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GMP- RAM V1.1: UMA PROPOSTA DE SOFTWARE COMO SISTEMA DE SUPORTE À DECISