DEPARTMENT OF AGRICULTURE

REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF AGRICULTURE
Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997)

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Guidance document for use by the applicant to complete the application forms for activities with genetically (living) modified organisms in South Africa

The objective of this document is to assist applicants in completing the relevant application forms for activities with living (genetically) modified organisms.

The Registrar's office made use of the following source to compile this document.
Mackenzie, R., Burhenne-Guilmin, F., Antonio G.M. and Werksman, Jacob, D. in cooperation with Ascencio, Alfonso, Kinderlerer, Julian Kummer, Katharina and Tapper, Ridchard (2203). *An Explanatory Guide to the Cartagena Protocol on Biosafety.* IUCN, Gland, Switzerland and Cambridge, UK. Xvi + 295pp.

Name, address and contact details of the exporter.
Name, address and contact details of the importer.

The name and address of the exporter and importer are to be specified; These will generally be "corporate entitities" rather than individuals. The exporter and importer are defined as follow:

"exporter" as defined in the Cartagena Protocol on Biosafety means any legal or natural person, under the jurisdiction of the Party of Export, who arranges for a LMO to be exported.

"importer" as defined in the Cartagena Protocol on Biosafety means any legal or natural person, under the jurisdiction of the Party of Import, who arranges for a LMO to be imported.

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.

A formal identification of the LMO is required. There may be many varieties of a particular organism on the market, each possibly distinct, uniform and stable. It must be possible to identify the specific LMO in question. A formal identification of the LMO could include any unique identification of the living modified organism that may have been ascribed to it, under any system that may be developed for this purpose.

Some States define a system of "biosafety levels" according to which some LMOs may be classified, according to various factors. Each biosafety level prescribes general levels of risk, and may also prescribe general requirements for handling.

Please refer to the guideline document for use by the applicant for more information on the assignment of containment levels with regard to contained use of genetically modified organisms.

It would be possible to designate similar levels for organisms introduced into the environment ranging from those unlikely to impact upon either the environment ranging from those that might be expected to have serious adverse effects on the environment or human health.

Intended date or dates of the transboundary movement, if known

The information given here will provide the Registrar with an indication of the date or dates, if known, on which the applicant (notifier) would like the transboundary movement to take place, subject to approval being granted by the Executive Council (Party of import). This information is provided to assist SA, i.e. Registrar (Parties of import) in monitoring imports of LMOs, including LMOs that are subject to the simplified procedure set out in Article 13 of the CPB.

On the exporter's side, there may be constraints on the timing due to, for example, a growing season and the need to begin the use of the LMO at a particular time of the year, or delay for up to one year. The latest date on which the exporter would like to have the LMO in place may, therefore, be of significance.

Taxonomic status

Taxonomic status refers to the biological classification of the organism, using the internationally agreed conventions of biological nomenclature. Organisms are classified into families, genera within those families and species within each genus. Species may be further classified into sub-species, varieties, cultivars, strains, or other sub-categories. The classification reflects evolutionary relationships: species within a genus are more closely related to each other than to species in other genera, and species and genera within a family are more closely related to each other than to those in other families.

The scientific or Latin names of organisms are formally accompanied by abbreviated lists of "authorities" which identify the taxonomists who have made the classification: this provides information that shows if changes may have been made to the classification as a result of new information concerning evolutionary relationships.

Common name

Common name refers to the names by which organisms are commonly known, other than their biological or Latin names. Common names for the same organism may vary from area to area: for example, *Zea mays* (Family: Graminea) is known commonly as maize in Europe, but as Corn in North America; *Brassica napus* sub-species *oleifera* (Family: Brassicaceae) is known commonly as oil seed rape in Europe, but as canola in North America.

Point of collection or acquisition

This is the point in the Party of Origin where the LMO will come from. This provision within the Protocol to provide information on the point of collection or acquisition, makes it possible to ensure that such consent has been provided by the Party of Export.

Characteristics related to biosafety

Characteristics related to biosafety would suggest that the information to be provided may be expected to cover any characteristics already identified by the Party of export and/or the exporter that may be related to possible adverse effects identified in a risk assessment, or as a result of observations subsequent to a risk assessment, and any other known characteristics which may represent risk of possible adverse effects in the potential receiving environment.

