዜ ገደብ ውስጥ በጽሑፍ መቅረብ አለባቸው

፲፪. ብሔራዊ የደህንነት ሕይወት መረጃ ስርዓት

፩/ ባለሥልጣኑ ብሔራዊ የደህንነት ሕይወት መረጃ ሥርዓት ማቋቋም አለበት።

፪/ በዚህ አንቀጽ ንዑስ አንቀጽ /፩/ መሠረት የሚቋቋመው የደህንነት ሕይወት መረጃ ሥርዓት የሚከተሉትን መረጃዎች መያዝ አለበት፡-

ሀ/ በልውጥ ህያዋን እውቀት ያላቸው በኢትዮጵያ ውስጥ የሚገኙ ባለሙያዎች ስም፣ አድራሻና ሌሎች ተዛማጅ መረጃዎች፤

ለ/ ወደ አገር ውስጥ እንዲገቡና ወደ ውጭ እንዲላኩ ፈቃድ የተሰጣቸውና የተከለከሉ የልውጥ ህያዋንን ዝርዝር፤

ሐ/ ይህ አዋጅ በሚፈቅደው መሠረት የቀረቡ ማመልከቻዎችን፤

መ/ አግባብነት ያላቸውን አዋጆች፣ ደንቦች፣ መመሪያዎችና የአሠራር ደንቦችን፤

ሠ/ ያልተጤነ ልቀትን ለመቋቋም የተዘረጋ ማንኛውንም ብሔራዊ የአደጋ ጊዜ ዝግጅትን፤

ረ/ ከግንዛቤ የመነጨ ስምምነት ለመስጠት ባለሥልጣኑ የሚፈልጋቸው መረጃዎችን፤

ሰ/ ማንኛውም አግባብነት ያለው የሁለትዮሽ፣ አህጉራዊና የብዙ አገሮች ስምምነቶችና የአሠራር ሂደቶችን፤

ሸ/ ልውጥ ህያዋን ወደ አገር ውስጥ እንዲገቡ እና የተጤነ ልቀት እንዲካሄድባቸው ባለሥልጣኑ የፈቀደበትን የመጨረሻ ውሳኔ፤

11. Public Participation

1/ The Authority shall, upon receipt of the risk assessment report, disseminate it to the relevant stakeholders through a public notice and accept comments for a period of not more than one month.

2/ Comments on the granting or refusal of an advance informed agreement for the transaction may be made in writing by any person within the time limit specified by the Authority.

12. National Biosafety Clearing-House

1/ The Authority shall establish a National Biosafety Clearing-House.

2/ The National Biosafety Clearing-House to be established pursuant to sub-article (1) of this Article shall contain information on:

a) a roster of experts that shall include the names, contact addresses and relevant information on experts in Ethiopia in modified organisms;

b) a list of modified organisms that have been approved and rejected for import and export;

c) applications lodged pursuant to the provisions of this Proclamation;

d) relevant proclamations, directives, guidelines and codes of practice;

e) any national emergency response plan to manage any accidental release;

f) information required by the Authority for giving an advance informed agreement;

g) any relevant bilateral, regional and multilateral agreements and arrangements;

h) the Authority's final decisions on the importation and on the deliberate release of modified organisms;

ቀ/ ይህን አዋጅ ለማስፈፀም የሚያስፈልጉ ሌሎች ተጨማሪ መረጃዎችን።

፫/ ወደ ብሔራዊ ደህንነት ሕይወት የመረጃ ስርዓት ውስጥ የገቡት ማናቸውም ዘገባዎችና ሰነዶች ለሕዝብ ክፍት መሆን አለባቸው።

፬/ በዚህ አዋጅ በአንቀጽ ፲፫ መሠረት በምስጢር እንዲያዝ የተወሰነበት መረጃ ወደ ብሔራዊ የደህንነት ሕይወት መረጃ ሥርዓቱ እንዳይገባ የተከለከለ ነው።

፲፫. <u>በምስጢር የሚያዝ መረጃ</u>

፩/ እያንዳንዱ አመልካች በምስጢር እንዲያዙ-ለት የሚፈልጋቸውን መረጃዎች ለባለሥል-ጣኑ የማሳወቅ መብት አለው።

፪/ ለደህንነተ ሕይወትና ለሌላ ምክንያት አስፈላጊ በመሆኑ በምስጢር መጠበቅ የለበትም ብሎ ባለሥልጣኑ ያመነበትን መረጃ ለይቶ ለአመልካቹ ይገልጽለታል። አመልካቹም በዚሁ ይስማማል ወይም ማመልከቻውን ይሰርዛል።

፫/ የዚህ አንቀጽ ንዑስ አንቀጽ /፩/ እና /፪/ ድንጋጌዎች ቢኖሩም በአመልካቹ የሚቀር-ቡት የሚከተሉት መረጃዎች ምንጊዜም በምስጢር እንዲያዙ አይፈቀድም፡-

ሀ/ የልውጥ ህያው ምንነት መግለጫ፣ የአ-መልካቹ ስምና አድራሻ፣ የእንቅስ-ቃሴው ዓላማና ቦታ፤

ለ/ ልውጥ ሕያውን ለመከታተል የሚያስ-ችል ዘዴና እቅድ እንዲሁም የአደጋ መቋቋሚያ ዝግጅት፤

ሐ/ ሊደርስ የሚችል አደጋ ግምገማ፣ በተለ-ይም በሽታ የማስያዝ ወይም አካባቢን የማወክ ተጽዕኖ።

፬/ አመልካቹ አቅርቦት የነበረውን ማመልከቻ ከሰረዘ በዚህ አንቀጽ በንዑስ አንቀጽ /፫/ ከተዘረዘሩት በስተቀር የመረጃውን ምስጢ-ራዊነት ባለሥልጣኑ መጠበቅ አለበት።

i) other information that is required to implement this Proclamation.

3/ The public shall have access to any record or document filed in the National Biosafety Clearing-House.

4/ Any information determined as confidential pursuant to Article 13 of this Proclamation shall not be placed on the National Biosafety Clearing-House.

13. <u>Confidential Information</u>

1/ Every applicant shall have a right to notify the Authority specifying the information to be treated as confidential.

2/ Following a written request by the applicant for keeping information confidential, the Authority shall determine the information which is essential for biosafety and for other reasons not to be confidential and inform the same to the applicant. The applicant may then agree with the Authority or withdraw his application.

3/ Notwithstanding the provisions of sub-article (1) and (2) of this Article, in no case may the following information supplied by an applicant be kept confidential:

a) description of the modified organism, name and address of the applicant, purpose and location of the transaction;

b) methods and plans for monitoring the modified organism and for emergency response;

c) the evaluation of possible effects, in particular any pathogenic or ecologically disruptive risks.

4/ If the applicant withdraws the application, the Authority shall respect the confidentiality of the information except for that part referred to in sub-article (3) of this Article.

፲፬. ውሳኔ አሰጣጥ

፩/ ባለሥልጣኑ በአመልካቹ የቀረበውን እንዲሁም በፕሮቶኮሉና በብሔራዊ የደህንነት ሕይወት የመረጃ ሥርዓት ውስጥ የሚገኘውን መረጃ፣ የባለሙያዎች አስተሳሰብንና የየባለድርሻዎች አስተያየትን በማጤንና ከሚመለከታቸው የመንግሥት አካላት ጋር በመመካከር በቀረበው ማመልከቻ ላይ ውሳኔ መስጠት አለበት።

፪/ ውሳኔ ከመሰጠቱ በፊት ባለሥልጣኑ አስፈላጊ መስሎ የታየውን ተጨማሪ መረጃ አመልካቹ እንዲያቀርብ ሊጠይቅ ይችላል። የተጠየቀውን መረጃ ያላቀረበ ማንኛውም አመለካች ማመልከቻውን እንደሰረዘ ይቆጠራል።

፫/ ባለሥልጣኑ የባለሙያዎች አስተሳሰብና የባለድርሻዎች አስተያየቶች በደረሱት በ፲፭ ቀናት ውስጥ የጠንቅ ግምገማ ዘገባውን በመገምገም፡-

ሀ/ እንቅስቃሴውን ከኢምንት ያለፈ ጠንቅ የማያስከትል መሆኑን ካመነ ዘገባውን ያለ ቅድመ ሁኔታ በማጽደቅ ከግንዛቤ የመነጨ ስምምነቱን ይሰጣል፤

ለ/ ሊከተሉ የሚችሉ ጠንቆች በአስተማማኝነት ሊወገዱ ወይም ወደ ኢምንትነት ደረጃ ሊቀነሱ እንደሚችሉ ካመነ ዘገባውን ያጸድቅና ጠንቆቹን ለመግታት የሚያስፈልጉ ግዴታዎች እንዲሚሉ ከግንዛቤ የመነጨ ስምምነቱን ይሰጣል፤

ሐ/ በተሻለ መረጃ የተደገፈ ውሳኔ ለመስጠት እንዲቻለው አመልካቹን ተጨማሪ መረጃ እንዲያቀርብ ይጠይቃል፤ ወይም

መ/ ዘገባውን ውድቅ በማድረግ ከግንዛቤ የመነጨ ስምምነቱን ይከለክላል።

፬/ በዚህ አንቀጽ ንዑስ አንቀጽ /፩/ መሠረት ውሳኔው ከተሰጠ በኋላ በአንድ ሳምንት ጊዜ ውስጥ ባለሥልጣኑ የውሳኔውን ቅጂ ወደ ብሔራዊ የደህንነት ሕይወት የመረጃ ሥርዓት ማስገባት አለበት።

14. Decision making

1/ The Authority shall make its decision on the application by taking into account the information presented by the applicant, the information found in the Protocol and the National Biosafety Clearing-Houses, expert opinion and stakeholders' comments, and in consultation with the concerned public agencies.

2/ The Authority may, prior to taking a decision, request for further information as it may deem necessary. Any applicant who fails to supply the required further information shall be deemed to have withdrawn the application.

3/ The Authority shall, within 15 days after it has received the opinion of experts as well as stakeholders' comments, evaluate the risk assessment report and:

a) approve the report without conditions and give its advance informed agreement if it is convinced that the transaction will not pose any significant risk;

b) approve the report and issue an advance informed agreement with conditions that must be fulfilled in order to eliminate or reduce to insignificant level risks if it is convinced that such risks can be effectively contained;

c) require the applicant to provide more information to enable better informed decision making; or

d) reject the report and deny an advance informed agreement.

4/ The Authority shall lodge a copy of the decision given in accordance with sub-article (1) of this Article in the National Biosafety Clearing-House within one week of issuing it.

፲፫. ውሳኔ ስለመከለስ

፩/ ባለሥልጣኑ ስለልውጥ ሕያው ያገኘው አዲስ መረጃ ወይም የነበረው መረጃ ሲገመገም ከባድ ጠንቅ ሊከተል እንደሚችል ካመለከተ ተሰጥቶ የነበረ ከግንዛቤ የመነጨ ስምምነት ሊሰረዝ፣ ወይም ተጨማሪ ግዴታዎች ሊካተቱበት ይችላል።

፪/ አመልካቹ ከግንዛቤ የመነጨ ስምምነቱን ካገኘ በኋላ ሊደርስ ስለሚችል ከባድ ጠንቅ መረጃ ካገኘ ለባለሥልጣኑ ወዲያውኑ ማሳወቅ አለበት።

፫/ በተሰጠው ከግንዛቤ የመነጨ ስምምነት የተካተተ ማንኛውም ግዴታ ሳይሟላ ከቀረ ባለሥልጣኑ እንቅስቃሴውን ሊያሰቆምና ልውጥ ሕያው እንዲወገድ አስከ ማድረግ ድረስ ተገቢ ሆኖ ያገኘውን እርምጃ ሊወስድ ይችላል።

፬/ ለማንኛውም እንቅስቃሴ ከግንዛቤ የመነጨ ስምምነት በመከልከሉ ምክንያት እንደገና እንዲታይ የሚቀርብ ማመልከቻ በአዲስ ሳይንሳዊ መረጃ ከተደገፈ እንደ አዲስ ማመልከቻ በድጋሚ ሊታይ ይችላል። ይህ ካለሆነ ግን ክልከላው የፀና ይሆናል።

፲፮. ከግንዛቤ የመነጨ ስምምነት ፀንቶ ሊቆይ የሚችልበት ጊዜ

፩/ በተቀመጠው የጊዜ ገደብ ውስጥ እንቅስቃሴው ካልተከናወነ ተሰጥቶ የነበረ ከግንዛቤ የመነጨ ስምምነት ተፈፃሚነት ይቋረጣል።

፪/ በዚህ አንቀጽ ንዑስ አንቀጽ /፩/ መሠረት ተሰጥቶ የነበረ ከግንዛቤ የመነጨ ስምምነት ተፈፃሚነት መቋረጥን ተገቢነት የሚቃወም አመልካች ተቃውሞውን በአሥራ አምስት ቀናት ውስጥ በጽሑፍ ለባለሥልጣኑ ማቅረብ ይችላል።

፫/ በዚህ አንቀጽ ንዑስ አንቀጽ /፪/ መሠረት ማመልከቻ ሲቀርብለት ባለሥልጣኑ ከግንዛቤ የመነጨው ስምምነት ተፈፃሚነት እንዲራዘም ወይም የጠንቅ ግምገማው እንዲከለስ ወይም በድጋሚ እንዲሰራ በ፴ የሥራ ቀናት ውስጥ መወሰን አለበት።

15. Review of Decision

1/ Any advance informed agreement given may be revoked or subjected to additional conditions if the authority obtains new information that shows, or a review of existing information indicates, any significant risk from the modified organism.

