PROCEDURES FOR ECOLOGICAL RISK ASSESSMENT OF HERBICIDE AND INSECT RESISTANT CROPS - FOCUS ON WEED ASPECTS

Plant Production and Protection Division
Food and Agriculture Organization
of the United Nations
Rome, 2003

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

CONTENTS

INTRODUCTION

SCOPE/OBJECTIVES OF THE PROCEDURES

There are several concerns about the consequences of development and deployment of herbicide-resistant (HR) and insect resistant (IR) crops, in particular when these traits have been inserted though methods of genetic engineering. This distinction between conventionally bred and genetically modified HR/IR crops, is based primarily on three arguments: this technology allows for genes to be exchanged between unrelated species or even phyllums, e.g. bacterial genes inserted into plants, the time frame for development of crops may be significantly reduced and there is limited experience with the long-term effects associated with this technology. Objections to the use of transgenic HR and IR crops rest, more specifically, on several issues related to the associated risks, such as:

- the potential transfer of genes from resistant crops (HRC/IRC) to wild relatives possibly creating weeds more adapted and aggressive in agricultural fields; or in the case of IRCs both in the field and in natural areas;
- the possibility of HRC/IRC volunteers to become weeds in subsequent crops or neighbouring fields;
- adverse effects on ecological processes and non-target organisms

All these concerns show the importance of assessment of possible risks from the use of HR and IR crops. Assessment is required to determine what risks they pose on the environment, whether these crops may be introduced, and whether or not they are likely to bring expected benefits to the farmers and/or the environment.

In this context government authorities of the Ministries of Agriculture, Environment or Rural Development need an appropriate tool to conduct the necessary assessments. To this end FAO decided to elaborate relevant procedures on this subject. The present procedures may require revision as data and experiences are gathered in the future.

These procedures describe a process for identification of ecological hazards associated with the introduction of HRCs or genetically modified IRCs such as those carrying genes coding for endotoxins from *Bacillus thuringiensis* and takes the first steps of a risk assessment. Furthermore, the procedures list the responsibilities of governmental authorities, applicant or permit holders and farmers growing HRCs and IRCs. The main aim of the procedures is to provide a framework, especially for countries that have not developed their own regulations, on assessing the ecological risks of HRC/IRCs.

Drs Kathrine H. Madsen, Bernal E. Valverde and Jens C. Streibig from Royal Veterinary and Agricultural University (KVL), Denmark, prepared the initial draft of the procedures, which was then sent to more than 30 specialists from all over the world for their comments and suggestions. The first draft was revised, thoroughly discussed and improved at a workshop organised by FAO and Royal Veterinary and Agricultural University (KVL), Department of Agricultural Sciences (Weed Science), held in

Copenhagen, Denmark, on 14 and 15 September 2000, with the participation of the specialists as follows:

Dr. Gualbert Gbèhounou (Benin), Prof. James F. Hancock (Michigan, USA), Dr. Barakat Abu-Irmaileh (Jordan), Dr. Fred Kanampiu (CIMMYT, Kenya), Drs. Ricardo Labrada and Le Hoan (FAO), M. Jorge A. Madriz (Costa Rica), Dr. Chanya Maneechote (Thailand), Dr. Shadrack Moephuli (South Africa), Ms. Heli Nammsalu (Estonie), Dr Maria Olofsdotter (Danemark), Prof. Dr. Ernesto Paterniani (Brazil), Dr. Cesar Fernandez Quintanilla (Spain), and Dr. Baruch Rubin (Israel).

The procedures were improved after the draft was published by FAO and in February and March 2003 the document went through a final revision in collaboration with the initial authors and FAO.

REFERENCES

Baker, H. G., 1974. The evolution of weeds. Ann. Rev. Ecol. Systematics 5: 1-24.

Cartagena Protocol, 2000. Cartagena Protocol on Biosafety to the Convention on Biological Diversity. http://www.biodiv.org/biosafety/

Conner, A. J., Glare, T.R. and Nap, J.-P., 2003. The Release of genetically modified crops into the environment, Part II. Overview of ecological risk assessment. The Plant Journal 33: 19-46.