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

A centre of origin is the term used to describe the area where a particular organism was first domesticated and brought into use by humans. The centre of origin for sheep is in the Middle East; the centre of origin for potatoes is in the Andes. Centres of origin may still retain a very high diversity of the genetic resource base and related wild relatives from which the organism concerned was domesticated.

A centre of genetic diversity is the term used to describe an area where there is a high diversity present amongst a particular group of related species - either within a family, genus, or of sub-species, varieties, cultivars, strains, or other sub-categories within a species. Mexico, for example, is recognized as a centre of genetic diversity for maize.

Because of the importance of the genetic diversity in centres of origin or of diversity, efforts may be in place to conserve and protect them and the genetic resources which they contain. Many such centres are found in developing countries. The level of diversity amongst closely related species may lead to a higher likelihood of gene transfer from a LMO of a similar species to naturally-occurring, wild or cultivated relatives which may be present with a higher frequency in centres of genetic diversity or origin than elsewhere. Therefore the introduction of a LMO of a similar species to naturally-occurring, wild, or cultivated relatives in centres of origin or genetic diversity, and any possible adverse effects in the context of such centres, may need to be given particular attention in a risk assessment.

A description of the habitats where the organisms may persist or proliferate

Organisms generally tend to grow and reproduce better in some habitats than in others. This depends on a variety of ecological factors, including climatic conditions, the presence or absence of predators, disturbance or particular stress factors. If a LMO is introduced into habitats where the recipient organisms and/or the parental organisms may persist or proliferate, then it may be expected that the LMO may also have the potential to persist or proliferate in such habitats. The provision of information on such habitats may help in identification of possible adverse effects that may need to be given particular attention in a risk assessment.

Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism

(a) Description of the nucleic acid introduced

It is important that a description of the nucleic acid introduced into the recipient organism be available. It provides information about all the genes including control elements that have actually been introduced, for example, through the use of a gene construct. In general, if there is an introduced nucleic acid, then it will contain a number of elements with functions important to the production of a gene product; to the amount of gene product produced and the organelles or tissues in which the genes are expressed; to the selection of the modified organisms from amongst those that have not been successfully modified; and other control elements which are Part of genes. These are important in considering how the introduced genetic information may be expressed in the modified organism.

It should be noted that in most cases, although the complete sequence of the introduced nucleic acid or gene construct is known, the sequence of the genome into which it is placed is not known. In general more than one copy of the introduced nucleic acid may occur in the new organism. Multiple copies may affect the introduced genes, either reducing or increasing their activity, and therefore further affect the characteristics of the modified organisms.

The information to be provided is a description of the nucleic acid introduced into the recipient organism in order to modify that organism to create a LMO - this relates to the use of *in vitro* nucleic acid techniques. The description would include details of the genetic material introduced, such as the sequence of nucleotides along with details of the origin of the various parts of the sequence from donor organisms, or from chemical synthesis or modification, and the functions of those parts. In some cases, rather than simply extracting a gene from one organism and then introducing it into a recipient, laboratory modifications may be made artificially to attempt to improve the manner in which that gene is expressed in the recipient organism.

(b) Description of the modification introduced

Introduction of nucleic acid into the recipient organism is intended to produce modifications to that recipient organism resulting in a LMO. Information is to be provided on the modification that is introduced in the LMO. Introduction of the same nucleic acid sequence to cells of the same recipient can result in a range of different effects for reasons that are not fully understood, but which may in part be related to the way in which the introduced nucleic acid becomes associated with the genome of different recipient cells.

Where cell fusion is used to introduce modifications to produce a LMO, it is unlikely that detailed information will be available on the sequences of the nucleic acids involved in the modifications that result, since the technique results in exchange and possible recombination and segregation of genes and chromosomes. In such cases, information may only be available concerning the modifications introduced.

(c) The technique used

As defined in the Protocol, modern biotechnology refers to application of *in vitro* nucleic acid techniques or of techniques for fusion of cells beyond the taxonomic family. Within these categories there are many variants and different types of techniques: the particular technique used in producing a LMO may affect the nature of the modification introduced, its stability, or other aspects of the modification.

