# A Proposed Risk Assessment Method for Genetically Modified Plants

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## Abstract

*An essential step in the development of products based on genetically modified plants (GMPs) is an assessment of safety, including an evaluation of the potential impact of the crop and practices related to its cultivation on the environment and human or animal health. The purpose of this safety assessment is to compare information about the GMP with that from a non-GM crop. However, at present this risk analysis may be faulty because there is no widely accepted and specific risk assessment method to evaluate GMPs that uses quantifiable parameters and allows for a comparative analysis among different technologies. This paper introduces a risk analysis method that focuses on the identification and evaluation of risks associated with the field release and cultivation of GMPs. Two tools bolster this proposed risk assessment method: (1) worksheets to compile* Evidence of Risks, *and (2) a* Matrix of Assessment. *The first tool identifies potential hazards related to the use of a specific GMP. This preformatted worksheet assigns values to the level of risk and its significance in terms of the activity to be developed. The second tool provides a structure to observe the potential hazards that illustrates what approach supports the use of GMPs in a manner as safe as any other traditional technology. To better understand this proposed risk assessment method, it is presented in a digital format (www.cnpma.embrapa.br/forms/gmp_ram.php3) (GMP-RAM v.1.1. software) where the two tools are linked so that the user can fill in the worksheets and automatically observe the results in the matrix. Compared to current processes, this proposed method represents a less subjective and more transparent process for risk assessment.*

## Introduction

An essential step in the development of a genetically modified plant (GMP) is the assessment of its safety. This procedure evaluates all possible influences of the plant and practices related to its cultivation on the environment and on plant, human, and animal health. This is accomplished by comparing appropriate comparators, for example, wild genotypes of the plant used to produce the GMP. This evaluation is performed by risk analysis.

Risk analysis follows a structured approach with three distinct but closely related steps: risk assessment, risk management, and risk communication. In addition, factors related to risk prevention, reduction, and remediation should also be considered. Following Codex Alimentarius, noted in the Food and Agriculture Organization's biotechnology glossary (FAO, 2001), risk assessment is defined as "a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment and (iv) risk characterization." Risk management is "the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practice, and, if needed, selecting appropriate prevention and control options." Risk communication is defined as "the interactive exchange of information and opinions throughout the risk analysis process concerning risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions."

The literature describes several ways to complete a risk analysis (Conner et al., 2003; EFSA, 2004; FAO, 2003; FAO, 2004; Krayer von Krauss et al., 2004). The evaluation is scientifically based, where parameters that comprise a risk (such as hazard and exposure) are submitted to qualitative analysis (Funtowicz et al., 1999; NRC, 2002; OECD, 2005). However, there is no widely accepted and specific risk assessment method for the evaluation of genetically modified plants that draws on quantifiable parameters and allows for a comparative analysis among different technologies.

This paper introduces a risk analysis method, focused on the risk assessment step that identifies and evaluates the risks associated with the release and cultivation of GMPs. The proposed method is based on other methods of risk analysis, such as Ambitec-Agro (Rodrigues et al., 2003a), Environmental Assessment System (Rodrigues et al., 2003b), Matrix of Leopold (Leopold, 1971), and Environmental Impact Assessment methods utilized during ISO 14000 implementation. Many validated issues or parameters of analysis described in previous reports (EFSA, 2004; NAS, 2002) were also considered.

The uniqueness of this risk assessment is the assignment of values for specific parameters; these values make it possible to describe and compare risk measurements with quantifiable tools. The hazards to be analyzed are organized according to their potential sources of exposure, such as genetic insert, expressed protein, features of the GMP, gene flow, introduction of the technology, and unexpected occurrences (accidents). All concerns related to GMPs, or at least the currently most debated ones, can be arranged in these groups.

All activities related to commercial release, field trial tests, greenhouse experiments, or even lab assays with GMPs are assessed with this proposed method. Therefore, it can be used throughout GMP development, from the researcher during new trait search to the regulators during assessment for market clearance. Obviously, the exchange of information and experience among all involved allows for an accurate analysis of GMP safety.