2/ Where information becomes available to the applicant after receiving the advance informed agreement on possible significant risk, the applicant shall immediately notify the Authority.

3/ If any condition contained in an advance informed agreement is not strictly complied with, the Authority may take any action that it may consider appropriate for the immediate cessation of the transaction, including the destruction of the modified organism.

4/ Any application to reconsider a refusal of an advance informed agreement for any transaction shall be treated as a new application if it is accompanied by new scientific information. Otherwise a refusal shall be final.

16. Duration of Validity of an Advance Informed Agreement

1/ An advance informed agreement shall expire if the transaction has not been performed within the time frame set out for it during its approval.

2/ Any applicant who wishes to challenge the appropriateness of expiry of an advance informed agreement pursuant to sub-article (1) of this Article may submit a written application to that effect to the authority within fifteen days from the date of expiry.

3/ Within 30 working days from the receipt of an application pursuant to sub-article (2) of this Article, the Authority shall decide whether to extend the validity of the advance informed agreement or to order the revision or the redoing of the risk assessment.

፲፯. ፈቃድ የተሰጣቸው ሰዎች ግዴታዎች

፩/ ፈቃድ የተሰጠው ማንኛውም ሰው በጸደቀው የጠንቅ ግምገማ ዘገባ በተመለከተው የጊዜ ገደብ ውስጥ ስለሚያካሂደው እንቅስቃሴ የዕሁፍ ዘገባ ለባለሥልጣኑ ማቅረብ አለበት።

፪/ ፈቃድ የተሰጠው ማንኛውም ሰው በይዞታው ያለውን ማንኛውንም ለገበያ ያልቀረበ ልውጥ ሕያው ከባለሥልጣኑ አዲስ ከግንዛቤ የመነጨ ስምምነት ሳያገኝ ለሌላ ሰው አሳልፎ እንዲሰጥ አይፈቀድለትም።

፫/ ማንኛውም ፈቃድ የተሰጠው ሰው የሰውንና የአንስሳትን ጤንነት እንዲሁም አካባቢን ከማንኛውም ጠንቅ የሚጠብቅበትን የአደጋ መቋቋሚያ ስልት በዚህ አዋጅ መሠረት በሚወጡ ደንቦችና መመሪያዎች መሠረት አዘጋጅቶ መተግበር አለበት።

፬/ ማንኛውም ፈቃድ የተሰጠው ሰው በይዞታው የነበረ ማንኛውም ልውጥ ሕያው ቢጠፋበት ወይም ቢሰረቅበት ወዲያውኑ ለባለሥልጣኑ ማሳወቅ አለበት።

፲፰. ሥልጣን የተሰጣቸው የፈቃድ ሰጪ መሥሪያ ቤቶች ተግባራት

፩/ ሥልጣን የተሰጠው ፈቃድ ሰጪ መሥሪያ ቤት ከግንዛቤ የመነጨ ስምምነት ላላቀረበ አመልካች እንቅስቃሴውን እንዲያካሂድ ከመፍቀድ የተከለከለ ነው።

፪/ ባለሥልጣኑ የሰጠውን ከግንዛቤ የመነጨ ስምምነት ሲያግድ ወይም ሲሰርዝ ሥልጣን የተሰጠው ፈቃድ ሰጪ መሥሪያ ቤት ሊዘያው እንቅስቃሴ ሰጥቶት የነበረውን ፈቃድ ማገድ ወይም መሰረዝ አለበት።

፲፱. የተቆጣጣሪዎች ሥልጣንና ተግባር

፩/ ማንኛውም ተቆጣጣሪ የዚህ አዋጅና በአዋጁ መሠረት የሚወጡ ደንቦችና መመሪያዎች መከበራቸውን ለማረጋገጥ፡-

ሀ/ ማንኛውም እንቅስቃሴ ወደሚካሄድበት ቦታ ወይም ተቋም ውስጥ ማግባት፣

ለ/ የሚካሄደውን እንቅስቃሴ መፈተሽና ማስተካከያ እርምጃዎች እንዲወሰዱ ትዕዛዝ መስጠት፣

17. Duties of Authorized Persons

1/ Every authorized person shall, within the time specified in the approved risk assessment report, submit to the Authority a written report on the transaction that he has been carrying out.

2/ No authorized person shall transfer any modified organism that has not been put on the market to any other person without obtaining a new advance informed agreement from the Authority.

3/ Any authorized person shall, in accordance with regulations and directives to be issued pursuant to this Proclamation, develop and implement his own risk management strategy to protect human and animal health and the environment from any risk.

4/ Every authorized person shall immediately inform the Authority whenever any modified organism is lost or stolen from him.

18. Duties of Competent Licensing Agencies

1/ Every competent licensing agency is prohibited from giving a license for any transaction uless the applicant has submitted to it an advance informed agreement.

2/ Every competent licensing agency shall suspend or cancel any license it has given following the decision of the Authority to suspend or cancel the advance informed agreement that it has granted.

19. Powers and Duties of Inspectors

1/ Any inspector may, for the purpose of ensuring compliance with provisions of this Proclamation and regulations and directives to be ıssued pursuant to this Proclamation:

a) enter any place or facility in which a transaction is taking place;

b) inspect and order the taking of any corrective measures on the transaction being carried out;

ሐ/ እንቅስቃሴ ከሚያካሂደው ሰው ወይም ከኃላፊው መረጃ መጠየቅና ማግኘት፣

መ/ ከእንቅስቃሴ ጋር ግንኙነት ያለውን ማንኛውንም መዝገብ ወይም ሰነድ መመርመርና ቅጅው እንዲሰጠው መጠየቅ፣ እና

ሠ/ የማንኛውንም ቁስ ናሙና ያለ ክፍያ መውሰድና አስፈላጊ የሆነ ፍተሻ ማካሄድ ወይም እንዲካሄድ ማድረግ፣ ይችላል።

፪/ ማንኛውም ተቆጣጣሪ በዚህ አዋጅ የተሰጠውን ሥልጣንና ተግባር በትጋትና ባለማዳላት ማከናወን እንዲሁም በተጠየቀ ጊዜ መታወቂያውን ማሳየት አለበት።

c) request and obtain information from any person carrying out or in charge of the transaction;

d) examine and obtain a copy of any record or document related to a transaction; and

e) take free of charge samples of any material or substance as required and carry out or cause to be carried out tests he considers appropriate.

2/ Every inspector shall exercise in due diligence and impartiality in the discharge of his powers and duties pursuant to this Proclamation and shall show his identity card whenever requested.

፳. በመግቢያና በመውጫ ቦታዎች የሚደረግ ቁጥጥር

፩/ ማንኛውንም ልውጥ ህያው ይዞ ወደ አገር ውስጥ የሚገባ ወይም ከአገር የሚወጣ ግለሰብ በመግቢያ ወይም በመውጫ በሩ በስራ ላይ ላለ የጉምሩክ ሠራተኛ ማሳወቅ አለበት።

፪/ ማንኛውም የጉምሩክ ሠራተኛ ከግንዛቤ የመነጨ ስምምነት ሳይኖር ማንኛውም ግለሰብ ልውጥ ህያው መያዙን ከጠረጠረ ወይም ልውጥ ህያው ይዟል ብሎ የጠረጠረውን ጭነት ካገኘ ያግተውና ለባለሥልጣኑ ያሳውቃል።

፫/ በዚህ አንቀጽ ንዑስ አንቀጽ /፪/ መሠረት የታገተውን ነገር የጉምሩክ ሠራተኛው በብዝሀ ሕይወት፣ በአካባቢ ወይም በሰው ወይም በእንስሳት ጤንነት ሊደርሱ የሚችሉ ጠንቆችን በሚያሳንስ ዘዴ ያስቀምጠዋል።

፬/ ባለሥልጣኑ በዚህ አንቀጽ ንዑስ አንቀጽ /፪/ መሠረት ከታገተው ነገር ላይ ናሙና ወስዶ በመመርመር ልውጥ ሕያው ያለበት መሆን አለመሆኑን ማረጋገጥ አለበት።

፭/ የጉምሩክ ሠራተኛ የተረከበው ሕያው ልውጥ አለመሆኑ በዚህ አንቀጽ ንዑስ አንቀጽ /፬/ መሠረት በተካሄደ ፍተሻ ከተረጋገጠ ለምርመራ በጥቅም ላይ የዋለው መጠን ብቻ ተቀንሶበት ለተያዘበት ሰው መመለስ አለበት።

20. Inspections at Points of Entry and Exit

1/ Any person in possession of any modified organism shall, on arrival or departure, declare such possession to the customs officer on duty at the point of entry or exit.

2/ Where a customs officer suspects that any person is in possession of a modified organism or any load contains any modified organism, without a written advance informed agreement, he shall impound it and notify the Authority.

3/ The customs officer shall store the suspected modified organism referred to under sub-article (2) of this Article in such a manner that risks to biodiversity, the environment or human health are minimized.

4/ The Authority shall, by examining samples, verify whether the impounded material referred to under sub-article (2) of this Article contains any modified organism or not.

5/ If any organism surrendered to a customs officer is determined by the Authority not to be modified, the impounded amount after reducing the amount used up during analysis shall be returned to the person who had surrendered it.

፮/ በዚህ አንቀጽ ንዑስ አንቀጽ /፪/ መሠረት ታግዶ የተቀመጠው ነገር ልውጥ ሕያው መሆኑ ከተረጋገጠና በ፴ ቀናት ውስጥ ከኢትዮጵያ እንዲወጣ ካልተደረገ ባለሥልጣኑ በማቃጠል ወይም ተገቢ በሆነ ሌላ መንገድ እንዲወገድ ያደርጋል።

፯/ ወደ አገር ውስጥ የገባ ልውጥ ሕያው ተቀባይ አጥቶ በደረሰበት ቦታ ከሁለት ሳምንታት በላይ ከቆየ ባለሥልጣኑ ከጉምሩክ ሠራተኛ ወይም ከሌላ ተገቢ የመንግሥት ባለሥልጣን ጋር በመሆን ልውጥ ህያው ወደ መጣበት አገር እንዲመለስ ወይም አካባቢያዊ ተቀባይነት ባለው ዘዴ እንዲወገድ እርምጃ ሊወሰድ ይችላል።

፰/ ተገቢው እርምጃ ላለመወሰዱ ግለጽ ጥፋት መኖሩ ካልተረጋገጠ በስተቀር በዚህ አንቀጽ ንዑስ አንቀጽ /፫/ መሠረት ታግዶ የተቀመጠው ነገር ይዘቱ ቢበላሽ ባለሥልጣኑም ሆነ የጉምሩክ ሠራተኛው ተጠያቂ አይሆኑም።

፱/ በዚህ አንቀጽ ንዑስ አንቀጽ /፪/ መሠረት ታግዶ የቆየውን ልውጥ ህያው ለማስወገድ ለማስቀመጥ ወይም መለሶ ወደ ውጪ ለመላክ የወጣው ማንኛውም ወጪ በታገተበት ሰው መሸፈን አለበት።

፳፩. ቅጣት

፩/ በወንጀል ሕግ ድንጋጌዎች የበለጠ የሚያስቀጣ ካለሆነ በስተቀር፡-

ሀ/ ማንኛውም ሰው ሆን ብሎ በሰው ጤንነት፣ በብዝሐ ሕይወት፣ በአካባቢ ወይም በንብረት ላይ ጉዳት ለማድረስ ወይም በሌላ መንገድ ለማወክ እንቅስቃሴ ካካሄደ ከ፲ አስከ ፲፭ ዓመት በሚደርስ ጽኑ እሥራት ይቀጣል፤

ለ/ የዚህን አዋጅ ድንጋጌ ወይም በዚህ አዋጅ መሠረት በወጣ ደንብ ወይም መመሪያ የተደነገገውን የተላለፈ ማንኛውም ሰው ከ፬ሺ እስከ ፯ሺ ብር በሚደርስ የገንዘብ መቀጮ ወይም ከአንድ እስከ ሦስት ዓመት በሚደርስ እሥራት ወይም በሁለቱም ይቀጣል።

፪/ የወንጀሉ ድርጊት የተፈጸመው በሕግ የሰውነት መብት በተሰጠው አካል ሲሆን የቅጣቱ አወሳሰን በኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ወንጀል ሕግ አንቀጽ ፺ ድንጋጌዎች መሠረት ይፈጸማል።

6/ If the material impounded and stored pursuant to sub-article (2) of this Article is proved to contain any modified organism and if it is not taken out of Ethiopia within 30 days, the Authority shall destroy it by incineration or by any other method it deems appropriate.

7/ Where any imported modified organism remains unclaimed at the port of entry for more than two weeks, the Authority, together with a customs officer or other appropriate government officer, may take any action necessary to send back the modified organism to the country if came from or to dispose of it in an environmentally sound manner.

8/ Neither the Authority nor the customs official shall be held liable for any deterioration in storage in the condition of the contents of the material impounded and stored under sub-article (3) of this Article unless manifest failure to take reasonable measure is proved.

9/ All costs of any disposal, safe-keeping or re-export of any load of modified organism that has been impounded under sub-article (2) of this Article shall be borne by the person who had surrendered it.

21. Penalties

1/ Unless the act entails higher penalty under the provisions of the Criminal Code:

a) any person who engages in any transaction with the intention of causing harm to human health, biological diversity, the environment or property shall be punishable with rigorous imprisonment from 10 to 15 years.

b) any person who violates any provision of this Proclamation or regulations or directives issued pursuant to this Proclamation shall be punishable with a fine from Birr 4,000 to Birr 7,000 or with imprisonment from one to three years or both.

2/ Where the offense is committed by a juridical person the penalty shall be determined in accordance with the provisions of Article 90 of the Criminal Code of the Federal Democratic Republic of Ethiopia.

፫/ በህግ የሰውነት መብት የተሰጠው አካል ጥፋት ሲፈፅም ከሚወሰንበት መቀጮ በተጨማሪ የሕጉን መከበር ለማረጋገጥ መፈፀም የሚገባውን ተግባር በትጋት ያልተወጣው የሥራ መሪ በዚህ አንቀፅ ንዑስ አንቀፅ /፩/ /ለ/ መሠረት ይቀጣል።

፳፪. ደንብና መመሪያ የማውጣት ሥልጣን

፩/ የሚኒስትሮች ምክር ቤት ይህን አዋጅ ለማስፈጸም የሚያስፈልጉ ደንቦችን ሊያወጣ ይችላል።

፪/ ባለሥልጣኑ ይህን አዋጅና በዚህ አንቀጽ ንዑስ አንቀጽ /፩/ መሠረት የወጡ ደንቦችን ለማስፈጸም የሚያስፈልጉ መመሪያዎችን ሊያወጣ ይችላል።

፳፫. አዋጁ የሚፀናበት ጊዜ

ይህ አዋጅ በፌዴራል ነጋሪት ጋዜጣ ታትሞ ከወጣበት ቀን ጀምሮ የፀና ይሆናል።

አዲስ አበባ ጳጉሜ ፬ ቀን ፪ሺ፩ ዓ.ም

ግርማ ወልደጊዮርጊስ

የኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ፕሬዚዳንት

3/ In the case of an offense committed by a juridical person, in addition to the penalty imposed to the entity, the officer of the entity who has failed to exercise all due diligence shall be punishable in accordance with sub-article (1) (b) of this Article.

22. Power to Issue Regulation and Directive

1/ The Council of Ministers may issue regulations necessary for the implementation of this Proclamation.

2/ The Authority may issue directives necessary for the implementation of this Proclamation and regulations issued pursuant to sub-article (1) of this Article.

23. Effective Date

This Proclamation shall enter into force up on the date of publication in the Federal Negarit Gazeta.

Done at Addis Ababa, this 9th day of September, 2009

GIRMA WOLDEGIORGIS

PRESIDENT OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

የኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ

ፌደራል ነጋሪት ጋዜጣ

FEDERAL NEGARIT GAZETTE

OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

ሃያ አንደኛ ዓመት ቁጥር ፷፮
አዲስ አበባ ነሀሴ ፰ ቀን ፪ሺ፯ ዓ.ም

በኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ
የሕዝብ ተወካዮች ምክር ቤት ጠባቂነት የወጣ

21st Year No.66
ADDIS ABABA 14th August , 2015

አዋጅ ቁጥር ፷፱፻፮/፪ሺ፯

የደሕንነተ ሕይወት አዋጅን ለማሻሻል የወጣ አዋጅ

ስለደሕንነተ ሕይወት የወጣውን አዋጅ ቁጥር ፮፻፺፭/፪ሺ፩ ማሻሻል በማስፈለጉ፤

በኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ ሕገ መንግሥት አንቀጽ ፶፭ (፩) መሠረት የሚከተለው ታውጇል።

፩. አጭር ርዕስ

ይህ አዋጅ "የደሕንነተ ሕይወት (ማሻሻያ) አዋጅ ቁጥር ፷፱፻፮/፪ሺ፯" ተብሎ ሊጠቀስ ይችላል።

፪.ማሻሻያ

የደሕንነተ ሕይወት አዋጅ ቁጥር ፮፻፺፭/፪ሺ፩ እንደሚከተለው ተሻሽሏል፡-

፩/ የአዋጁ አንቀጽ ፪ ንዑስ አንቀጾች (፩)፣ (፬)፣ (፮)፣ (፱)፣ (፲፪)፣ (፲፯) እና (፲፰) ተሰርዘው በሚከተሉት አዲስ ንዑስ አንቀጾች (፩)፣ (፬)፣ (፲፪)፣ (፲፯) እና (፲፰) ተተክተዋል፡-

"፩/ 'ልውጥ ሀያው' ማለት ሰው ሰራሽ የሆነ ወይም ከሌላ ሀያው የተወሰደ ይሁን ከቅሪት የተወሰደ ወይም እንደ አዲስ የተቀመመ ባይተዋር ዘረመል

PROCLAMATION No. 896/2015

A PROCLAMATION TO AMEND THE BIOSAFETY PROCLAMATION

WHEREAS, it has become necessary to amend the Biosafety Proclamation No. 655/2009;

NOW, THEREFORE, in accordance with Article 55(1) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follows:

1. Short Title

This Proclamation may be cited as the "Biosafety (Amendment) Proclamation No.896 /2015".

2. Amendment

The Biosafety Proclamation No. 655/2009 is hereby amended as follows:

1/ Sub-articles (1), (4), (6), (9), (12), (17) and (18) of Article 2 are deleted and replaced by the following new sub-articles (1), (4), (6), (9), (12), (17) and (18):

"1/ 'modified organism' means any biological entity which has been artificially synthesized, or in which the genetic material or the expression of any of its traits has been changed by the

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introduction of any foreign gene whether taken from another organism, from a fossil organism or artificially synthesized;

፬/ 'ዝግ አጠቃቀም' ማለት በሰው ወይም በእንስሳት ጤና ወይም በአካባቢ ላይ የሚከተል ያልታቀደ ተጽዕኖን ለመከላከል በቁሳዊና በንጥረ ነገራዊ ከለላ ታጥረውና በሚኒስቴሩ በወጣው በተገቢው መመሪያ በተፈቀደው ስፋት ባልበለጠ ቦታ ተወስነው ልውጥ ሀያውን እንዲሰሩ፣ እንዲወገዱ ወይም ትምህርትንና ምርምርን ጨምሮ እስከ መስክ ምርምር ሙከራ ድረስ ያለውን ያጠቃልላል፤

4/ 'contained use' means any operation up to field trial in which modified organisms are produced ,destroyed or used in some other way including for teaching and research isolated by physical and chemical barriers in space not exceeding the requirement stated in the appropriate directive issued by the Ministry with a view to effectively preventing their contact with, and their unintended impact on ,human, animal and the external environment;

፮/ 'ከግንዛቤ የመነጨ ስምምነት' ማለት ለዝግ አጠቃቀም ሳይሆን በአገር ውስጥ ወደ አካባቢ ለመልቀቅ በአንድ ልውጥ ሕያው ላይ እንቅስቃሴ እንዲደረግ ከሚኒስቴሩ የሚሰጥ የአዎንታ ጽሑፍ ነው፤

6/ 'advance informed agreement' means a written consent granted by the Ministry for the undertaking of any transaction of modified organism destined to release into the environment in the country other than for contained use;

፱/ 'ጠንቅ' ማለት በአጭር፣ በመካከለኛ እና በረጅም ጊዜ ሂደት ሲታይ በሰው ወይም በእንስሳት ጤና፣ በብዝሐ ሕይወት፣ በአካባቢ ወይም በማህበራዊና ኢኮኖሚያዊ ሁኔታ ላይ ከልውጥ ሕያዋን ተፅዕኖ በመመንጨቱ በብዝሐ ሕይወት ጥበቃና ዘላቂ ጠቃሚነት በተለይም በብዝሐ ሕይወት እሴት፣ በአገር በቀል የዕውቀት ሥርዓትና በአካባቢያዊ ማህበረሰቦች ላይ ሊደርስ የሚችል ጉዳት ነው፤

9/ 'risk' means short, medium or long-term danger that may befall on human or animal health, biological diversity, the environment or socio-economic conditions arising from the impact of modified organism on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity, indigenous knowledge systems and local communities;

፲፪/ 'ሚኒስቴር' ወይም 'ሚኒስትር' ማለት እንደቅደም ተከተሉ የአካባቢና የደን ሚኒስቴር ወይም ሚኒስትር ነው፤

12/ 'Ministry' or 'Minister' means the Ministry or Minister of Environment and Forest ,respectively;

፲፯/"አመልካች" ማለት የሚጠይቀውን እንቅስቃሴ ለማካሄድ ከግንባቤ የመነጨ ስምምነት ወይም ልዩ ፈቃድ እንዲሰጠው ለሚኒስቴሩ ያመለከተ ሰው ነው፤

፲፰/ "ፈቃድ የተሰጠው ሰው" ማለት ከግንባቤ የመነጨ ስምምነት ወይም ልዩ ፈቃድ ከሚኒስቴሩ የተሰጠው ሰው ነው፤"

፪/ በአዋጁ ከአንቀጽ ፪ ንዑስ አንቀጽ (፲፰) ቀጥሎ የሚከተሉት አዲስ ንዑስ አንቀጾች (፲፱)፣ (፳)፣ (፳፩) እና (፳፪) ተጨምረው ነባር ንዑስ አንቀጾች (፲፱) እና (፳) ንዑስ አንቀጾች (፳፫) እና (፳፬) ሆነው ተሸጋሽገዋል፡-

፲፱/ "ዘመናዊ ጥበበ ሕይወት" ማለት፡-

ሀ) በመርፌ በመውጋት ኑክለይክ አሲድን ወደ ሕዋስ በቀጥታ መክተትን ጨምሮ በቤተ ሙከራ እንዲካሄድ የዲኦክሲራይቦኑክለይክ አሲድን የማቀናጀት ሥራን በማካሄድ፣

ለ) ከስነ ስያሜ አኳያ ሲታይ ከአንድ ፋሚሊ ውጪ የተገኙ ሕዋሳትን ወደ አንድ ሕዋስነት በማቀላቀል፣

ተፈጥሯዊ ፊዚዮሎጂካዊና የመዳቀል መከላከያዎችን አስዘልሎ ከባህላዊ የማዳቀል ሂደቶች ውጪ የሚደረግ አዲስ ዝርያን የማዳቀልና የመምረጥ ተግባር ነው፤

፳/ "ልዩ ፈቃድ" ማለት በዚህ አዋጅ መሠረት ልውጥ ሕያውን ወደ አካባቢ መልቀቅን ሳይጨምር በዝግ አጠቃቀም ለምርምር ወይም ለትምህርት ለማዋል ልውጥ ሕያውን ወደ አገር ለማስገባት ከሚኒስቴሩ በጽሁፍ የሚሰጥ ፈቃድ ነው፤

17/ 'applicant' means any person who submits an application to the Ministry seeking an advance informed agreement or a special permit to engage in a transaction;

18/ 'authorized' person' means a person who has been given an advance informed agreement or a special permit by the Ministry to engage in a transaction;"

2/ sub-articles (19), (20), (21) and (22) are added after sub-article (18) of Article 2 of the Proclamation and the existing sub-articles (19) and (20) are re-numbered as sub-articles (23) and (24):

"19/ 'modern biotechnology' means the application of:

a) In vitro nucleic acid techniques, including recombinant deoxyribonuclic acid and direct injection of nucleic acid into cells or organelles;

b) fusion of cells beyond the taxonomic family;

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

20/ 'special permit' means a written permit granted by the Ministry for importation of a modified organism for contained use in research or teaching but not for release into the environment in accordance with this Proclamation;

፳፩/ 'የውጭ ላኪ' ማለት ልውጥ ሕያውን ከውጭ አገር ሆኖ ወደ አገር ውስጥ ለማስገባት የሚልክ ሰው ነው፤"

፫/ በአዋጁ በማናቸውም ሥፍራ "ባለሥልጣን" የሚለው ስያሜ ተሠርዞ "ሚኒስቴር" በሚለው ተተክቷል፤

፬/ የአዋጁ አንቀጽ ፬ ተሠርዞ በሚከተለው አዲስ አንቀጽ ፬ ተተክቷል:-

"፬.<u>የአዋጁ ዓላማ</u>

የአዋጁ ዓላማ፡-

፩/በሰውና በእንስሳት ጤና፣ በብዝሐ ሕይወት፣ በአካባቢ፣ በማህበረሰቦችና በአጠቃላዩ በአገር ላይ ከልውጥ ሕያዋን ሊደርስ የሚችለውን አሉታዊ ተጽእኖ ማስቀረት ወይም ቢያንስ እስከ ኢምንታዊነት ደረጃ ድረስ ማሳነስ፤ እና

፪/ ዘመናዊ ጥበበ ሕይወትን ጨምሮ ለብዝሐ ሕይወት ጥበቃና ዘላቂ አጠቃቀም የሚያገለግል ቴክኖሎጂ ተደራሽነትንና በቴክኖሎጂ ዝውውር መጠቀምን ማሻሻል፤

ነው።"

፭/ የአዋጁ አንቀጽ ፭ ተሠርዞ በሚከተለው አዲስ አንቀጽ ፭ ተተክቷል:-

"፭.<u>ከግንዛቤ የመነጨ ስምምነት</u>

፩/ የዚህ አዋጅ አንቀጽ ፫ ድንጋጌ እንደተጠበቀ ሆኖ ማንኛውም ሰው ከግንዛቤ የመነጨ ስምምነትን ከሚኒስቴሩ ሳያገኝ ልውጥ ሕያውን ወደ ክፍት አካባቢ የመልቀቅ እንቅስቃሴን ማካሄድ አይችልም።

21/ 'foreign exporter' means any person under the jurisdiction of another country who exports a modified organism;"

3/ the designation "Authority" appearing anywhere in the Proclamation is deleted and replaced by "Ministry";

4/ Article 4 of the Proclamation is deleted and replaced by the following new Article 4:

"4. <u>Objective of the Proclamation</u>

The objective of the Proclamation shall be to:

1/protect human and animal health, biological diversity and in general, the environment, local communities and the country at large by preventing or at least managing down the adverse effects of modified organisms to levels of insignificance; and

2/enhance access to and transfer of technologies, including modern biotechnology, that serve for conservation and sustainable use of biological diversity."