(d) The resulting characteristics of the living modified organism

This refers to the characteristics that result from the nucleic acid and/or the modification introduced to produce a LMO. The resulting characteristics refer to the actual characteristics that result from the introduction of the nucleic acid or modification, which may differ in degree and detail from the characteristics that it was intended to introduce. For example, in the modification of trout, through *in vitro* nucleic acid techniques, to create genetically modified trout that express high levels of growth hormone, considerable variation can be found between the growth of the different recipient individuals and their offspring. The resulting characteristics of the introduced modification include expression of growth hormone at a particular level, a particular growth rate, any effects that may have resulted concerning maturation, reproduction, etc. in the trout, and the spread or variability in the way these characteristics are manifest in different individuals.

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.

Information is required on the intended use(s) of the living modified organism, or the products of the LMO. The information concerning products of LMOs is only required in relation to products that contain detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology. This reflects concern that the genetic material in products might, under some circumstances, be transferred in a viable state to other organisms, resulting in their transformation by that novel genetic material. If genetic material is present, it may be capable of being replicated under some circumstances (e.g. if it is taken up by an organism and enters its cells) if introduced into another organism.

Depending on processing, nucleic acids may be removed from purified products during the processing steps. If nucleic acids containing the novel combination of genetic material are not present in a product, there can be no risk of transfer of a genetic modification to another organism. Therefore information concerning a processed product that does not contain detectable novel combinations of replicable genetic material is not required. Products vary in their nucleic acid content. For example, refined sugar is highly purified and does not contain nucleic acids under normal conditions; flour obtained by milling of grain will contain nucleic acids, often as short sequences of nucleotides (less than 50 nucleotides in length), but under some conditions as longer sequences that may be equivalent to the length of some genes.

Quantity or volume of the living modified organism to be transferred.

The quantity, volume or amount of a LMO that it is intended to transfer, may affect the level and exposure of the potential receiving environment to the LMO. The way in which this information is provided may vary according to the type of LMO concerned - examples of the type of information that might be provided could include: 5000ml of a 10^7 bacterial per ml suspension; 5 tonnes of seed; 20 individuals (e.g. fish).

Any differences in level and exposure to the LMO concerned need to be taken into account in the risk assessment.

Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

If an organism has been used elsewhere, conditions for its handling etc. may have been specified following a previous risk assessment and would provide information that could be of assistance on these issues to the Party of import. Information is required on suggested methods for safe handling, storage, transport and use, including any requirements that may be necessary according to specific circumstances in the Party of import and/or the intended use of the LMO in the Party of import.

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.

Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

The purpose of the above paragraphs are the sharing of information on action taken in the Party of Export, and in other States, in relation to the LMO concerned. It is, for instance, important that Parties of Import are aware of any restrictions that any other countries may have imposed on the use of these organisms within their territories and their reasons for this, so that similar considerations may be assessed by the Party of Import in its risk assessment and/or in the decision procedure.

Any unique identification of the living modified organism.

Work is underway to develop an international system of unique identifiers that would apply to each individual modification. The unique identifier system is similar in concept, for example, to the ISBN system for book publishing. The unique identifier would take the form of a code that would then provide a link to a database which would include full information about the specific modification to which the unique identifier referred. Guidance on an unique identifier for transgenic plants has been developed by an OECD working group. Further information on progress on development of a uniquie identifier system for the Protocol can be found through the Biosafety Clearing-House website.

Under the unique identifier system, an identifier would be given to each modification event. For example, modification of a plant by introduction of the Bt toxin gene into two different individuals of the same species would represent two separate modification events, each of which, if commercialised as LMO-FFPs, would be allocated a unique identifier. If, for example, a cross were to be made between a LMO containing a Bt toxin gene modification and a LMO containing a herbicide resistance gene modification, the resultant LMO progeny from that cross would contain two separate modifications, which would therefore be indicated by the use of the two relevant unique identifiers. Alternatively, a further unique identifier could be allocated for the particular combination of modifications created by such a cross.

The system for unique identifiers, when it is developed and implemented, will assist the identification and monitoring of LMO-FFPs that have been approved by one or more national authorities, and will also assist the flow of information between Parties and their competent authorities, and with the public.

Approved uses of the living modified organism.

Information on approved uses of the LMO in the Party of Export. This may be expected to include information on any restrictions or conditions that the authority responsible for the decision on the use may have set in giving approval for particular uses of the LMO.

Risk assessment

(a) Objective:

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.