Although some risk assessment methods already propose how to weight the evidence of risks (EC, 2002; EFSA, 2004), they do not allow the user to find out which are the most relevant issues that should be managed during the risk analysis. In contrast, the risk assessment method presented in this paper introduces tools that give the user the opportunity to identify and rank potential hazards; consequently, mitigations are made according to the context of the risks.

## Methods

The proposed new risk assessment methodology is performed in two steps: (1) Complete a preformatted worksheet to compile the evidence of risks, and (2) Plot the outcome on the Matrix of Assessment.

### Evidence of Risk Worksheet

First, a worksheet is constructed to characterize all potential GMP-related hazards and to assign a level of risk and its significance in the context of the activity to be developed. Table 1 shows the worksheet, and the following topics describe the worksheet's different fields.

#### Fields for Sources of Exposure, Potential Hazards, and Criteria of Assessment

On the worksheet the potential hazards are grouped according to their source of exposure, along with at least one criterion for assessment of each one. These items are predetermined on the worksheet to allow for an accurate evaluation of related risks. For example, altering the dynamic of population of weeds is a "potential hazard" resulting from the gene flow that is the "source of exposure." The characterization of this hazard is performed by analyzing the "criterion of assessment" that is the feasible outcrossing between the GMP and the related weeds.

The data presented in the worksheet are based on features of current GMP traits (James, 2004; OECD, 2005). In addition, public concerns about genetically modified organisms and the impact of environmental assessment were also considered when deciding which issues to analyze in the worksheet (MAFF, 2000; NAS, 2002; SCIENTISTS, 2002). However, new features and genetic characteristics have been developed, resulting in new potential hazards, sources of exposure, and criteria for assessment. Thus, new aspects must be added to the worksheets as needed.

In Table 1 each hazard is coded with a letter (from "a" to "o") to identify it in the Matrix of Assessment. The user may also add parameters to the tool (e.g., potential hazards can be inserted in rows coded "p" to "z") according to the specificity of the technology and on a case-by-case basis. Likewise, it is possible not to complete the parameters that are not related to the object under analysis.

#### Data/Information for the Evaluation Field

This central column is the field where the user describes all information related to the criterion of assessment. Experimental results and literature searches must be the source of the scientific data described. For example, in the previous example where the criterion of assessment was the outcrossing between GMP and related weeds, the user could cite the sexual compatibility, distance and rate of outcrossing, barriers for pollen containment, and the usual isolation distance in seed production as data for evaluation. These data are crucial to support the risk characterization since the assignment of values must correspond with the information described by the user in the corresponding field.

#### Indexes of Moderation Fields

Based on scientific data, the risk characterization is accomplished by attributing values separately for two specific indexes: Index of Risk and Index of Significance. These comprise the "Factors of Moderation," such as damage, exposure, precedent, extent, and reversibility.

(1) Index of Risk: This index is calculated taking into account the factors below:

Index of Risk = Damage x Exposure x Precedent

- **Damage:** Level or intensity of the *impact* (damage)

## Table 1

### Worksheets for the Compilation of the Evidence of Risk

"Potential hazards" are listed according to their "potential source of exposure." For each identified hazard, at least one criterion to assess it is listed. Risk characterization is performed by attributing values to the "factors of moderation" and, consequently, estimating values to the "indexes of moderation." The fields in the central column are to be filled in with current scientific data that supports the values assigned to each factor of moderation.