5/ Article 5 of the Proclamation is deleted and replaced by the following new Article 5:

"5. <u>Advance Informed Agreement</u>

1/ Without prejudice to the provision of Article 3 of the Proclamation no person may engage in any transaction destined for release of modified organism to the environment without obtaining an advance informed agreement from the Ministry.

፪/ ልውጥ ሕያውን ወደ አካባቢ የመልቀቅ እንቅስቃሴን ለማካሄድ የሚፈልግ ማንኛውም ሰው በዚህ አዋጅና በአዋጁ መሠረት በወጡ ደንቦች እና መመሪያዎች መሠረት የተዘጋጀ ማመልከቻ ለሚኒስቴሩ ማቅረብ አለበት።

፫/ ከግንባቤ የመነጨ ስምምነት ለማግኘት ማንኛውም አመልካች በዚህ አዋጅ መሰረት በወጡት ደንቦች እና መመሪያዎችየተመለከቱትን መስፈርቶች ማሟላት አለበት።"

፮/ የአዋጁ አንቀጽ ፮ እስከ አንቀጽ ፳ እንደ ቅደም ተከተላቸው ከአንቀጽ ፯ እስከ አንቀጽ ፳፩ ሆነው የሚከተለው አዲስ አንቀጽ ፮ ተጨምሯል፡-

"፮.<u>ልዩ ፈቃድ</u>

፩/ ማንኛውም ሰው ልዩ ፈቃድ ሳይሰጠው የዝግ አጠቃቀም እንቅስቃሴ ሊያካሄድ አይችልም።

፪/ የዝግ አጠቃቀም እንቅስቃሴ ሊያካሄድ የሚፈልግ ማንኛውም ሰው ልዩ ፈቃድ እንዲሰጠው ይህን አዋጅ ለማስፈጸም በሚወጡ ደንቦች እና መመሪያዎች መሠረት ለሚኒስቴሩ ማመልከቻ ማቅረብ አለበት።

፫/ ልዩ ፈቃድ የተሰጠው ማንኛውም ሰው ልውጥ ሕያውን ወደ አካባቢ መልቀቅ የለበትም።

፬/ በዝግ አጠቃቀም ምርምር የሚያካሄድ ማንኛውም ሰው ተገቢውን የጥንቃቄ እርምጃ በመውሰድ ከእንቅስቃሴው ሊመጡ የሚችሉትን ጠንቆች በሙሉ ማስወገድ አለበት።"

2/ Any person who intends to engage in any transaction destined for release of modified organism to the environment shall submit to the Ministry an application prepared in accordance with this Proclamation and the regulations and directives issued hereunder.

3/ Any applicant intending to obtain an advance informed agreement shall comply with the requirements set in the regulations and directives issued hereunder."

6/ Articles 6 to 20 of the Proclamation are renumbered as Articles 7 to 21, respectively, and the following new Article 6 is added:

"6. <u>Special Permit</u>

1/ No person may engage in any contained use transaction without obtaining a special permit.

2/ Any person who intends to obtain a special permit for contained use transaction shall submit an application to the Ministry in accordance with the regulations and directives issued hereunder.

3/ A person granted a special permit may not release a modified organism into the environment.

4/ Any person who is conducting research in a contained use shall take all necessary measures to completely avoid the risks that may arise from the transaction."

፯/ የአዋጁ አንቀጽ ፱ (ቁጥሩ በዚህ አንቀጽ ንዑስ አንቀጽ (፮) መሠረት እንደተሸጋሸገው) ተሠርዞ በሚከተለው አዲስ አንቀጽ ፱ ተተክቷል፡-

"፱.ልውጥ ሕያውን ወደ አገር ውስጥ ማስገባት

፩/ ከግንዛቤ የመነጨ ስምምነት ወይም ልዩ ፈቃድ ሳይገኝ ልውጥ ሕያውን ወደ አገር ውስጥ ማስገባት የተከለከለ ነው።

፪/በዝግ የመጠቀም ፈቃድን ለማግኘት የሚቀርብ ማመልከቻ ልዩ ፈቃድ እንጂ ከግንዛቤ የመነጨ ስምምነት ሊያሰጥ አይችልም።

፫/ ከግንዛቤ የመነጨ ስምምነት እንዲሰጠው ለሚኒስቴሩ ማመልከቻ የሚያቀርብ ማንኛውም ሰው በላኪው አገር ህግ መሰረት እውቅና ያለው መሆን አለበት።

፬/ ልዩ ፈቃድ እንዲሰጥ ለሚኒስቴሩ የሚቀርብ ማመልከቻ በውጪ ላኪው የተፈረመ የልውጥ ሕያዉን ምንነት ከሚገልፅ ሰነድ ጋር ተያይዞ መቅረብ አለበት።"

፰/ የአዋጁ አንቀጽ ፲፭ ንዑስ አንቀጽ (፬) (ቁጥሩ በዚህ አንቀጽ ንዑስ አንቀጽ (፮) መሠረት እንደተሸጋሸገው) ንዑስ አንቀጽ (፭) ሆኖ የሚከተለው አዲስ ንዑስ አንቀጽ (፬) ተጨምሯል፡-

"፬/ ሚኒስቴሩ የሚከተሉት ቅድመ ሁኔታዎች ሲሟሉ ለአመልካች ልዩ ፈቃድ ይሰጣል፡

ሀ) የተጠየቀውን ምርምር ይህን አዋጅ ለማስፈጸም በወጡ ደንቦችና መመሪያዎች መሠረት ለማካሄድ የሚያስፈልጉ ተቋሞችና ሥርዓቶች መኖራቸው ሲረጋገጥ፤

7/ Article 9 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) is deleted and replaced by the following new Article 9:

"9. Importation of Modified Organisms

1/ Importation of any modified organism without obtaining an advance informed agreement or a special permit is prohibited.

2/ An application for contained use is not subject to an advance informed agreement but to a special permit.

3/ A person who applies to the Ministry for an advance informed agreement shall have a recognition as the law of the exporting country authorizes the exporter to take such responsibility.

4/ An application for a special permit for the importation of a modified organism shall be accompanied by a statement signed by the foreign exporter indicating the identity of the modified organism."

8/ sub-article (4) of Article 15 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) is renumbered as sub-article (5) and the following new sub-article (4) is added:

"4/ The Ministry shall issue special permit to an applicant if:

a) there are facilities and institutional systems required to conduct the specified research as per the regulations and directives issued pursuant to this Proclamation;

ለ) ዝውውሩ ወደ አካባቢ የማይለቀቅ ከሆነ፤

ሐ) አመልካቹ ምርምሩን ለማካሄድ ተፈላጊው ብቃት ያለው ከሆነ፤ እና

መ) ጉዳቱን ለመቀነስ ወይም ወደ ኢምንትነት ለማውረድ የሚያስችል ደረጃውን የጠበቀ የአሠራር ሥርዓት ያለ ከሆነ።"

፱/ የአዋጁ አንቀጽ ፲፯ (ቁጥሩ በዚህ አንቀጽ ንዑስ አንቀጽ (፮) መሠረት እንደተሸጋሸገው) ተሠርዞ በሚከተለው አዲስ አንቀጽ ፲፯ ተተክቷል:-

"፲፯. <u>ከግንዛቤ የመነጨ ስምምነትና ልዩ ፈቃድ ፀንተው የሚቆዩበት ጊዜ</u>

፩/ ልውጥ ሕያው ለንግድ ሥራ ወደ አካባቢ እንዲለቀቅ የተሰጠ ከግንዛቤ የመነጨ ስምምነት ለአስር ዓመት የፀና ይሆናል።

፪/ ለዝግ አጠቃቀም የተሰጠ ልዩ ፈቃድ ለአምስት ዓመት የፀና ይሆናል።

፫/ በትራንዚት ለማስተላለፍ የተሰጠ ከግንዛቤ የመነጨ ስምምነት ለሦስት ወር የፀና ይሆናል።

፬/ ለንግድ ሥራ ወደ አካባቢ እንዲለቀቅ የተፈቀደው ከግንዛቤ የመነጨ ስምምነት ወይም ለዝግ አጠቃቀም የተሰጠ ልዩ ፈቃድ ሊያከትም አንድ ዓመት ሲቀረው ስምምነቱ ወይም ልዩ ፈቃዱ ፀንቶ የሚቆይበት ጊዜ እንዲራዘምለት ፈቃድ የተሰጠው ሰው ሊያመለክት ይችላል።

፭/በትራንዚት ለማስተላለፍ የተሰጠ ከግንዛቤ የመነጨ ስምምነት ሊያከትም አንድ ወር ሲቀረው ስምምነቱ ፀንቶ የሚቆይበት ጊዜ እንዲራዘምለት ፈቃድ የተሰጠው ሰው ሊያመለክት ይችላል።

b) the transaction is not destined for release to the environment;

c) the applicant has the required qualification to conduct the research; and

d) if standard operating procedures that prevent or minimize risks to the insignificant level are in place."

9/ Article 17 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) is deleted and replaced by the following new Article 17:

"17. <u>Validity Period of Advance Informed Agreement and Special Permit</u>

1/ An advance informed agreement for commercial release of modified organism shall be valid for ten years.

2/ A special permit for contained use shall be valid for five years.

3/ An advance informed agreement for transit of modified organism shall be valid for three months.

4/ The authorized person may request for extension of the validity period of advance informed agreement for a commercial release or a special permit for contained use of modified organism one year before the expiry date of the validity period.

5/ The authorized person may request for extension of the validity period of advance informed agreement for transit of modified organism one month before the expiry date of the validity period.

፮/ በዚህ አንቀጽ ንዑስ አንቀጽ (፬) መሠረት ማመልከቻ ሲቀርብለት ሚኒስቴሩ ከግንባቤ የመነጨው ስምምነት እንዲራዘም ወይም የጠንቅ ግምገማው እንዲከለስ ወይም በድጋሜ እንዲሠራ ሊወስን ይችላል።"

6/ The Ministry may, upon the receipt of an application pursuant to sub-article (4) of this Article, decide whether to extend the validity period of an advance informed agreement or to order the revision or the doing of the risk assessment."

፲/ የአዋጁ አንቀጽ ፳፩ (ቁጥሩ በዚህ አንቀጽ ንዑስ አንቀጽ (፮) መሠረት እንደተሸጋሸገው) ንዑስ አንቀጾች (፫) እና (፬) ተሠርዘው በሚከተሉት አዲስ ንዑስ አንቀጾች (፫) እና (፬) ተተክተዋል:-

10/ sub-articles (3) and (4) of Article 21 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) are deleted and replaced by the following new sub-articles (3) and (4):

"፫/ የጉምሩክ ሠራተኛው በዚህ አንቀጽ ንዑስ አንቀጽ (፪) መሠረት የታገተውን ልውጥ ሕያው በብዝሐ ሕይወት፣ በአካባቢ እና በሰው ጤና ላይ የከፋ ጠንቅ በማያስከትል ማከማቻ ቦታ ማስቀመጥ አለበት።

"3/ The custom's officer shall store the modified organism impounded pursuant to sub-article (2) of this Article in an appropriate storage facility in such a manner that potential risks to biodiversity, the environment and human health are minimized.

፬/ ሚኒስቴሩ በዚህ አንቀጽ ንዑስ አንቀጽ (፪) መሠረት ተጠርጥሮ የታገተውን ዕቃ ናሙና በመፈተሽ በአምስት የሥራ ቀናት ውስጥ ልውጥ ሕያውን ማካተቱን ወይም አለማካተቱን ማረጋገጥ አለበት።"

4/ The Ministry shall, by examining the samples within five working days, verify whether the material impounded pursuant to sub-article (2) of this Article contains any modified organism or not."

፲፩/ ከአዋጁ አንቀጽ ፳ (ቁጥሩ በዚህ አንቀጽ ንዑስ አንቀጽ (፮) መሠረት እንደተሸጋሸገው) ቀጥሎ የሚከተለው አዲስ አንቀጽ ፳፪ እና ፳፫ ተጨምረው ነባሮቹ አንቀጾች ፳፩፣ ፳፪ እና ፳፫ እንደ ቅደም ተከተላቸው አንቀፅ ፳፬፣ ፳፭፣ እና ፳፮ ሆነው ተሸጋሸገዋል፡-

11/ the following new Article 22 and Article 23 are added after Article 21 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) and the existing Articles 21, 22 and 23 are re-numbered as Articles 24, 25 and 26 respectively:

"፳፪. <u>ብሄራዊ የደህንነተ ህይወት አማካሪ ኮሚቴ</u>

ለሚኒስትሩ ተጠሪ የሆነ እና ደህንነተ ህይወትን በሚመለከት መንግስትን የሚያማክር ብሄራዊ የደህንነተ ህይወት አማካሪ ኮሚቴ በሚኒስትሮች ምክር ቤት በሚወጣ ደንብ መሠረት ይቋቋማል።

"22. <u>National BioSafety Advisory Committee</u>

A National Biosafety Advisory Committee, accountable to the Minister shall be established by regulation to be issued by the Council of Ministers.