Dale, P. J., 1994. The impact of hybrids between genetically modified crop plants and Their related species: General considerations. Molecular Ecology 3: 31-36.

Darmency, H., L. Assémat *and* ***Wang T.***, 1999. Millet as a model crop to assess the impact of gene flow toward weed populations. Pages 261-267 in Gene Flow and Agriculture. Relevance for transgenic crops. BCPC Symposium Proceedings 72.

Ellstrand, N.C. and Hoffman C. A., 1990. Hybridization as an avenue of escape for engineered genes. BioScience 40: 438-442.

FAO, 2001. Draft of guidelines for assessment of ecological hazards of herbicide- and insect-resistant crops. Food and Agriculture Organization of the United Nations. Plant Protection Division, Rome, 18 pp.

Gressel, J. & Rotteveel T., 2000. Genetic and ecological risks from biotechnologically-derived herbicide-resistant crops: Decision trees for risk assessment. Plant Breeding Reviews 18: 251-303.

Hancock, JF, Grumet, R. & Hokanson, **SC.**, 1996. The opportunity for escape of engineered genes from transgenic crops. HortScience 31: 1080-1085.

Nap, J.-P., Metz P.L.J., Escaler M. and Conner A. J., 2003. The Release of genetically modified crops into the environment, Part I. Overview of current status and regulations. The Plant Journal 33: 1-18.

Norris, C. E., E. C. Simpson, J. B. Sweet and Thomas J. E., 1999. Monitoring weediness and persistence of genetically modified oilseed rape (*Brassica napus*) in the UK. Pages 255-260 in Gene flow and agriculture. Relevance for transgenic crops. BCPC Symposium Proceedings 72.

Sweet, J. B., C. E. Norris, E. Simpson and Thomas J. E., 1999. Assessing the impact and consequences of the release and commercialization of genetically modified crops. Pages 241-246 in Gene flow and agriculture. Relevance for transgenic crops. BCPC Symposium Proceedings 72.

DEFINITIONS AND ABBREVIATIONS

Applicant/notifier	The party (e.g. seed producer, exporter/importer, agro-chemical company or farmers' organisation) that requests permission to experimentally release or otherwise introduce an HRC/IRC in a country.
Authority	A governmental institution, organisation or entity officially designated by the government to deal with matters arising from the responsibilities set forth in the Procedures.
Bacillus thuringiensis (Bt)	Bacterium species producing endotoxins, currently formulated as a microbiological agent to control larvae of Lepidoptera, Diptera or Coleoptera.
Competitiveness	A plant's ability to exploit essential resources such as light, water and nutrients at the expense of other plants. This may be influenced by resistance to herbivores, herbicides or pathogens.
Congeners	Refers to species belonging to the same genus.
Conspecific	Refers to individuals and populations of the same species.
Crop production system	A particular agricultural scheme, including monocultures, rotations and polycultures, and their associated practices such as tillage, plant protection and harvesting.
Ecosystem	A dynamic complex of plant, animal and micro-organism communities and their non/living environment interacting as a functional unit.
Effective population size	The number of reproducing individuals in the population.
Fitness	Reproductive success or the proportion of genes contributed by an individual to the gene pool of a population.
Gene flow	The transfer of genes (specifically, alleles) from one population to another

Gene pool	All of the alleles available among the reproductive members of a particular population from which gametes can be drawn.
Genetic engineering	Altering the genetic material of cells or organisms with the intention to make them capable of producing new substances or performing new functions.
Genetically modified (GM) plant	A plant whose genetic material has been altered in a way that has not occurred naturally by mating, natural recombination and/or mutagenesis.
Hazard	The inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property).
Herbicide	A chemical substance or mixture of substances designed to control weeds.
Herbicide resistant crop (HRC)	A crop plant that by genetic modification(s) or conventional breeding has acquired resistance towards a herbicide it would otherwise be susceptible to.
Transgenic insect resistant crop (IRC)	A crop that by genetic engineering has become protected from damage by one or more harmful insects.
Insecticide	A chemical substance used to kill insects
IPM	Integrated Pest Management is a decision-making process that considers all possible control measures, such as cultural, mechanical, biological and chemical ones, selecting a control method to suit each individual situation. Where chemical control is indicated, specific pest populations are targeted for treatment at the time when they are most vulnerable rather than simply carrying out a general pesticide application.
Introgression	The transfer of genes from one population to another by backcrossing.