| Potential Hazards | Criteria for Assessment | Data/ Information for Evaluation | Factors of Moderation | | | Index of Risk | Factors of Moderation | | Index of Significance |
|---|---|---|---|---|---|---|---|---|---|
| | | | Damage | Exposure | Precedent | | Extent | Reversibility | |
| *Potential Source of Exposure –* ***Genetic Insert*** | | | | | | | | | |
| (a) Dissemination of diseases, development of antibiotic resistance | Donor features | | | | | | | | |
| | Recipient features | | | | | | | | |
| | Presence of unwanted or regulatory or marker nucleotide sequences that present some risk | | | | | | | | |
| (b) Appearance of other negative characteristics | Stability of the insert | | | | | | | | |
| | Phenotypic and compositional assessment, pest and disease reactions | | | | | | | | |
| *Potential Source of Exposure –* ***Expressed Protein*** | | | | | | | | | |
| (c) Occurrence of negative effects on plant, human or animal health | Protein specificity | | | | | | | | |
| | Homology with known allergenic or toxic proteins | | | | | | | | |
| | Protein stability | | | | | | | | |
| (d) Occurrence of negative effects on nontarget organisms | Protein toxicity or allergenicity for non-target organisms | | | | | | | | |
| *Potential Source of Exposure –* ***Features of GM Plant*** | | | | | | | | | |
| (e) Generation of plants with weedy aspects | Recipient features | | | | | | | | |
| | Reproductive, competitive, or adaptive ability | | | | | | | | |
| (f) Outbreak of additional attributes | Gene specificity | | | | | | | | |

*Table 1 is continued on the next page.*

**Table 1 (Continued)**
**Worksheets for the Compilation of the Evidence of Risk**

| Potential Hazards | Criteria for Assessment | Data/ Information for Evaluation | Factors of Moderation | | | Index of Risk | Factors of Moderation | | Index of Significance |
|---|---|---|---|---|---|---|---|---|---|
| | | | Damage | Exposure | Precedent | | Extent | Reversibility | |
| *Potential Source of Exposure –* ***Gene Flow*** | | | | | | | | | |
| (g) Unexpected dissemination due to outcrossing with conventional genotype | Rate and distance of outcrossing | | | | | | | | |
| (h) Alteration in the population distribution of weed or native species | Outcrossing with weed or wild species | | | | | | | | |
| (i) Alteration in other nontarget organisms | Gene flow to nontarget organisms (horizontal flow) | | | | | | | | |
| *Potential Source of Exposure –* ***Introduction of the Technology*** | | | | | | | | | |
| (j) Threat to the agricultural management practices | Comparative analysis with conventional methods | | | | | | | | |
| (k) Decreases in the efficacy of the technology | Probability to generate mutations in the target organisms | | | | | | | | |
| (l) Increasing the demand for natural resources | Comparative analysis regarding soil and water usage and quality | | | | | | | | |
| *Potential Source of Exposure –* ***Unexpected Occurrences (accident)*** | | | | | | | | | |
| (m) GMO dissemination due to extreme climatic events | Geographic relationship in the region to sensitive areas | | | | | | | | |
| | Localization of the site (e.g., position of field trial inside the property) | | | | | | | | |
| | Period of occurrence of extreme climatic event | | | | | | | | |
| (n) GMO dissemination due to operational failure | Training of the team | | | | | | | | |
| | Final destination of the GMO regulations | | | | | | | | |
| (o) Dissemination due to theft of material | Physical safety of the property | | | | | | | | |

that the GMP could have on the system, if the proposed adverse effect actually occurs. The intensity (low, medium, or high) is quantified according to the values in Table 2.

- **Exposure:** This is related to the level that some component (e.g., soil, animal, native plant, etc.) is exposed to the damage. The higher the exposure the higher the possibility of an adverse effect occurring. The values attributed to different levels of exposure are shown in Table 2.
- **Precedent:** Precedent considers the previous occurrence of the adverse effect, as a consequence of the event in question, as shown in Table 2.

Based on the definition of Index of Risk, the score may range from 1 (1x1x1) to 32 (4x4x2); therefore, the Index of Risk is able to classify a risk as very low, low, medium, and high, as seen in Table 3.