Assessment of risk is intended to identify and evaluate potential adverse effects of LMOs on the conservation and sustainable use of biological diversity taking also into account risks to human health.

Risk assessment is linked to the likely potential receiving environment. It will often be necessary to assess risks of potential adverse effects of LMOs at various stages of their development and use, in relation to the potential receiving environment e.g. at the field test stage, and again before permitting the wide spread release or marketing of LMOs.

Risk assessments will need to take into account new developments in applications of modern biotechnology - for example, some LMOs are designed to produce pharmacologically active compounds and industrial feedstock, and in the future LMOs may be designed to produce a range of other compounds. Risk assessments will need to consider the possible impact on biological diversity and on human health in these circumstances, and identify the measures needed to avoid or minimize risk.

(b) Use of risk assessment:

Risk assessment is, *inter alia,* used by competent authorities to make informed decisions regarding living modified organisms.

The main purpose of risk assessment is to provide information to be taken into account in the decision procedure and to provide a basis for risk management mechanisms, measures and strategies on risk management.

Thus, the risk assessment is to be used by Parties in order to make informed decisions as to whether or not to approve an import of the LMO concerned, and whether or not to attach any conditions, including requirements for risk management measures, to any approval.

(c) General principles:

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 organisations.

Relevant scientific expertise must carry out a risk assessment.

The statement that risk assessment should be carried out in a "scientifically sound and transparent manner" suggests that risk assessment is to be undertaken in a systematic way, and that each risk assessment should provide sufficient information to enable others to repeat the stages of the risk assessment independently.

Expert advice of and guidelines developed by international organisations may be relevant and be taken into account in the course of risk assessment. Examples of such advice and guidance would include the UNEP Technical Guidelines on Biosafety, and the work of the OECD in relation to biosafety. Existing or future work of other international or regional organisations may also be relevant.

Parties may also call on the Protocol's roster of experts for advice and guidance to assist them in undertaking risk assessments.

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.

This is a reflection of the precautionary approach in relation to risk assessment. With regard to biosafety, it may be that there are gaps in the information available in relation to some aspects of risk assessment. For example, where ecological issues are being considered, and/or where the number of variables may be such as to make prediction difficult or virtually impossible. In some circumstances, data needed may be absent or even unobtainable. The risk assessment might result in the identification of areas that need further research, or may indicate that even where further research is identified, the risk assessment may remain equivocal.

Such circumstances allow a Party of import to take a decision in these circumstances, in order to avoid or minimize potential adverse effects.

In cases where there may be a lack of scientific knowledge or consensus on relevant issues, different countries may legitimately decide to make different choices in relation to the acceptability of any given level or type of risk.

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.

This provides a point of reference for risk assessment. To assess the behaviour of a LMO in any environment requires extensive observation and testing. It may assist in the assessment of the possible adverse effects and associated risks of LMOs, if it is possible to consider the risks posed by the similar, non-modified varieties of the same organism, or the parental organisms, for example, through an understanding of the habitats where those organisms may persist or proliferate.

This part includes a requirement for consideration of the risks posed by processed materials that are not themselves LMOs but which still contain "detectable novel combinations of replicable genetic material". Processed materials that as a result of processing do not contain genetic material, even though they contain the LMO product, are not required to be considered. For example, flour made from seeds of an LMO will still contain genes that might in some circumstances be replicable, and would therefore need to be considered in the risk assessment; refined sugar, however, would not normally contain genetic material, and would therefore not need to be considered by the risk assessment.

Processed LMO materials contain LMO products, even where the nucleic acid is not present itself - for example, if the oil content and composition of an oilseed has been modified through genetic modification, then the extracted oil will exhibit the new characteristics whether or not the nucleic acid is present in the final product. If this is for food or feed, then allergenic properties of the LMO product(s) may be important. If a modified organisms has been modified to produce pharmacologically active compounds, then the presence of those compounds rather than only the nucleic acid alone will be important to any risk assessment.

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.

The case-by-case basis is fundamental to risk assessment of LMOs. A case-by-case approach is one where each release of a LMO is considered relative to the environment in which the release is to occur, and/or to the intended use of the LMO in question. A risk assessment performed for a particular LMO intended to be introduced to one environment may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be released under different environmental conditions, or into different receiving environments. A risk assessment performed for a particular use of a particular LMO may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be used in different ways. Because of this, it is important for each case to be addressed separately, taking into account specific information on the LMO concerned, its intended use, and its potential receiving environment

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.