፳፫.ስለቅሬታ አቀራረብ

፩/ በዚህ አዋጅ መሠረት በግንባቤ ላይ የተመሠረተ ስምምነት ወይም ልዩ ፈቃድ ለማግኘት ወይም ፀንቶ የሚቆይበትን ጊዜ ለማረዘም የቀረበን ማመልከቻ ውድቅ በማድረግ ወይም ስምምነቱን ወይም ልዩ ፈቃዱን ለማገድ ወይም ለመሠረዝ በተሰጠ ውሳኔ ላይ ቅሬታ ያለው ማንኛውም ሰው ውሳኔው በተሰጠ በ፵፭ ቀናት ውስጥ በሚኒስቴሩ ለተቋቋመ ቅሬታ ሰሚ ኮሚቴ ቅሬታውን ማቅረብ ይችላል።

፪/ በዚህ አንቀጽ ንዑስ አንቀጽ (፩) በተወሰነው የጊዜ ገደብ ውስጥ ከአቅም በላይ በሆነ ምክንያት የቅሬታውን ማመልከቻ ሊያቀርብ ያልቻለ ማንኛውም ሰው ከአቅም በላይ የሆነው ምክንያት በተወገደ በ፲ ቀናት ውስጥ ማመልከቻውን ሊያቀርብ ይችላል።

፫/ የቅሬታ ሰሚ ኮሚቴው አባላት እና አደረጃጀት ይህን አዋጅ ለማስፈጸም በሚወጡ ደንቦች እና መመሪያዎች መሠረት ይወሰናል።

፬/ ቅሬታ ሰሚ ኮሚቴው በዚህ አንቀጽ ንዑስ አንቀጽ (፩) መሠረት የቀረበለትን ቅሬታ መርምሮ ውጤቱን ከውሳኔ ሃሳብ ጋር በ፭ የሥራ ቀናት ውስጥ ለሚኒስትሩ ያቀርባል።

፭/ በዚህ አንቀጽ ንዑስ አንቀጽ (፬) መሠረት በሚኒስትሩ የተሰጠ ውሳኔን በሚመለከት በሕግ አተረጓጎም ስህተት ቅር የተሰኘ አመልካች ውሳኔው በተሰጠ በ፷ ቀናት ውስጥ ለፌደራል ከፍተኛ ፍርድ ቤት ይግባኝ ማቅረብ ይችላል።"

23.Grievance Handling

1/ Any person aggrieved by the rejection of an application submitted in accordance with this Proclamation for the issuance or extension of the validity period of an advance informed agreement or special permit, or the suspension or revocation of the agreement or the special permit may, within 45 days from the date of such decision, lodge his complaint with the Grievance Hearing Committee established by the Ministry.

2/ Any person who cannot submit his complaint in accordance with sub-article (1) of this Article due to force majeure may submit his application within 10 days after the end of the force majeure.

3/ The grievance handling committee members and their composition shall be determined by the regulations and directives issued pursuant to this Proclamation.

4/ The grievance handling committee shall up on examining the compliant submitted to it pursuant to sub-article (1) of this Article provide its findings and recommendation to the Minister within five working days.

5/ An applicant aggrieved by the decision of the Minister given under sub-article (4) of this Article may, with respect to error of interpretation of law, appeal to the Federal High Court within 60 days from the date of the decision.''

፫.አዋጁ የሚፀናበት ጊዜ

ይህ አዋጅ በፌደራል ነጋሪት ጋዜጣ ታትሞ ከወጣበት ቀን ጀምሮ የፀና ይሆናል።

አዲስ አበባ ነሐሴ ፰ ቀን ፪ሺ፯ ዓ.ም

ዶ/ር ሙላቱ ተሾመ

የኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ

ፕሬዚዳንት

3. Effective Date

This Proclamation shall enter into force on the date of publication in the Federal Negarit Gazette.

Done at Addis Ababa, this 14th day of August, 2015.

MULATU TESHOME (DR.)

PRESIDENT OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

የኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ

ፌዴራል ነጋሪት ጋዜጣ

FEDERAL NEGARIT GAZETTE

OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

ሃያ ሶስተኛ ዓመት ቁጥር ፹፫
አዲስ አበባ መስከረም ፱ ቀን ፪ሺ፲ ዓ.ም

በኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ
የሕዝብ ተወካዮች ምክር ቤት ጠባቂነት የወጣ

23rd Year No.83
ADDIS ABABA, 19th September 2017

የሚኒስትሮች ምክር ቤት ደንብ ቁጥር ፬፻፲፩/፪ሺ፱

የብሔራዊ ደህንነት ህይወት አማካሪ ኮሚቴ ለማቋቋም የወጣ የሚኒስትሮች ምክር ቤት ደንብ

የሚኒስትሮች ምክር ቤት የኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ አስፈጻሚ አካላትን ሥልጣንና ተግባር ለመወሰን በወጣዉ አዋጅ ቁጥር ፱፻፲፭/፪ሺ፰ አንቀፅ ፭ እና የደህንነት ሕይወት አዋጅ ቁጥር ፮፻፶፭/፪ሺ፩ (በአዋጅ ቁጥር ፰፻፺፮/፪ሺ፮ እንደተሻሻለ) አንቀጽ ፳፪ መሰረት ይህን ደንብ አውጥቷል፡

ክፍል አንድ
ጠቅላላ

፩. አጭር ርዕስ

ይህ ደንብ "የብሔራዊ ደህንነት ህይወት አማካሪ ኮሚቴ ማቋቋሚያ የሚኒስትሮች ምክር ቤት ደንብ ቁጥር ፬፻፲፩/ ፪ሺ፱" ተብሎ ሊጠቀስ ይችላል።

Council of Ministers Regulation No. 411/2017

COUNCIL OF MINISTERS REGULATION TO PROVIDE FOR THE ESTABLISHMENT OF NATIONAL BIO-SAFETY ADVISORY COMMITTEE

This Regulation is issued by the Council of Ministers pursuant to Article 5 of the Definition of Powers and Duties of the Executive Organs of the Federal Democratic Republic of Ethiopia Proclamation No. 916/2015 and Article 22 of the Bio-safety Proclamation No. 655/2009 (as amended by Proclamation No. 896/2015).

PART ONE
GENERAL

1. Short Title

This Regulation shall be cited as the "National Bio-safety Advisory Committee Establishment Council of Ministers Regulation No. 411/2017".

ያንዱ ዋጋ
Unit Price

ነጋሪት ጋዜጣ ፖ.ሣ.ቁ. ፹ሺ፩
Negarit G. P.O.Box 80001

፪. ትርጓሜ

በዚህ ደንብ ውስጥ፤

፩/"ሚኒስቴር" እና "ሚኒስትር" ማለት እንደቅደም ተከተላቸው የአካባቢ የደንና የአየር ንብረት ለውጥ ሚኒስቴር እና ሚኒስትር ነው፤

፪/"አዋጅ" ማለት የደህንነት ሕይወት አዋጅ ቁጥር ፮፻፶፭/፪፻፩ (በአዋጅ ቁጥር ፹፻፶፮/፪፻፯ እንደተሻሻለ) ነው፤

፫/በወንድ ፆታ የተገለፀው ድንጋጌ ሴትንም ያካትታል።

ክፍል ሁለት

የብሔራዊ ደህንነተ ህይወት አማካሪ ኮሚቴ

፫. መቋቋም

፩/የብሔራዊ ደህንነት ህይወት አማካሪ ኮሚቴ (ከዚህ በኋላ በዚህ ደንብ ውስጥ "ኮሚቴ" እየተባለ የሚጠራ) በዚህ ደንብ ተቋቁሟል።

፪/የኮሚቴው ተጠሪነት ለሚኒስትሩ ይሆናል።

፬. ዓላማ

የኮሚቴው ዓላማ ደህንነተ ህይወትን በሚመለከት መንግስትን ማማከር ነው።

፭. የኮሚቴው ተግባርና ኃላፊነት

ኮሚቴው፡-

፩/በልውጠ ህያዋን እንቅስቃሴ፣

፪/በደህንነተ ህይወት ጉዳዮች የሚወጡ ፖሊሲዎችና ሕጎች፣

፫/በልውጠ ህያዋን እንቅስቃሴ በተመለከተ ለማህበረሰብ ግንዛቤ ለመፍጠር የሚያግዙ ውጤታማ ዘዴዎች መለየት እና

፬/በማናቸውም የደህንነተ ህይወት ጉዳዮች ላይ ከሚኒስትሩ በሚቀርብ ጥያቄ ወይም ከሌሎች ሚኒስቴር መሥሪያ ቤቶች በሚኒስትሩ በኩል በሚቀርብ ጥያቄ መሠረት መንግስትን የማማከር ተግባርና ኃላፊነቶች ይኖሩታል።

2. Definition

In this Regulation:

1/"Ministry" and "Minister" means the Ministry and Minister of Environment, Forest and Climate Change, respectively;

2/"Proclamation" means the Bio-safety Proclamation No. 655/2009 (as amended by Proclamation No. 896/2015);

3/any expression in the masculine gender includes the feminine.

PART TWO

NATIONAL BIOSAFETY ADVISORY COMMITTEE

3. Establishment

1/ The National Bio-safety Advisory Committee (in this Regulation to be referred as the "Committee") is hereby established.

2/ The committee shall be accountable to the Minister.

4. Objective

The objective of the Committee shall be to advise the Government on issues related to bio-safety.

5. Powers and Duties of the Committee

The Committee shall, upon request by the Minister, or by the request of other ministries through the Minister have the powers and duties to advise the Government on:

1/transactions of genetically modified organisms;

2/the issues of national policies and laws of bio-safety;

3/identifying effective methods to create public awareness regarding transactions of genetically modified organisms;

4/ on any other matters related to bio-safety

፮. የኮሚቴ አባላት

፩/የኮሚቴው አባላት ሰብሳቢውንና ምክትል ሰብሳቢውን ጨምሮ በሚኒስትሩ አቅራቢነት በመንግስት ይሰየማሉ፤ ቁጥራቸውም እንደ አስፈላጊነቱ ይወሰናል፡፡

፪/የኮሚቴው አባላት አግባብነት ያለው ሙያዊ ክህሎትና ልምድን እንዲሁም ተቋማዊ አግባብነት ያለው ውክልናን መሠረት በማድረግ ከመንግሥታዊ አካላት እንዲሁም ከከፍተኛ የትምህርት ተቋማት፣ ብዙሃን ማህበራትና መንግሥታዊ ካልሆኑ ተቋማት የተውጣጡ ይሆናል።

፫/በዚህ አንቀጽ ንዑስ አንቀጽ (፪) የተደነገገው እንደተጠበቀ ሆኖ የሚቋቋመው ኮሚቴ ከተለያዩ ተቋማት የተውጣጡ የሚከተሉትን የሙያ ስብጥሮች የሚያካተት ይሆናል፡-

ሀ)ባዮቴክኖሎጂ፤

ለ)በዘረመል ምህንድስና፣

ሐ)የብዝሃ ህይወት፣

መ)የተፈጥሮ ሳይንስ፣

ሠ)የአካባቢ ሳይንስ፣

ረ)የህክምና ወይም የጤና ሳይንስ

ሰ)የምግብ ሳይንስ

ሸ)የእንስሳት ሳይንስ

ቀ)በማኅበራዊ ሳይንስ እና

በ)እንደ አስፈላጊነቱ አግባብ ያለውን ሌላ ሙያ ዘርፍ።

7. Members of the Committee

1/The Committee members, including the Chairperson and Deputy Chairperson, shall be nomination by the Minister and be assigned by the Government; and their numbers shall be determined as appropriate

2/The Committee shall be comprised of members with relevant qualification, experience and organizational representations from government bodies, higher education institutions, civil societies and non-governmental institutions.

3/Without prejudice to sub-article (2) of this Article the Committee shall be drawn from different institutions comprise the following professional:

a)Biotechnology;

b)Genetic Engineering;

c)Biodiversity;

d)Natural Science;

e)Environmental Science;

f)Medical or Health science;

g)Nutrition Science;

h)Animal Science;

i)Social Science and

j)other disciplines as appropriate.

፯. የኮሚቴው ሰብሳቢ ስልጣንና ተግባር

የኮሚቴው ሰብሳቢ የሚከተሉት ሥልጣንና ተግባራት ይኖሩታል፡-

፩/ ኮሚቴውን ይሰበስባል፣ ሥራዎች ይመራል፤

፪/ በዚህ ደንብ አንቀጽ ፭ የተመለከቱትን ኃላፊነትና ተግባራት በሥራ ላይ እንዲውል ያደርጋል፤

፫/ መደበኛና አስቸኳይ ስብሰባ ይጠራል።

7. Powers and Duties of the Chairperson

The Chairperson of the Committee shall have the following powers and duties:

1/preside and lead the activities of the committee;

2/cause the execution of powers and duties defined in Article 5 of this Regulation;

3/call regular and extraordinary meetings.