(2) Index of Significance: For additional characterization, the risks must be evaluated according to the context of the activity to be developed. For example, the Index of Significance takes into account the location where the GMP will be cultivated, the identification and evaluation of potential adverse effects, and the evaluation of the current environmental situation. This index is calculated by:

- **Extent:** This factor of moderation reflects the extent of dispersal or the distribution of the damage, classified as shown in Table 2.
- **Reversibility:** This is the ability of the system to return to the previous condition (considering the activity with GMPs). The values to quantify this factor are shown in Table 2.

Extent and Reversibility are factors of moderation that directly affect decisions on how to manage actions for risk mitigation or risk prevention. The Index of Significance also ranges from 1 (1x1) to 32 (4x8), being classified from "very low" to "high," as shown in Table 3.

The potential hazards identified with the letters (a), (b), (c), (e), (m), and (n) present more than one Criterion of Assessment. In these cases, it is suggested that the higher value among the criteria be selected to measure the indexes. This ensures a high confidence for the proposed method.

## Matrix of Assessment

After hazard identification, hazard characterization, exposure assessment, and the significance analysis of related risks comes the final step in this risk assessment

**Table 2**

Values to be attributed to the Factors of Moderation that Comprise the Index of Risk (damage, exposure, and precedent) and the Index of Significance (extent and reversibility).

| Factors of Moderation | Levels | Values |
|---|---|---|
| **Damage** | Low | 1 |
| | Medium | 2 |
| | High | 4 |
| **Exposure** | Low | 1 |
| | Medium | 2 |
| | High | 4 |
| **Precedent** | No | 1 |
| | Yes | 2 |
| **Extent** | Local (contained where GMP is cultivated) | 1 |
| | Regional (property or distance of pollination) | 2 |
| | Abroad (area affected indirectly) | 4 |
| **Reversibility** | Naturally reversible (without management) | 1 |
| | Reversible with simple management (e.g., changing technology) | 2 |
| | Reversible with complex management (high costs and use of nonconventional methods) | 4 |
| | Irreversible | 8 |

**Table 3**
**Range of Values**
These values allow us to classify the Index of Risk and the Index of Significance in several classes, from "very low" to "high" as follows:

| Risk | Index of Risk |
|---|---|
| Very low | 1-3 |
| Low | 4-7 |
| Medium | 8-15 |
| High | 16-32 |
| **Significance** | **Index of Significance** |
| Very low | 1-3 |
| Low | 4-7 |
| Medium | 8-15 |
| High | 16-32 |

process—reviewing the potential hazards and establishing at which level risk management, by preventive or corrective actions, must be taken in order to allow safe use of the GMPs. This is performed by the Matrix of Assessment step.

The Matrix (Figure 1) is constructed with two axes, where the "x" axis stands for the classes of the Index of Risk and the "y" axis stands for the classes of the Index of Significance. The results from the Index of Risk and the Index of Significance are plotted in the Matrix according to their position (points are plotted using letters that represent each potential hazard). The level of mitigation recommended is classified as:

(a) No restrictions—when the hazard does not have a significant chance of being a risk
(b) Monitoring required—when the hazard must be observed to avoid adverse effects
(c) Management required—when additional measures must be taken to prevent impacts
(d) Restrictions required—when the activity can be done under restrictive rules or measures and, additionally, frequent observations are required to avoid potential impacts
(e) Not recommended—when hazards show a high level of risk and significance. In this case biosafety measures could be ineffective to prevent or mitigate such risks.

### Compiled Analysis

The following step involves compiling and analyzing the results from the matrix and worksheets. Each potential hazard plotted in the matrix requires some measures according to the level of mitigation. These biosafety measures must consider all data described in the worksheet, such as the specificity of the GMP, the activity under analysis, and the environmental situation. Essentially, this compilation is the core structure to perform risk management.

### Digital Format—Introduction of the Software GMP–RAM (v. 1.1)

The software GMP–RAM v. 1.1 is an eletronic format of the worksheets that was created in Borland Delphi 2005 Professional and can be accessed via two different links: (1) www.cnpma.embrapa.br/forms/gmp_ram.php3 (risk assessment file to download) (preferable) and (2) ftp://ftp.cbi.cnptia.embrapa.br/ or www.cbi.cnptia.embrapa.br/gmp_ram/ (alternative). To run the GMP-RAM, just download the file to your PC and execute it with a left mouse double click. By using this electronic format, it is possible to attribute the values for the factors of moderation and the results of the indexes (Risk and Significance). These will be calculated and plotted in the Matrix of Assessment automatically.