Marketing	The overall process of product promotion, including advertising, product public relations and information services as well as the distribution and sale on local or international markets.
Maternal inheritance	The transmission of nuclear and extra-nuclear genes from the mother.
Mode of action (MOA)	The biochemical mechanism by which a herbicide causes growth to cease in target weeds. Herbicides can be classified into groups according to their site of activity within the plant.
Notification	Submission of information required for the process to regulate or control genetically modified HRCs or IRCs.
Permit	Decision document allowing for experimental release or placing on the market of the transgenic HRC/IRC
Pest	Any organism judged as a threat to human beings or to their interests.
Pesticide	Refers to any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.
Placing on the market	Making available to third parties, whether in return for payment or free of charge

Refuge	A refuge, in the context of *Bt* crops, is a non-*Bt* portion of a grower's field or set of fields that provides for the production of susceptible insects that may randomly mate with rare resistant insects surviving the *Bt* crop to produce susceptible heterozygotes that will be killed by the *Bt* crop.
Release	Introduction into the environment of a genetically modified organism (GMO) with or without provisions for containment. Release can be deliberate, e.g. experimental or commercial, or accidental.
Resistance	In the case of plant populations, their inherited ability to grow and reproduce normally when exposed to high doses or levels of a specific agent (e.g. herbicide, insect attacks or pathogens), which normally would harm plants.
Risk	Function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure.
Risk assessment	In the context of genetically modified HRC/IRCs an evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the release or placing on the marked of the HRC or IRC may pose.
Spread	Expansion of the geographical distribution of plants in particular those containing a genetically modified gene.
Tolerance	Referred to plants, it is an increased ability of a plants within a population to endure damage, survive and reproduce after a limited exposure to a specific stress factor (in this context, herbicide applications or insect pests) compared to other plants of the species.
Transgene	A gene or DNA fragments from one organism that has been stably incorporated into the genome of another organism.
Transgene vector	A plasmid that can be used to transfer DNA

	sequences from one organism to another.
Volunteer	A crop plant regenerated from seed or vegetative propagules left after a previous harvest and which can act as a weed in the present crop.
Weed	A plant that is growing where it is not wanted.

DELIMITATIONS

The procedures are confined to describe and identify hazards and deal with ecological risk assessment of HRC based on a strictly scientific and technical approach. The risk assessment must be performed on a case-by-case basis and adapted to the local conditions and agricultural production system. Furthermore, for IRCs increased weediness only, is addressed in these procedures, whereas other hazards e.g. development of resistant insect populations or unintentional non-target effects are not included. We have chosen to include weediness aspects of IRCs because gene stacking with both HRC and IRC in the same variety is common and may affect the selective advantage of the plant itself. Other relevant aspects related to HRC/IRCs such as food safety, pleiotropic effects associated with transgenes, ethical concerns, socio-economic consequences and liability issues are not considered in these procedures. Finally, these procedures do not address the uncertainties involved when performing a risk assessment, e.g. the statistical variation of the data, interpretation of results and whether or not we have identified all relevant hazards that may only become apparent after long-term use of HRC/IRCs.

1. RESPONSIBILITIES

1.1. Designation of authorities prior to release of HRC/IRC

Governments should implement a process to regulate or otherwise control and, where appropriate, issue permits for the experimental release or commercial introduction of genetically modified HRCs or IRCs. The authority may exercise its powers by applying national, regional or local legislation or by using an internationally accepted standard. Import or export of genetically modified HRC or IRC for any purpose should only be carried out with the prior informed consent of the proper authority and in accordance with the Cartagena Protocol on Biosafety.