As each risk assessment proceeds, it may become apparent that further information is needed on certain subjects, while information that may be available concerning other subjects may not be relevant in certain cases. One example of where further information may be needed is where a risk assessment carried out in relation to one receiving environment is used as a point of reference for a risk assessment relating to release of the same LMO into a different receiving environment.

Differences between the receiving environments may mean that the profile of risks to be considered, and their likelihood and consequences, are also different. Further information may therefore be required in order to assess risks in relation to the potential receiving environment. This information might be obtained through various means, including through the undertaking of more research, monitoring, or assistance from experts.

Methodology for a risk assessment in terms of the Cartagena Protocol on Biosafety

This section sets out the methodology for risk assessment to be used in the context of the Protocol.

To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(1) 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.

The risk assessment identification of each adverse effect that may arise from modification of the genotypic and/or phenotypic characteristics of the LMO and its introduction to a potential receiving environment, taking into account risks to human health.

(2) An evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism.

Once the possible adverse effects have been identified, the likelihood of each of these being realised is to be evaluated.

(3) An evaluation of the consequences should these adverse effects be realised.

The evaluation of the consequences of possible adverse effects, should they occur, is undertaken separately from the evaluation of the likelihood of those adverse effects occurring. The consequences of adverse effects, should they occur, may take many forms, including damage to biodiversity, damage to genetic resources, damage to livelihoods, damage to agriculture, etc., and also include the magnitude of any damage. The consequences may arise either directly as a result of the adverse effect occurring, or indirectly through a chain of events as a result of the occurrence of the adverse effect. Adverse effects may arise in the short-term, or may only become apparent on a longer time-scale.

(4) 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 realised.

Estimation of the overall risk brings together both the evaluation of the likelihood that a possible adverse effect may occur, and consequences of the identified adverse effect should it occur. Risk may be expressed qualitatively or quantitatively in risk assessments.

Estimation of overall risk will also need to take into account the precautionary approach that is embodied in the Protocol's objective, and to highlight areas of uncertainty, for example where there is a lack of knowledge concerning aspects of key risk.

(5) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks

A recommendation, made by those undertaking the risk assessment, is required as to whether or not the risks of potential adverse effects that have been identified in the risk assessment are acceptable, or manageable - and if so how. The recommendation will be considered by the Advisory Committee and Executive Council in reaching their decision on import.

Considering the acceptability of a given risk is complex, and may involve many factors, a potential adverse effect which has a low likelihood of occurrence, but which would have serious consequences in the (unlikely) event that it should occur, may be less acceptable than a potential adverse effect which has a high likelihood of occurrence, but which would have only small consequences in the (likely) event that it should occur, even if the overall estimate of risk in both instances were similar. It is therefore important to consider acceptability in the context of both nature of the risk, and the nature of the consequences. Furthermore a level of risk which might not be acceptable in one Party or region, may be acceptable in others elsewhere.

(6) 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.

This suggests that it may be possible to address uncertainties concerning a particular level of risk by obtaining further information - to seek to resolve the uncertainty - or by implementing appropriate risk management strategies.

It may also be possible to address uncertainty by monitoring the LMO in the receiving environment. This would provide further information on the LMO, and should any adverse effects be detected, would enable additional appropriate risk management measures to be instituted. In many cases, monitoring of the LMO may be required in any case for regulatory purposes once approval has been given for its use and environmental release.

It may be relevant to consider these possibilities in formulating recommendations. This provision may be taken into consideration along with other provisions that set out the need that may arise for further information to be obtained in order to complete the risk assessment, and does not obviate the importance of obtaining such information prior to a decision being made under the decision procedure.

(7) Points to consider in a risk assessment

Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects.

Please refer to the common format for conducting a risk assessment. This document sets out a range of factors that may need to be considered in a risk assessment, depending on the particular case. Not al points will necessarily be relevant to every case. Other subjects may also need to be considered depending on the specific case. Technical and scientific information relevant to the case being considered is required.

Where a need for further information is identified during the risk assessment, obtaining this information may, as appropriate, require further research, testing, field trials, expert advice or other activities, in order to provide sufficient technical and scientific details.