## Method Validation

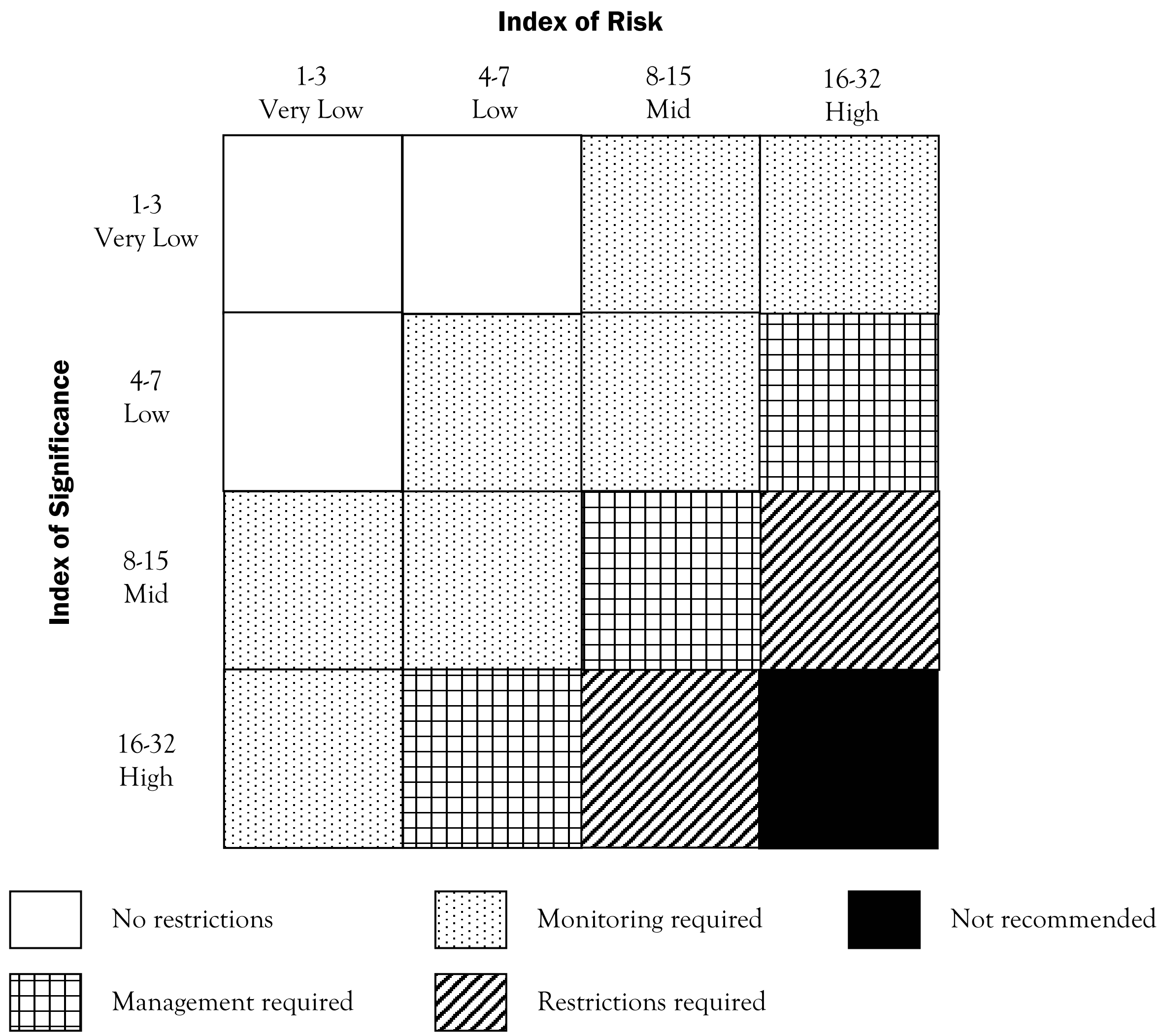
This new risk assessment tool will be validated as soon as several users test it with different crops and traits or perform comparative analyses with other methods. It is expected that some fine-tune adjustments and/or improvements in the method will be needed.