1.2. Responsibilities of authorities

- Introduce and implement the necessary requirements to regulate the experimental release or marketing of HRC/IRC in their countries, and make provision for effective enforcement.
- Evaluate the notification prepared by an applicant, including documented technical information. The information in the technical document could be derived from the list of 'information desirable for hazard identification and risk assessment', which should provide the authority with a basis for identification of hazards and a first assessment of risks involved.
- Issue a decision document in response to the notifications stating conditions to be fulfilled by the applicant or stating the grounds for rejection.
- In case of a permit, keep records of notifications and ensure compliance with both pre- and post-approval regulations of experimental release/marketing.
- Develop procedures for the full documentation of the HRC/IRC and their use. These include experimental release (numbers/quantities, dates, localities) or commercial production, impact of each HRC/IRC in each country and any other data relevant to assessing the outcome, and make these records available to the public as may be appropriate while making provision for protecting any proprietary rights to data.

1.3. Responsibilities of applicant/permit holder

- To comply with all the regulations established by the country, where the HRC/IRC will be introduced or grown.
- To prepare a document with relevant technical information for submission to the authorities with each application for experimental release or commercial production including all pertinent and required information on the HRC/IRC to be released.

- Ensure that persons involved in distribution of HRC or IRC products are adequately trained, such that they are capable of providing a user with advice on efficient use at minimum risk.
- Notify the authorities and voluntarily take corrective action and, when requested by authorities, help to find solutions to any problem related to, or arising from the release and use of the HRC/IRCs.

1.4. Responsibilities of farmers growing HRC/IRC

The responsibilities of the farmer are those stated in the binding labels of HRC/IRC products and any contractual agreement signed with an importer, distributor or supplier of seed and by the regulations associated with the use of pesticides.

Farmers should:

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

2. HAZARD IDENTIFICATION AND RISK ASSESSMENT

2.1. Hazard identification of HRC/IRC

The identification of hazards from growing HRC/IRC crops concerns both the crop itself and its impact on the wild flora, crop volunteers, adjacent crops, and other non/target organisms. In particular, understanding the interaction between the transgenic crops and all compatible relatives is crucial for realistic hazard identification. Consideration is also necessary to the fauna associated with the crop, especially both insect pests and beneficial organisms, pathogens and soil microflora; however note that for IRCs these procedures are limited to the identification of hazards associated with weediness.

- The HRC/IRC itself may establish beyond its agricultural boundaries and growing season and become a weed in neighbouring or succeeding crops.

- The HRC/IRC may contaminate the gene pool of non-target relatives growing in the same or adjacent areas, depending on cross pollination characteristics and agents such as wind or insects. In some instances where the effective population size of native relatives is low, genes from the transgenic crop may come to dominate the native population and may contribute to their extinction. The compatibility between the HRC/IRC and non-target populations is of utmost importance in this regard.

- The HRC/IRC may have botanically identical or closely related populations/species that can hybridise with the crop, either in the agricultural field or in the adjacent ecosystems. Hybridisation could lead to contamination of non-transgenic crops and/or gene stacking in volunteer plants and transfer of the resistance trait to weedy or wild species, which in turn could lead to loss of efficacy from the herbicide(s).

- The continuous use of herbicides associated with HRCs over large areas for several years may unintentionally change the composition of the weed flora by selecting for naturally tolerant weeds. This is particularly important in monocultures or in cropping systems with limited crop rotation or minimum tillage.

- Intensive use of HRC/IRC may have a detrimental effect on the populations of non-target organisms (i.e. birds, beneficial insects, soil living organisms and microflora)

- In case of IRC the engineered traits may increase fitness of volunteers or weedy hybrids; thus making a crop, a crop volunteer or a hybrid with wild relatives turn more weedy, which can interfere with future crop production or aggravate the negative impact of existing weed species. The transfer of resistance into non-target populations may also alter its competitive ability and displace native species growing in natural habitats.

2.2. Risk assessment

The main objective of ecological hazard identification of HRC/IRCs is to make a comprehensive list of relevant adverse effects on the environment from the growing of these crops. Hazard identification is only the first step in a conventional risk assessment, the other steps being hazard characterisation (magnitude of the hazard), exposure assessment (in this context an estimate of likelihood or frequency of identified hazards) and finally risk characterisation. Risk characterisation takes into account the results of the previous three steps to provide an estimation of the likelihood by which the adverse effects occur combined with their magnitude. This risk assessment may be quantitative or qualitative. The latter has prevailed in previous cases with approval of genetically modified organisms, because the complexity of biological systems makes it difficult to pursue a quantitative approach.