An explanation of phrases/words not described above are provided below.

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, as a description of the habitat where the organisms may persist or proliferate.

Most of these terms have been explained previously. Biological characteristics may be assumed to refer to any biological characteristics, and the wording here would seem to allow for all such characteristics to be taken into account in risk assessment.

Vector

Characteristics of the vector, including its identity, if any, and its source or origin, and its host range.

A vector is an organism or object used to transfer genetic material from a donor organism to a recipient organism. There is a need to take into account in a risk assessment, the characteristics of the vector, its identity, its source or origin, and its host range.

The characteristics of the vector could include its nucleic acid sequence, as well as any characteristics concerning the way it interacts with its hosts, or the way it is used to transfer genetic material. The identity of the vector will be given by a standard code or name given to the vector.

The source or origin of the vector refers to the original source from which the vector was isolated, and may include the laboratory or facility where it was first isolated. The host range describes the range of organisms (species, or sub-species, etc.) with which the vector is capable of interacting.

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.

"Insert" refers to the nucleic acid introduced into an organism through the application of *in vitro* nucleic acid techniques. "Modification" refers to modifications to the genetic material introduced by the application of modern biotechnology - covering *in vitro* nucleic acid techniques and cell fusion techniques.

Information concerning the nucleic acid introduced and the function that is specifies is to be considered. The characteristics of the modification introduced are also to be considered, referring to the modifications that are actually obtained, and not just to what it may have been intended to obtain, bearing in mind that introduction of novel genetic material into an organism may result in a variety of effects being manifest.

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.

Information on the differences between the biological characteristics of the LMO and those of the recipient organism or parental organisms must be provided. This may help in considering how a LMO may behave in relation to the recipient organism or parental organisms.

Differences in biological characteristics could cover both the direct effects of the modification introduced to the LMO that may include biochemical changes, behavioural changes and physical or growth changes; and indirect effects, for example, effects on other organisms that may feed on or be associated with the recipient or parental organisms. Such differences may affect its behaviour, including its ability to persist and propagate, in the potential receiving environment.

Detection and identification of the living modified organism.

Suggested detection and identification methods and their specificity, sensitivity and reliability.

It is important for the Department of Agriculture and other regulatory authorities to be able to detect and identify each LMO, and the product(s) of each LMO, in order to monitor their transboundary movement, handling and use. It is generally not possible by visual inspection to distinguish between LMOs and non-LMOs of the same species or sub-species.

A range of tests that enable LMOs to be detected, are available, and are based on detection of the novel genetic material introduced into a LMO, or on the gene-products that are produced as a result of incorporation of that genetic material. Tests to detect LMOs are continually being developed, and are increasing in their specificity, sensitivity and reliability.

In the absence of specific, sensitive and reliable detection and identification methods, it may be difficult to implement risk management measures and/or monitoring, effectively.

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 organism.

Information on the intended use of the LMO and products thereof, needs to be taken into account in the risk assessment.

One must also taken into account that new or changed use compared to the recipient organism or parental organisms. An example of such a new or changed use is where an organism normally used for one purpose is modified to be used for a significantly different purpose, as is the case with the modification of oil seed rape (canola) to produce high concentrations of biochemicals for specific use as feedstocks for industrial processes, rather than its normal use to produce oil for food or feed purposes. Similar considerations apply where organisms are modified so as to produce pharmaceutically active compounds.

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.

A potential receiving environment is an eco-system or habitat, including humans and animals, which is likely to come in contact with a released organism.

The potential adverse effects that may result from introduction of a LMO into a particular receiving environment, depend on the interaction between the LMO, the physical conditions of the environment, and the other organisms present in that environment.

Relevant information might include:

- the geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;
- the proximity of the site to humans and to significant biota;
- any flora, fauna and ecosystems that could be affected by the release, including keystone, rare, endangered or endemic species, potential competitive species and non-target organisms; and
- the potential of any organism in the potential receiving environment to receive genes from the released organism.

The climatic and ecological characteristics of the receiving environment, including relevant information on biological diversity and centres of origin are to be considered when undertaking the risk assessment.

The characteristics of the receiving environment may affect the way a LMO might behave in that environment. They may also indicate particular sensitivities in the receiving environment and the organisms its contains, which need to be taken into account.