## Hypothetical Example

For better understanding Table 4 shows a hypothetical example of a partially completed worksheet and the corresponding Matrix of Assessment (Figure 2) plotted with the letters. The potential hazards characterized in this example were related to "unexpected occurrences" (coded with the letters "m", "n," and "o").

**Figure 1**

Matrix of Assessment is the final step of this Risk Assessment tool. The Matrix of Assessment gives an overview of potential hazards and establishes at which level risk management must be taken. The “x” axis represents the classes of the Index of Risk and the “y” axis represents the classes of the Index of Significance.




Obviously, during a risk assessment of a GMP, the user must complete the whole worksheet.

The assigned values for the factors of moderation are based on the information described in the worksheet (“data/information for evaluation” field) (Table 4). These do not describe the characteristics of the GMP, since this is not relevant at this point, but they do illustrate what we would consider if the GMP is a crop such as maize, cotton, or soybean and the activity to be developed is a field trial release.

Considering the distribution of the “letters” inside the matrix (Figure 2), the following risk management could be suggested:

- **Potential hazard coded as “m”** (GMO dissemination due to extreme climatic event)—Based on the information presented in the worksheet (Table 4), it seems highly feasible that the GM seeds could be undesirably disseminated as a consequence of flooding. The assessment of this potential hazard (“m”) indicates that it requires some “restrictions” to mitigate the risk. Considering that the more critical criterion of assessment was the “localization of the site,” it is mandatory that the field trial be installed at another site and not subjected to flooding or location near the river (or swamp)
- **Potential hazard coded as “n”** (GMO dissemination due to operational failure)—Assuming there is frequent biosafety training for the team and rules in place regarding discarding the material, this issue does not pose significant risk, so it does not require additional actions.
- **Potential hazard coded as “o”** (dissemination due to

## Table 4
### Worksheet of Evidence of Risks Partially Filled-In

This hypothetical example aims to show how to complete the worksheet during risk characterization. This example considered that the GMP is a crop (such as maize, cotton, or soybean) and the activity to be developed would be a field trial release. Only one "potential source of exposure" is to be filled in.