፰. ስለኮሚቴው ስብሰባ

፩/ ኮሚቴው ቢያንስ በዓመት አራት ጊዜ መደበኛ ስብሰባ ያካሂዳል።

፪/ የዚህ አንቀጽ ንዑስ አንቀጽ (፩) እንደተጠበቀ ሆኖ በሰብሳቢው ጥሪ ኮሚቴው በማንኛውም ጊዜ አስቸኳይ ስብሰባ ሊያካሂድ ይችላል።

፫/ ከኮሚቴው አባላት ከሁለት ሦስተኛው በላይ በስብሰባ ከተገኙ ምልዓተ ጉባኤ ይሆናል፣

፬/ የኮሚቴው ምክረ ሀሳብ በስምምነት የሚተላለፍ ይሆናል፤ ልዩነት በሚፈጠር ወቅት አብላጫው ምክረ ሀሳብ እና የልዩነት ሀሳቦች ተካተው ለሚኒስትሩ ይቀርባሉ።

፱. የኮሚቴው አባላት የሥራ ዘመን

፩/የኮሚቴ አባላት የአገልግሎት ዘመን ለሶስት ዓመት ይሆናል።

፪/የዚህ አንቀጽ ንዑስ አንቀጽ (፩) ድንጋጌ ቢኖርም ሚኒስትሩ ከሚመለከተው አካል ጋር በመመካከር የኮሚቴ አባል በድጋሚ ለተጨማሪ አንድ የሥራ ዘመን እንዲሰየም ማድረግ ይችላል።

፲. ምስጢር ስለመጠበቅ

፩/በኮሚቴው በይፋ እንዳይወጣ የተወሰነን መረጃ የኮሚቴው አባላት ሚስጢራዊነቱን መጠበቅ አለባቸው።

፪/በዚህ አንቀጽ ንዑስ አንቀጽ (፩) የተደነገገውን የተላለፈ የኮሚቴ አባል አግባብነት ባለው ሕግ ተጠያቂ ይሆናል።

ክፍል ሶስት
የብሔራዊ ደህንነተ ህይወት አማካሪ ኮሚቴ ጽሕፈት ቤት

፲፩. ጽሕፈት ቤት

የብሔራዊ ደህንነተ ሕይወት አማካሪ ኮሚቴ ጽሕፈት ቤት በሚኒስቴሩ ስር የሚደራጅ ይሆናል።

፲፪. የጽሕፈት ቤቱ ተግባርና ኃላፊነት

ጽሕፈት ቤቱ ፡-

፩/ማንኛውንም የደህንተ ህይወት ጥያቄ በማደራጀት ለኮሚቴው ያቀርባል፤

፪/የኮሚቴውን ምክረ ሀሳብ ለሚኒስትሩ ያቀርባል፤

፫/የኮሚቴውን የክንውን ሪፖርት በማዘጋጀት ለሚኒሰትሩ ያቀርባል፤

8. Meetings of the Committee

1/The Committee shall hold its regular meeting at least four times a year.

2/Without prejudice to sub-article (1) of this Article the committee may have extraordinary meeting any time upon the call of the Chairperson.

3/There shall be a quorum where more than two third of the members of the Committee are present at a meeting.

4/The Committee shall present its recommendation in consensus provided, however, if consensus is not reached, the majority recommendation together with the dissenting opinion shall be sent to the Minister.

9. Terms Committee members

1/The term of office of the Committee members shall be three years.

2/Notwithstanding sub-article (1) of this Article, the Minister may, in consultation with appropriate body, assign a member of committee for one additional term.

10. Confidentiality

1/The Committee members shall keep any information that has been decided not to be disclosed.

2/Any Committee member who violates sub-article (1) of this provision shall be liable according to relevant laws.

PART THREE
NATIONAL BIOSAFETY ADVISORY COMMITTEE SECRETARTIAT

11 .Secretariat

The Secretariat of the National Bio-safety Advisorv Committee shall be organized under the Ministry.

12 .Powers and Duties of the Secretariat

The Secretariat shall:

1/organize and submit any bio-safety requests made to the committee;

2/submit the recommendation of the Committee to the Minister;

3/prepare and submit performance report of the Committee to the Minister.

፱/የኮሚቴውን ምክረ ሀሳብ እና ሌሎች ሰነዶችን በአግባቡ አደራጅቶ ይይዛል።

ክፍል አራት

ልዩ ልዩ ድንጋጌዎች

፲፫. መመሪያ ስለማውጣት

ይህን ደንብ ለማስፈጸም ሚኒስቴሩ መመሪያዎችን ሊያወጣ ይችላል።

፲፬. ደንቡ የሚፀናበት ጊዜ

ይህ ደንብ በፌደራል ነጋሪት ጋዜጣ ታትሞ ከወጣበት ቀን ጀምሮ የፀና ይሆናል።

አዲስ አበባ መስከረም ፱ቀን ፪ሺ፲ ዓ.ም

ኃይለማሪያም ደሳለኝ

የኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ጠቅላይ ሚኒስትር

4/compile and maintain recommendations and other documents of the Committee.

PART FOUR

MISCELLANEOUS PROVISIONS

13. Power to Issue Directive

The Minister may issue directives necessary for the implementation of this Regulation.

14. Effective Date

This Regulation shall come into force on the date of publication in the Federal Negarit Gazette.

Done at Addis Ababa this 19th day of September , 2017

HAILEMARIAM DESSALEGN

PRIME MINISTER OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

3. International Treaties Ratified by Ethiopia

የኢትዮጵያ ፌደራላዊ ዲሞክራሲያዊ ሪፐብሊክ

ፌዴራል ነጋሪት ጋዜጣ

FEDERAL NEGARIT GAZETA

OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

ዘጠነኛ ዓመት ቁጥር ፹፯
አዲስ አበባ–ሐምሌ ፳፱ ቀን ፲፱፻፺፭ ዓ.ም

በኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ
የሕዝብ ተወካዮች ምክር ቤት ጠባቂነት የወጣ

9th Year No. 87
ADDIS ABABA–31st July, 2003

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በኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ሕገ መንግሥት አንቀጽ ፶፭/፩/እና (፲፪) መሠረት የሚከተለው ታውጇል።

፩· አጭር ርዕስ

ይህ አዋጅ "የካርታጎና የደህንነት ህይወት ፕሮቶኮል ማፅደቂያ አዋጅ ቁጥር ፫፻፷፪/፲፱፻፺፭" ተብሎ ሊጠቀስ ይችላል።

፪· ፕሮቶኮሉ ስለመጽደቁ

ጃንዋሪ ፳፱ ቀን ፪ ሺ ዓ.ም በብዝሃ ሕይወት ዓለም አቀፍ ውል መሠረት የወጣው የካርታጎና የደህንነት ሕይወት ፕሮቶኮል "የካርታጎና የደህንነት ሕይወት ፕሮቶኮል ማፅደቂያ አዋጅ አፅድቋል።

PROCLAMATION NO. 362/2003

A PROCLAMATION TO RATIFY THE CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

WHEREAS, the Cartagena an Protocol on Biosafety to the Convention on Biological Diversity was adopted on the 29th January, 2000;

WHEREAS, the House of Peoples' Representatives of the Federal Democratic Republic of Ethiopia ratifed the Cartagena Protocol on Biosafety to the Convention on Biological Diversity at its session held on 31st July, 2003

NOW, THEREFORE, in accordance with Article 55 (1) and (12) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follows:

1. *Short Title*

This Proclamation may be cited as the "Cartagena Porotocol on Biosafety Ratification Proclamation No. 362/2003".

2. *Ratification of the Protocol*

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted on the 29th day of Junuary, 2000 is hereby ratified.

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፫· የአካባቢ ጥበቃ ባለሥልጣን ኃላፊነት

የአካባቢ ጥበቃ ባለሥልጣን አግባብ ካላቸው የፌዴራል፣ የክልልና የከተማ የመንግሥት መሥሪያ ቤቶች ጋር በመተ ባበር ፕሮቶኮሉን በሥራ ላይ እንዲውል የማድረግ ኃላፊነት በዚህ አዋጅ ተሰጥቶታል።

፬· አዋጁ የሚፀናበት ጊዜ

ይህ አዋጅ ከሐምሌ ፳፩ ቀን ፲፱፻፺፭ ዓ·ም ጀምሮ የጸና ይሆናል።

አዲስ አበባ ሐምሌ ፳፩ ቀን ፲፱፻፺፭ ዓ·ም

ግርማ ወልደጊዮርጊስ
የኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ
ፕሬዚዳንት

3. *Responsibility of the Environmental Protection Authority*

The Environmental Protection Authority is hereby authorized to take, in cooperation with the appropriate Federal, Regional and city government organs, actions necessary to implement the Protocol.

4. *Effective Date*

This Proclamation shall enter into force as of the 31st day of July, 2003.

Done at Addis Ababa this 31st day of July, 2003.

GIRMA WOLDEGIORGIS
PRESIDENT OF THE FEDERAL
DEMOCRATIC REPUBLIC OF ETHIOPIA

ብርሃንና ሰላም ማተሚያ ድርጅት ታተመ
BERHANENA SELAM PRINTING ENTERPRISE

አምሳ ሰባተኛ ዓመት ቁጥር ፹፰
53rd Year — No. 88

አዲስ አበባ ግንቦት ፳፫ ቀን ፲፱፻፹፯ ዓ. ም.
Addis Ababa, 31st May, 1994

የኢትዮጵያ የሽግግር መንግሥት

ነጋሪት ጋዜጣ

NEGARIT GAZETA

OF THE TRANSITIONAL GOVERNMENT OF ETHIOPIA

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አዋጅ ቁጥር ፺፰/፲፱፻፹፯

የብዝሀ ሕይወት ዓለም አቀፍ ስምምነት ለማጽደቅ የወጣ አዋጅ

የብዝሀ ሕይወት ዓለም አቀፍ ስምምነት የተባበሩት መንግሥታት የአካባቢና የልማት ጉባዔ በተካሄደበት በሪዮ ዲጃንሮ ፣ ብራዚል ሰኔ ፲፩ ቀን ፲፱፻፹፬ በኢትዮጵያ የተፈረመ ስለሆነ ፣

ይህንኑ ስምምነት የኢትዮጵያ የሽግግር መንግሥት ተወካዮች ምክር ቤት ያጸደቀው ስለሆነ ፣

በሽግግር መቅትት ቻርተር አንቀጽ ፱/መ/ እና (ሸ) መሠረት የሚከተለው ታውጇዋል ።

፩. አጭር ርዕስ

ይህ አዋጅ «የብዝሀ ሕይወት ዓለም አቀፍ ስምምነት ማጽደቂያ አዋጅ ቁጥር ፺፰/፲፱፻፹፯» ተብሎ ሊጠቀስ ይችላል ።

፪. ስምምነቱ ስለመጽደቁ

ግንቦት ፭፰ ቀን ፲፱፻፹፬ ዓ. ም. በሪዮ ዲጃኔሮ ከተማ የተፈረመው የብዝሀ ሕይወት ዓለም አቀፍ ስምምነት ጸድቋል ።

PROCLAMATION No. 98/1994

A PROCLAMATION TO RATIFY THE BIODIVERSITY CONVENTION

WHEREAS, the Biodiversity Convention has been signed by Ethiopia on June 10, 1992, in Rio di Janeiro, Brazil, where the United Nations Conference on Environment and Development was held;

WHEREAS the Council of Representatives of the Transitional Government of Ethiopia has ratified said Convention;

NOW, THEREFORE, in accordance with Article 9 (d) and (h) of the Transitional Period Charter, it is hereby proclaimed as follows:

1. *Short Title*

This Proclamation may be cited as the "Biodiversity Convention Ratification Proclamation No. 98/1994."

2. *Ratification of the Convention*

The Biodiversity Convention, done at Rio di Janeiro on the 5th day of June 1992 is ratified.

፫. የተፈጥሮ ሀብት ልማትና የአካባቢ ጥበቃ ሚኒስትር ሥልጣን

የተፈጥሮ ሀብት ልማትና የአካባቢ ጥበቃ ሚኒስትር ስምምነቱ በሥራ ላይ እንዲውል የሚደረግ ሥልጣን በዚህ አዋጅ ተሰጥቶታል ።

፬. አዋጁ የሚጸናበት ጊዜ

ይህ አዋጅ በኔጋሪት ጋዜጣ ታትሞ ከወጣበት ጊዜ ጀምሮ የጸና ይሆናል ።

አዲስ አበባ ግንቦት ፳፫ ቀን ፲፱፻፹፯ ዓ. ም.

መለስ ዜናዊ

የኢትዮጵያ የሽግግር መንግሥት

ፕሬዚዳንት

3. *Power of the Minister of Natural Resources and Environmental Protection*

The Minister of Natural Resources Development and Environmental Protection is hereby empowered to undertake all acts necessary for the implementation of the Convention.

4. *Effective Date*

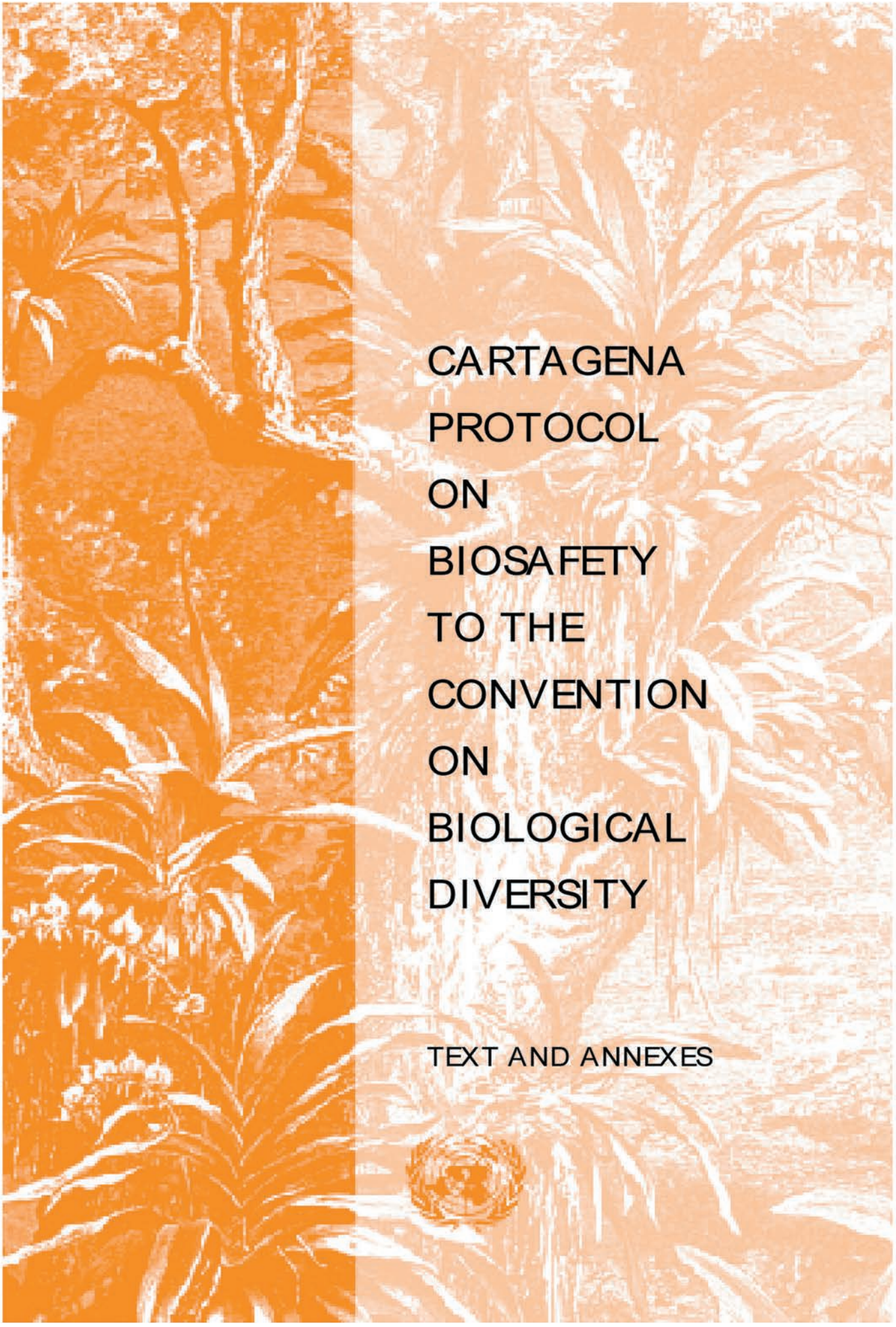
This Proclamation shall enter into force on the date of its publication in the Negarit Gazeta.