In most established regulations of HRC/IRCs, the applicant is required to deliver the relevant information and the authorities may then base the evaluation upon this information combined with expert opinions and, sometimes, public hearings including scientific institutions, consumer organisations, non-governmental organisations (NGO's) and the general public. The objective of this guideline is, however, only to identify ecological hazards to the environment and make the first step towards assessment of risk by using simple decision keys. It should be noted that the procedures do not attempt to estimate the magnitude of the identified hazards, first of all because the severity of these cannot be generalised over farming systems and environments, secondly risk is a relative term depending on interest at stake, values etc. Nevertheless, we shall in the following refer to risk when we associate the identified hazards with a probability.

2.3. Information desirable for hazard identification and risk assessment

Information related to the HRC/IRC:

- Taxonomic description and scientific name
- Cultivar's name
- Diagnostic phenotypic and genetic markers
- Description of geographic distribution and of the natural habitat of the plant
- Potential for vertical gene flow and exchange with other plant populations
- Ecological and physiological traits:
    - Generation time in natural ecosystems, sexual and asexual reproductive cycles
    - Information on survival, including the incidence of volunteers and the ability to form perennial structures (propagules)
- Information related to the genetic modification process
    - Description of the inserted genetic material and vector construction
    - Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question
- Information on the genetic material inserted in the HRC/IRC
    - Description of genetic trait(s) or phenotypic characteristic(s), particularly new traits and characteristics which may be expressed or suppressed
    - Characteristics of the vector
    - Stability of the genetic trait(s)
    - Rate and level of expression of the new genetic material
    - Description of identification and detection techniques
    - History of previous releases or uses of the HRC/IRC

Information on the receiving environment:

- Geographical location of the site
- Proximity to protected habitats or areas

- Proximity to compatible, related species
- Climatic characteristics and flora and fauna of the region
- Description of target and non-target ecosystems likely to be affected
- Any known planned developments or observed changes in land use in the region which could influence the environmental impact of the released crop
- Description of ecosystems to which the HRC/IRC could be disseminated by wind, animals or human activity
- Proximity to genetic centres of origin

Information related to the interactions between the HRC/IRC and the environment:

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

Potential environmental impact:

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

Information on the conditions of experimental release:

- Description of the proposed release including the purposes and foreseen products
- Foreseen dates of the release and time planning of experiment including frequency and duration of release
- Size of the site
- Method to be used for the release
- Quantities of HRC/IRC to be released
- Method of cultivation and description of general agricultural practices
- Post-release treatment of the site

- Techniques which will be applied for the elimination or inactivation of the HRC/IRC upon experiment completion
- Information on and results of previous releases of the HRC/IRC, especially at different scales in different ecosystems

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

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

Information on monitoring and control of release:

- Methods for tracing the HRC/IRC and monitoring its effects
- Specificity, sensitivity and reliability of monitoring techniques
- Techniques for detecting transgenes introgressed into non-target plants
- Methods and procedures to avoid and minimise the spread of the HRC/IRC beyond the site of release or the designated area for use
- Methods and procedures for controlling the HRC/IRC in case of unexpected spread through gene flow, seed dispersal or propagules.

2.4. Procedure for risk assessment

In assessing risks associated with the introduction or planting HRC/IRCs in a particular area or country, a starting point will be to identify the agricultural scenarios and environmental conditions under which the crop will be released and select the appropriate procedure to identify the specific hazards associated with it. Whatever approach is used to identify hazards, care should be taken to consider hazards to both agronomic and natural ecosystems.