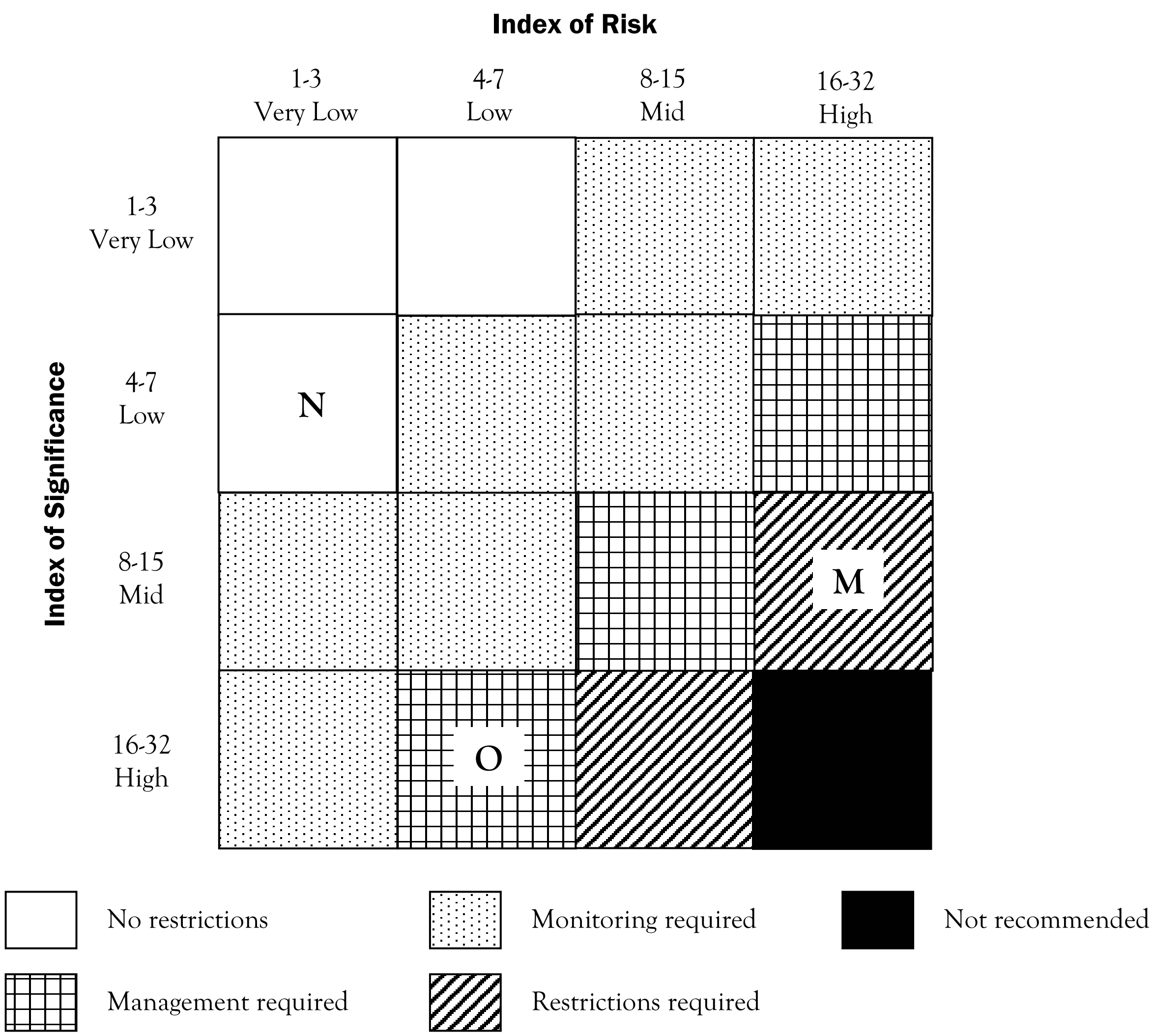
| Potential Hazards | Criteria for Assessment | Data/Information for Evaluation | Factors of Moderation | | | Index of Risk | Factors of Moderation | | Index of Significance |
|---|---|---|---|---|---|---|---|---|---|
| | | | Damage | Exposure | Precedent | | Extent | Reversibility | |
| *Potential Source of Exposure –* ***Unexpected Occurrences (accident)*** | | | | | | | | | |
| (m) GMO dissemination due to extreme climatic events | Geographic relationship in the region to sensitive areas | *The property is located in a region target of storms and flooding* | 4 | 2 | 1 | | 2 | 4 | |
| | Localization of the site (e.g., position of field trial inside the property) | *The site for GMP cultivation is near to a river (swamp)* | 4 | 4 | 1 | 16 | 2 | 4 | 8 |
| | Period of occurrence of extreme climatic event | *High pluviosity season does not match with planting season* | 2 | 1 | 1 | | 2 | 4 | |
| (n) GMO dissemination due to operational failure | Training of the team | *The employees frequently attend biosafety courses running by expertises* | 1 | 1 | 1 | 2 | 1 | 2 | 4 |
| | Final destination of the GMO regulations | *There are specific rules that guide on how to discard the material resultant from GMP* | 2 | 1 | 1 | | 2 | 2 | |
| (o) Dissemination due to theft of material | Physical safety of the property | *The area is easily accessed but there is police round service at night* | 2 | 2 | 1 | 4 | 4 | 4 | 16 |

theft of material)—The level of mitigation of this issue was "management" because some failures in the security to access the property were observed. Evaluation of the data described in the worksheet suggests that safety measures must be implemented in the area. These would include a private security service and/or additional monitoring improvements.