Done at Addis Ababa, this 31st day of May 1994.

MELES ZENAWI

PRESIDENT OF THE TRANSITIONAL GOVERNMENT OF ETHIOPIA

4. Cartagena Protocol on Biosafety (CPB, 2000)



CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

TEXT AND ANNEXES

Montreal, 2000

Montreal, 2000

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Introduction

The Convention on Biological Diversity was finalized in Nairobi in May 1992 and opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro on 5 June1992. It entered into force on 29 December 1993. Today, the Convention is the main international instrument for addressing biodiversity issues. It provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of genetic resources.

Biosafety is one of the issues addressed by the Convention. This concept refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care. The Convention clearly recognizes these twin aspects of modern biotechnology. On the one hand, it provides for the access to and transfer of technologies, including biotechnology, that are relevant to the conservation and sustainable use of biological diversity (for example, in Article 16, paragragh 1, and Article 19, paragraphs 1 and 2). On the other hand, Articles 8(g) and 19, paragraph 3, seek to ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity, taking also into account the risks to human health. Article 8(g) deals with measures that Parties should take at national level, while Article 19, paragraph 3, sets the stage for the development of an international legally binding instrument to address the issue of biosafety.

At its second meeting, held in November 1995, the Conference of the Parties to the Convention established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, focusing specifically on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. After several years of negotiations, the Protocol, known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was finalized and adopted in Montreal on 29 January 2000 at an extraordinary meeting of the Conference of the Parties.

The conclusion of the Biosafety Protocol has been hailed as a significant step forward in that it provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry. The Protocol thus creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article

1
OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article

2
GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article
3
USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by

this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article
4
SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article
5
PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article
6
TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on

import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article
7
APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article
8
NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article
9
ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article
10
DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within

which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article

11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article
12
REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article
13
SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article
14
BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article
15
RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article
16
RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article
17
UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article
18
HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article
19
COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article
20
INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article

21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing

reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article
22
CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial

resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article
23
PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article
24
NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article
25
ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article
26
SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article
27
LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article
28
FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of,

financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article
29
CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article
30
SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article
31
SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article
32
RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article
33
MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article
34
COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article
35
ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article
36
SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article
37
ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article
38
RESERVATIONS

No reservations may be made to this Protocol.

Article
39
WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article
40
AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I
INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material

obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) *Vector*. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) *Insert or inserts and/or characteristics of modification.* Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) *Living modified organism.* Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) *Detection and identification of the living modified organism.* Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) *Information relating to the intended use.* Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) *Receiving environment.* Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

5. Convention on Biological Diversity (CBD, 1992)

CONVENTION
ON BIOLOGICAL DIVERSITY

UNITED NATIONS
1992

CONVENTION ON BIOLOGICAL DIVERSITY

Preamble

The Contracting Parties,

Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components,

Conscious also of the importance of biological diversity for evolution and for maintaining life sustaining systems of the biosphere,

Affirming that the conservation of biological diversity is a common concern of humankind,

Reaffirming that States have sovereign rights over their own biological resources,

Reaffirming also that States are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner,

Concerned that biological diversity is being significantly reduced by certain human activities,

Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,

Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,

Noting further that the fundamental requirement for the conservation of biological diversity is the *in-situ* conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings,

Noting further that *ex-situ* measures, preferably in the country of origin, also have an important role to play,

Recognizing the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising

from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components,

Recognizing also the vital role that women play in the conservation and sustainable use of biological diversity and affirming the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation,

Stressing the importance of, and the need to promote, international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and the sustainable use of its components,

Acknowledging that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,

Acknowledging further that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies,

Noting in this regard the special conditions of the least developed countries and small island States,

Acknowledging that substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits from those investments,

Recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries,

Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential,

Noting that, ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among States and contribute to peace for humankind,

Desiring to enhance and complement existing international arrangements for the conservation of biological diversity and sustainable use of its components, and

Determined to conserve and sustainably use biological diversity for the benefit of present and future generations,

Have agreed as follows:

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 2. Use of Terms

For the purposes of this Convention:

"*Biological diversity*" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems.

"*Biological resources*" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"*Biotechnology*" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"*Country of origin of genetic resources*" means the country which possesses those genetic resources in *in-situ* conditions.

"*Country providing genetic resources*" means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

"*Domesticated or cultivated species*" means species in which the evolutionary process has been influenced by humans to meet their needs.

"*Ecosystem*" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"*Ex-situ conservation*" means the conservation of components of biological diversity outside their natural habitats.

"*Genetic material*" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"*Genetic resources*" means genetic material of actual or potential value.

"*Habitat*" means the place or type of site where an organism or population naturally occurs.

"*In-situ conditions*" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*In-situ conservation*" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*Protected area*" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

"*Regional economic integration organization*" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"*Sustainable use*" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"*Technology*" includes biotechnology.

Article 3. Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 4. Jurisdictional Scope

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:

(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and

(b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Article 5. Cooperation

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

Article 6. General Measures for Conservation and Sustainable Use

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, *inter alia*, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

Article 7. Identification and Monitoring

Each Contracting Party shall, as far as possible and as appropriate, in particular for the purposes of Articles 8 to 10:

(a) Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I;

(b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;

(c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and

(d) Maintain and organize, by any mechanism data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.

Article 8. In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;

(b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;

(c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;

(d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;

(e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;

(f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, *inter alia*, through the development and implementation of plans or other management strategies;

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

(h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;

(i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components;

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

(k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;

(l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and

(m) Cooperate in providing financial and other support for *in-situ* conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.

Article 9. Ex-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing *in-situ* measures:

(a) Adopt measures for the *ex-situ* conservation of components of biological diversity, preferably in the country of origin of such components;

(b) Establish and maintain facilities for *ex-situ* conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources;

(c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;

(d) Regulate and manage collection of biological resources from natural habitats for *ex-situ* conservation purposes so as not to threaten ecosystems and *in-situ* populations of species, except where special temporary *ex-situ* measures are required under subparagraph (c) above; and

(e) Cooperate in providing financial and other support for *ex-situ* conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of *ex-situ* conservation facilities in developing countries.

Article 10. Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;

(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

Article 11. Incentive Measures

Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.

Article 12. Research and Training

The Contracting Parties, taking into account the special needs of developing countries, shall:

(a) Establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries;

(b) Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, *inter alia*, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice; and

(c) In keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

Article 13. Public Education and Awareness

The Contracting Parties shall:

(a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes; and

(b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

Article 14. Impact Assessment and Minimizing Adverse Impacts

1. Each Contracting Party, as far as possible and as appropriate, shall:

(a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures;

(b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;

(c) Promote, on the basis of reciprocity, notification, exchange of information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;

(d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and

(e) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international cooperation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans.

2. The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms

which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17. Exchange of Information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Article 18. Technical and Scientific Cooperation

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.

2. Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, *inter alia*, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.

3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Article 19. Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling

such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Article 20. Financial Resources

1. Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes.

2. The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and the institutional structure referred to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria and an indicative list of incremental costs established by the Conference of the Parties. Other Parties, including countries undergoing the process of transition to a market economy, may voluntarily assume the obligations of the developed country Parties. For the purpose of this Article, the Conference of the Parties, shall at its first meeting establish a list of developed country Parties and other Parties which voluntarily assume the obligations of the developed country Parties. The Conference of the Parties shall periodically review and if necessary amend the list. Contributions from other countries and sources on a voluntary basis would also be encouraged. The implementation of these commitments shall take into account the need for adequacy, predictability and timely flow of funds and the importance of burden-sharing among the contributing Parties included in the list.

3. The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.

4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties.

5. The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

6. The Contracting Parties shall also take into consideration the special conditions resulting from the dependence on, distribution and location of, biological diversity within developing country Parties, in particular small island States.

7. Consideration shall also be given to the special situation of developing countries, including those that are most environmentally vulnerable, such as those with arid and semi-arid zones, coastal and mountainous areas.

Article 21. Financial Mechanism

1. There shall be a mechanism for the provision of financial resources to developing country Parties for purposes of this Convention on a grant or concessional basis the essential elements of which are described in this Article. The mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties for purposes of this Convention. The operations of the mechanism shall be carried out by such institutional structure as may be decided upon by the Conference of the Parties at its first meeting. For purposes of this Convention, the Conference of the Parties shall determine the policy, strategy, programme priorities and eligibility criteria relating to the access to and utilization of such resources. The contributions shall be such as to take into account the need for predictability, adequacy and timely flow of funds referred to in Article 20 in accordance with the amount of resources needed to be decided periodically by the Conference of the Parties and the importance of burden-sharing among the contributing Parties included in the list referred to in Article 20, paragraph 2. Voluntary contributions may also be made by the developed country Parties and by other countries and sources. The mechanism shall operate within a democratic and transparent system of governance.

2. Pursuant to the objectives of this Convention, the Conference of the Parties shall at its first meeting determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources including monitoring and evaluation on a regular basis of such utilization. The Conference of the Parties shall decide on the arrangements to give effect to paragraph 1 above after consultation with the institutional structure entrusted with the operation of the financial mechanism.

3. The Conference of the Parties shall review the effectiveness of the mechanism established under this Article, including the criteria and guidelines referred to in paragraph 2 above, not less than two years after the entry into force of this Convention and thereafter on a regular basis. Based on such review, it shall take appropriate action to improve the effectiveness of the mechanism if necessary.

4. The Contracting Parties shall consider strengthening existing financial institutions to provide financial resources for the conservation and sustainable use of biological diversity.

Article 22. Relationship with Other International Conventions

1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

Article 23. Conference of the Parties

1. A Conference of the Parties is hereby established. The first meeting of the Conference of the Parties shall be convened by the Executive Director of the United Nations Environment Programme not later than one year after the entry into force of this Convention. Thereafter, ordinary meetings of the Conference of the Parties shall be held at regular intervals to be determined by the Conference at its first meeting.

2. Extraordinary meetings of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat, it is supported by at least one third of the Parties.

3. The Conference of the Parties shall by consensus agree upon and adopt rules of procedure for itself and for any subsidiary body it may establish, as well as financial rules governing the funding of the Secretariat. At each ordinary meeting, it shall adopt a budget for the financial period until the next ordinary meeting.

4. The Conference of the Parties shall keep under review the implementation of this Convention, and, for this purpose, shall:

(a) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 26 and consider such information as well as reports submitted by any subsidiary body;

(b) Review scientific, technical and technological advice on biological diversity provided in accordance with Article 25;

(c) Consider and adopt, as required, protocols in accordance with Article 28;

(d) Consider and adopt, as required, in accordance with Articles 29 and 30, amendments to this Convention and its annexes;

(e) Consider amendments to any protocol, as well as to any annexes thereto, and, if so decided, recommend their adoption to the parties to the protocol concerned;

(f) Consider and adopt, as required, in accordance with Article 30, additional annexes to this Convention;

(g) Establish such subsidiary bodies, particularly to provide scientific and technical advice, as are deemed necessary for the implementation of this Convention;

(h) Contact, through the Secretariat, the executive bodies of conventions dealing with matters covered by this Convention with a view to establishing appropriate forms of cooperation with them; and

(i) Consider and undertake any additional action that may be required for the achievement of the purposes of this Convention in the light of experience gained in its operation.

5. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State not Party to this Convention, may be represented as observers at meetings of the Conference of the Parties. Any other body or agency, whether governmental or non-governmental, qualified in fields relating to conservation and sustainable use of biological diversity, which has informed the Secretariat of its wish to be represented as an observer at a meeting of the Conference of the Parties, may be admitted unless at least one third of the Parties present object. The admission and participation of observers shall be subject to the rules of procedure adopted by the Conference of the Parties.

Article 24. Secretariat

1. A secretariat is hereby established. Its functions shall be:

(a) To arrange for and service meetings of the Conference of the Parties provided for in Article 23;

(b) To perform the functions assigned to it by any protocol;

(c) To prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;

(d) To coordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and

(e) To perform such other functions as may be determined by the Conference of the Parties.