Much of the information needed for a risk assessment (section 2.3) can be obtained from experiences with HRC/IRC in other regions or locations combined with practical experience with traditional crops growing in the same environment and knowledge about the HRC/IRC, but in some cases further experimentation and analysis is needed particularly regarding gene flow and fitness. As indicated before, any assessment of risk requires a case-by-case study and is location-specific. Specific local conditions would determine the relative importance of each type of hazard. For example, cropping patterns and landscape could have an important role in the possible escape of transgenes into related species, a process that involves hybridisation followed by the subsequent establishment and persistence of the hybrid. The likelihood of HRC/IRC crops and wild relatives forming hybrids is particularly pertinent

in the centres of origin and diversity of crops, thus hazards derived from gene flow should be the priority in assessing the overall risk of release of HRC/IRC crops in these areas. Another special case is that of a crop that has conspecific weeds or wild relatives, which increases the risk of gene movement from the HRC/IRC crop.

Continuous plantings of HRCs, especially over large areas, allows for extensive use of one herbicide. This could impose high selection pressure on weeds and thus lead to unintentional selection for herbicide resistance

An important aspect, besides those mentioned above, that should be considered is the possible impact of HRC/IRCs on non-target organisms (e.g. pollinators, soil fauna or other organisms associated with the crop plant). These risks are currently difficult to assess because of inadequate knowledge, therefore specific decision keys targeting this issue have not been developed in these procedures; scientific experts should, therefore, be consulted regarding this on a case-by-case basis.

The final decision on releasing HRCs and IRCs is ultimately a balance between science, economics, ethics, local benefits and public interest. Consequently, the perceived risk sometimes reflects conflicts of interests. The use of the keys aims to facilitate arriving to a conclusion about ecological risk of HRCs (IRCs) based on scientific knowledge rather than on perceptions, although a quantitative approach is yet to be developed. The keys presented below were designed only as a guide in assessing the ecological risks based on the most likely relevant scenarios. They have limitations and should be considered carefully according to local conditions and experience. It is important to take into account that cropping practices and local environmental conditions and characteristics can affect the risks and how they are assessed or perceived. For example, crop rotation or rotating or mixing herbicides with different modes of action would delay the rate at which resistance would occur in a weed population

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

Scenario 1

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

When a HRC is to be released into an area where there are compatible wild or weedy relatives there is a possibility that the transgenes will escape and introgress into those compatible species. As a result, the wild or weedy relatives (congeneric or conspecific) could become resistant to the herbicide, making them a more noxious agricultural or environmental pest. There is also the possibility that the competitive ability of wild relatives might be altered. The HR wild relative will only have a selective advantage within the agricultural field where the associated herbicide is used and is therefore unlikely to be more competitive in natural areas than the non-transgenic counterpart, however, genes from IRCs may become established in native populations and increase the competitive ability of these plants. This possibility is of particular concern when the IRC is to be released into its wild progenitor's centre of origin or diversity, which serve as a particularly valuable source of genes for plant breeding. Useful genes might be lost if introgression with transgenic crops results in the extinction of native genes. Under these conditions, assessment should consider all the corresponding keys below.

Scenario 2
The HRC/IRC is to be released in an agricultural system where there is minimal risk of gene flow to other species.

Under this scenario, there are three main concerns to consider. The HRC/IRC could contaminate neighbouring crops either though pollen or seed dispersal. Secondly, weeds could evolve resistance to the herbicide that the HRC withstands because of the selection pressure imposed by its use. And third, management of HRC/IRC volunteers in succeeding plantings of the conventional crop or in rotation crops could become increasingly difficult. Initiate the assessment by considering key no. 3.

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

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

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

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

3. *Do these wild relatives occur in the proximity of the crop?*

If yes: Go to No. 4. If no: Stop, and go to key 2.

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

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

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

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

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

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

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

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

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

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

6. *Can HR hybrids or introgressants easily be controlled by other means besides the herbicides associated with the HRC?*
   If yes: Likelihood of losing one herbicide. If no: Go to No. 7.

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

8. *Does the IR trait confer an increased fitness in the wild/weedy relative compared to non-IR relative?*

If yes: Likelihood of increased weed problems.

If no: Stop and go to key 3.

Key 3: Likelihood of contaminating non-target crops or areas through pollen, seed dispersal or propagules

1. *Does the HRC/IRC disperse viable pollen?*
   If yes: Go to No. 2.
   If no: Go to No. 7.