Based on the recommendations and suggestions above, this hypothetical activity would be environmentally safe if the restrictions and managements above were duly implemented. The Matrix of Assessment presented in Figure 2 shows which potential hazards could affect the user's choice of where to develop the GMP activities.

**Figure 2**

Hypothetical example of the Matrix of Assessment with plotted letters from Table 4.




## Conclusions

Risk analysis must be undertaken to predict the occurrence of negative impacts on the environment and human and/or animal health. These assessments allow us to define predictive measures to mitigate or avoid the adverse effects that could result from potential or identified hazards. Thus, it is possible to develop the GMP with a high probability of success and safety.

The risk assessment proposed here includes parameters that allow for an estimation of the level of risk based on the assignment of numeric values for several factors reported to correlate with risk. This results in lower subjectivity and higher transparency in the analysis processes. Recognition and characterization of risk significance (context of the risk) result in the definition of specific measures to be implemented, focusing on minimizing the chance of adverse effects.

NAS (2002) observed that a number of comparisons are appropriate for assessing the risks of transgenic crops. For example, the environmental effects of a transgenic crop could be compared to chemically intensive farming practices and to farming practices developed to be more ecologically sustainable.

In a risk assessment it is appropriate to draw on previous knowledge about the biology of the plant and to compare non-GM crops to the GM crop in order to highlight differences associated with the genetic modification and the subsequent management of the GM crop (EFSA, 2004). Technologies with the same objectives can also be compared using this proposed method, such as GM herbicide tolerant crop x mutant herbicide crop x traditional herbicide pulverization. The comparative analysis between conventional and genetically modified genotypes relies on the fact that all environmental regulations, such as isolation distance, water use management, etc., are duly followed. Therefore, the impact on preserved areas, bodies of water, etc., must be considered only if some specific GMP characteristics threaten such resources even when those regulations were respected.

Although this risk assessment is focused on GM plants, the range of the parameters analyzed in the risk characterization allow for the possibility of applying this method to the assessment of different technologies or activities, for example the introduction of an exotic plant species in a region or the cultivation of a conventionally improved crop for some abiotic stress-tolerance.

Considering the range of traits for GMP to be developed and the safety concerns that must be addressed on a case-by-case basis, this proposed method may not cover all aspects related to a given GMP, although it does present a broad approach to risk assessment. Since there is always the possibility of developing a new and better method that could be utilized in a wide range of situations, the user is encouraged to expand the possibilities of this tool by adding or deleting parameters (e.g., potential hazards) according to the specificity of the technology. On the other hand, regulators must assess if the chosen parameters are the best ones to define the potential impact of the technology under analysis.

This strategy is crucial to result in a less superficial method, since it is able to attribute which parameters are more correlated to the technology. In addition, characterizing risk by measuring with quantifiable tools demonstrates a quantitative method where subjectivity is drastically decreased.

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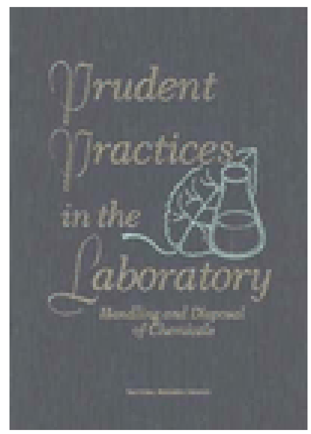
**Safety Library Reference**

The National Academies Press provides, free of charge, *Prudent Practices in the Laboratory: Handling and Disposal of Chemicals*, 1995, in a searchable, printable format at:

www.nap.edu/openbook/0309052297/html/index.html




**NIOSH Guide**

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www.cdc.gov/niosh.docs/2006-115/#d