2. At its first ordinary meeting, the Conference of the Parties shall designate the secretariat from amongst those existing competent international organizations which have signified their willingness to carry out the secretariat functions under this Convention.

Article 25. Subsidiary Body on Scientific, Technical and Technological Advice

1. A subsidiary body for the provision of scientific, technical and technological advice is hereby established to provide the Conference of the Parties and, as appropriate, its other subsidiary bodies with timely advice relating to the implementation of this Convention. This body shall be open to participation by all Parties and shall be multidisciplinary. It shall comprise government representatives competent in the relevant field of expertise. It shall report regularly to the Conference of the Parties on all aspects of its work.

2. Under the authority of and in accordance with guidelines laid down by the Conference of the Parties, and upon its request, this body shall:

(a) Provide scientific and technical assessments of the status of biological diversity;

(b) Prepare scientific and technical assessments of the effects of types of measures taken in accordance with the provisions of this Convention;

(c) Identify innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies;

(d) Provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity; and

(e) Respond to scientific, technical, technological and methodological questions that the Conference of the Parties and its subsidiary bodies may put to the body.

3. The functions, terms of reference, organization and operation of this body may be further elaborated by the Conference of the Parties.

Article 26. Reports

Each Contracting Party shall, at intervals to be determined by the Conference of the Parties, present to the Conference of the Parties, reports on measures which it has taken for the implementation of the provisions of this Convention and their effectiveness in meeting the objectives of this Convention.

Article 27. Settlement of Disputes

1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.

2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.

3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:

(a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;

(b) Submission of the dispute to the International Court of Justice.

4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.

5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.

Article 28. Adoption of Protocols

1. The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention.

2. Protocols shall be adopted at a meeting of the Conference of the Parties.

3. The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting.

Article 29. Amendment of the Convention or Protocols

1. Amendments to this Convention may be proposed by any Contracting Party. Amendments to any protocol may be proposed by any Party to that protocol.

2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties. Amendments to any protocol shall be adopted at a meeting of the Parties to the Protocol in question. The text of any proposed amendment to this Convention or to any protocol, except as may otherwise be provided in such protocol, shall be communicated to the Parties to the instrument in question by the secretariat at least six months before the meeting at which it is proposed for adoption. The secretariat shall also communicate proposed amendments to the signatories to this Convention for information.

3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention or to any protocol by consensus. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-third majority vote of the Parties to the instrument in question present and voting at the meeting, and shall be submitted by the Depositary to all Parties for ratification, acceptance or approval.

4. Ratification, acceptance or approval of amendments shall be notified to the Depositary in writing. Amendments adopted in accordance with paragraph 3 above shall enter into force among Parties having accepted them on the ninetieth day after the deposit of instruments of ratification, acceptance or approval by at least two thirds of the Contracting Parties to this Convention or of the Parties to the protocol concerned, except as may otherwise be provided in such protocol. Thereafter the amendments shall enter into force for any other Party on the ninetieth day after that Party deposits its instrument of ratification, acceptance or approval of the amendments.

5. For the purposes of this Article, "Parties present and voting" means Parties present and casting an affirmative or negative vote.

Article 30. Adoption and Amendment of Annexes

1. The annexes to this Convention or to any protocol shall form an integral part of the Convention or of such protocol, as the case may be, and, unless expressly provided otherwise, a reference to this Convention or its protocols constitutes at the same time a reference to any annexes thereto. Such annexes shall be restricted to procedural, scientific, technical and administrative matters.

2. Except as may be otherwise provided in any protocol with respect to its annexes, the following procedure shall apply to the proposal, adoption and entry into force of additional annexes to this Convention or of annexes to any protocol:

(a) Annexes to this Convention or to any protocol shall be proposed and adopted according to the procedure laid down in Article 29:

(b) Any Party that is unable to approve an additional annex to this Convention or an annex to any protocol to which it is Party shall so notify the Depositary, in writing, within one year from the date of the communication of the adoption by the Depositary. The Depositary shall without delay notify all Parties of any such notification received. A Party may at any time withdraw a previous declaration of objection and the annexes shall thereupon enter into force for that Party subject to subparagraph (c) below:

(c) On the expiry of one year from the date of the communication of the adoption by the Depositary, the annex shall enter into force for all Parties to this Convention or to any protocol concerned which have not submitted a notification in accordance with the provisions of subparagraph (b) above.

3. The proposal, adoption and entry into force of amendments to annexes to this Convention or to any protocol shall be subject to the same procedure as for the proposal, adoption and entry into force of annexes to the Convention or annexes to any protocol.

4. If an additional annex or an amendment to an annex is related to an amendment to this Convention or to any protocol, the additional annex or amendment shall not enter into force until such time as the amendment to the Convention or to the protocol concerned enters into force.

Article 31. Right to Vote

1. Except as provided for in paragraph 2 below, each Contracting Party to this Convention or to any protocol shall have one vote.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their member States which are Contracting Parties to this Convention or the relevant protocol. Such organizations shall not exercise their right to vote if their member States exercise theirs, and vice versa.

Article 32. Relationship between this Convention and Its Protocols

1. A State or a regional economic integration organization may not become a Party to a protocol unless it is, or becomes at the same time, a Contracting Party to this Convention.

2. Decisions under any protocol shall be taken only by the Parties to the protocol concerned. Any Contracting Party that has not ratified, accepted or approved a protocol may participate as an observer in any meeting of the parties to that protocol.

Article 33. Signature

This Convention shall be open for signature at Rio de Janeiro by all States and any regional economic integration organization from 5 June 1992 until 14 June 1992, and at the United Nations Headquarters in New York from 15 June 1992 to 4 June 1993.

Article 34. Ratification, Acceptance or Approval

1. This Convention and any protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.

2. Any organization referred to in paragraph 1 above which becomes a Contracting Party to this Convention or any protocol without any of its member States being a Contracting Party shall be bound by all the obligations under the Convention or the protocol, as the case may be. In the case of such organizations, one or more of whose member States is a Contracting Party to this Convention or relevant protocol, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under the Convention or protocol, as the case may be. In such cases, the organization and the member States shall not be entitled to exercise rights under the Convention or relevant protocol concurrently.

3. In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

Article 35. Accession

1. This Convention and any protocol shall be open for accession by States and by regional economic integration organizations from the date on which the Convention or the protocol concerned is closed for signature. The instruments of accession shall be deposited with the Depositary.

2. In their instruments of accession, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

3. The provisions of Article 34, paragraph 2, shall apply to regional economic integration organizations which accede to this Convention or any protocol.

Article 36. Entry Into Force

1. This Convention shall enter into force on the ninetieth day after the date of deposit of the thirtieth instrument of ratification, acceptance, approval or accession.

2. Any protocol shall enter into force on the ninetieth day after the date of deposit of the number of instruments of ratification, acceptance, approval or accession, specified in that protocol, has been deposited.

3. For each Contracting Party which ratifies, accepts or approves this Convention or accedes thereto after the deposit of the thirtieth instrument of ratification, acceptance, approval or accession, it shall enter into force on the ninetieth day after the date of deposit by such Contracting Party of its instrument of ratification, acceptance, approval or accession.

4. Any protocol, except as otherwise provided in such protocol, shall enter into force for a Contracting Party that ratifies, accepts or approves that protocol or accedes thereto after its entry into force pursuant to paragraph 2 above, on the ninetieth day after the date on which that Contracting Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which this Convention enters into force for that Contracting Party, whichever shall be the later.

5. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 37. Reservations

No reservations may be made to this Convention.

Article 38. Withdrawals

1. At any time after two years from the date on which this Convention has entered into force for a Contracting Party, that Contracting Party may withdraw from the Convention by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

3. Any Contracting Party which withdraws from this Convention shall be considered as also having withdrawn from any protocol to which it is party.

Article 39. Financial Interim Arrangements

Provided that it has been fully restructured in accordance with the requirements of Article 21, the Global Environment Facility of the United Nations Development Programme, the United Nations Environment Programme and the International Bank for Reconstruction and Development shall be the institutional structure referred to in Article 21 on an interim basis, for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties or until the Conference of the Parties decides which institutional structure will be designated in accordance with Article 21.

Article 40. Secretariat Interim Arrangements

The secretariat to be provided by the Executive Director of the United Nations Environment Programme shall be the secretariat referred to in Article 24, paragraph 2, on an interim basis for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties.

Article 41. Depositary

The Secretary-General of the United Nations shall assume the functions of Depositary of this Convention and any protocols.

Article 42. Authentic Texts

The original of this Convention, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Convention.

Done at Rio de Janeiro on this fifth day of June, one thousand nine hundred and ninety-two.

Annex I

IDENTIFICATION AND MONITORING

1. Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological processes;

2. Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species; and

3. Described genomes and genes of social, scientific or economic importance.

Annex II

Part 1

ARBITRATION

Article 1

The claimant party shall notify the secretariat that the parties are referring a dispute to arbitration pursuant to Article 27. The notification shall state the subject-matter of arbitration and include, in particular, the articles of the Convention or the protocol, the interpretation or application of which are at issue. If the parties do not agree on the subject matter of the dispute before the President of the tribunal is designated, the arbitral tribunal shall determine the subject matter. The secretariat shall forward the information thus received to all Contracting Parties to this Convention or to the protocol concerned.

Article 2

1. In disputes between two parties, the arbitral tribunal shall consist of three members. Each of the parties to the dispute shall appoint an arbitrator and the two arbitrators so appointed shall designate by common agreement the third arbitrator who shall be the President of the tribunal. The latter shall not be a national of one of the parties to the dispute, nor have his or her usual place of residence in the territory of one of these parties, nor be employed by any of them, nor have dealt with the case in any other capacity.

2. In disputes between more than two parties, parties in the same interest shall appoint one arbitrator jointly by agreement.

3. Any vacancy shall be filled in the manner prescribed for the initial appointment.

Article 3

1. If the President of the arbitral tribunal has not been designated within two months of the appointment of the second arbitrator, the Secretary-General of the United Nations shall, at the request of a party, designate the President within a further two-month period.

2. If one of the parties to the dispute does not appoint an arbitrator within two months of receipt of the request, the other party may inform the Secretary-General who shall make the designation within a further two-month period.

Article 4

The arbitral tribunal shall render its decisions in accordance with the provisions of this Convention, any protocols concerned, and international law.

Article 5

Unless the parties to the dispute otherwise agree, the arbitral tribunal shall determine its own rules of procedure.

Article 6

The arbitral tribunal may, at the request of one of the parties, recommend essential interim measures of protection.

Article 7

The parties to the dispute shall facilitate the work of the arbitral tribunal and, in particular, using all means at their disposal, shall:

(a) Provide it with all relevant documents, information and facilities; and

(b) Enable it, when necessary, to call witnesses or experts and receive their evidence.

Article 8

The parties and the arbitrators are under an obligation to protect the confidentiality of any information they receive in confidence during the proceedings of the arbitral tribunal.

Article 9

Unless the arbitral tribunal determines otherwise because of the particular circumstances of the case, the costs of the tribunal shall be borne by the parties to the dispute in equal shares. The tribunal shall keep a record of all its costs, and shall furnish a final statement thereof to the parties.

Article 10

Any Contracting Party that has an interest of a legal nature in the subject-matter of the dispute which may be affected by the decision in the case, may intervene in the proceedings with the consent of the tribunal.

Article 11

The tribunal may hear and determine counterclaims arising directly out of the subject-matter of the dispute.

Article 12

Decisions both on procedure and substance of the arbitral tribunal shall be taken by a majority vote of its members.

Article 13

If one of the parties to the dispute does not appear before the arbitral tribunal or fails to defend its case, the other party may request the tribunal to continue the proceedings and to make its award. Absence of a party or a failure of a party to defend its case shall not constitute a bar to the proceedings. Before rendering its final decision, the arbitral tribunal must satisfy itself that the claim is well founded in fact and law.

Article 14

The tribunal shall render its final decision within five months of the date on which it is fully constituted unless it finds it necessary to extend the time-limit for a period which should not exceed five more months.

Article 15

The final decision of the arbitral tribunal shall be confined to the subject-matter of the dispute and shall state the reasons on which it is based. It shall contain the names of the members who have participated and the date of the final decision. Any member of the tribunal may attach a separate or dissenting opinion to the final decision.

Article 16

The award shall be binding on the parties to the dispute. It shall be without appeal unless the parties to the dispute have agreed in advance to an appellate procedure.

Article 17

Any controversy which may arise between the parties to the dispute as regards the interpretation or manner of implementation of the final decision may be submitted by either party for decision to the arbitral tribunal which rendered it.

Part 2

CONCILIATION

Article 1

A conciliation commission shall be created upon the request of one of the parties to the dispute. The commission shall, unless the parties otherwise agree, be composed of five members, two appointed by each Party concerned and a President chosen jointly by those members.

Article 2

In disputes between more than two parties, parties in the same interest shall appoint their members of the commission jointly by agreement. Where two or more parties have separate interests or there is a disagreement as to whether they are of the same interest, they shall appoint their members separately.

Article 3

If any appointments by the parties are not made within two months of the date of the request to create a conciliation commission, the Secretary-General of the United Nations shall, if asked to do so by the party that made the request, make those appointments within a further two-month period.

Article 4

If a President of the conciliation commission has not been chosen within two months of the last of the members of the commission being appointed, the Secretary-General of the United Nations shall, if asked to do so by a party, designate a President within a further two-month period.

Article 5

The conciliation commission shall take its decisions by majority vote of its members. It shall, unless the parties to the dispute otherwise agree, determine its own procedure. It shall render a proposal for resolution of the dispute, which the parties shall consider in good faith.

Article 6

A disagreement as to whether the conciliation commission has competence shall be decided by the commission.

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