2. *Are cross-compatible crops grown within the likely distance for pollen dispersal of the HRC/IRC crop?*
   If yes: Go to No. 3.
   If no: Go to No. 7.

3. *Do the HRC/IRC crop and the neighbouring crops overlap in flowering periods?*
   If yes: Go to No. 4.
   If no: Go to No. 7.

4. *Are cross-pollinated inflorences in the non-target crop harvested before they produce viable seed?*
   If yes: Likelihood of contaminating non-target crops with HRC/IRC genes
   If no: Go to No. 5.

5 *Does the non-target crop produce fertile seed, which may be shed before or at harvest?*
   If yes: Likelihood introducing. resistant non-target crop volunteers, go to No. 6.
   If no: Go to No. 6.

6 *Is seed from the non-target crop harvested?*
   If yes: likelihood of contaminating non-target crops with HRC/IRC genes
   If no: Go to No. 7.

7. *Could seed or propagules from the HRC/IRC be dispersed to non-target areas by farm implements, harvest equipment, transport vehicles, wind, water or animals?*
   If yes: Go to No. 8
   If no: Stop, go to key 4.

8. *Are these seeds or other reproductive structures able to become established in other areas/fields?*
   If yes: Likelihood of contaminating non-target crop with the HRC/IRC, and/or introducing resistant non-target crop volunteers, and/or dispersal to non-target areas with the HRC/IRC
   If no: Likelihood of contaminating non-target crop with the HRC/IRC.

Key 4: Likelihood that the transgenic crop will become a volunteer problem on arable land or wild areas

1. *Is the crop known to leave volunteers in succeeding crops?*
   If yes: Go to No. 2 — If no: Stop. There should not be a volunteer problem. For HRCs assess likelihood of herbicide resistance (key 5).

2. *Does the crop have weedy traits?*
   If yes: Go to No. 3 — If no: Stop, and go to key 5.

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

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

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

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

7. *Can the IR volunteer easily be controlled in succeeding crops?*
   If no: Go to No. 8 — If yes: Stop.

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

Key 5: Likelihood of build-up of HR-resistant weeds

1. *Have cases of resistance already occurred to the herbicide that the HRC withstands or herbicides belonging to the same chemical family or having the same mode of action (MOA) or degradation known to occur, or is gene flow possible from HRC to related weedy species, or is the herbicide a new chemical?*

If yes: Go to No. 2	If no: Stop. There should be a low likelihood of evolution of herbicide resistant weeds, especially if integrated weed management is used

2. *Is the cropping system primarily a monoculture or the HRC is or will be fully rotated with other crops?*

If monoculture: Go to No. 5	If fully rotated: Go to No. 3

3. *Is weed management primarily based on an integrated strategy or on chemical control?*

If chemical control: Go to No. 4.	If integrated strategy: Stop. Very small likelihood of herbicide resistance development.

4. *Is the MOA of the herbicide used in HRC crop similar or different to that used in the other rotational crops?*

If same: consider likelihood of selection for resistant weeds	If other: Stop. Very small likelihood of herbicide resistance evolution.

5. *Is weed management under the monoculture system primarily dependent on herbicides?*

If yes: Go to No. 6	If no: Stop. Very limited likelihood of herbicide resistance evolution.

6. *Is the herbicide to be used in the HRC a new persistent compound or a chemical to be used twice or more in cropping cycle?*

If yes: consider the likelihood of selecting new resistant weeds	If no: Go to No. 7

7. *Does the herbicide used in HRC share MOA with others in use?*

If yes: Risk of aggravating or speeding resistance problems	If no: Stop. Limited likelihood of herbicide resistance evolution.

For further information please contact:

By mail: Dr. Ricardo Labrada
Plant Protection Service
Food and Agriculture Organization of the United Nations (FAO)
Via Delle Terme di Caracalla, B-756
00100 Rome, Italy

By e-mail: ricardo.labrada@fao.org

Fax: + (39) (06) 57056347

Or visit our Website at:

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/IPM/Weeds/Default.htm
http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/IPM/Web_Brom/Default.htm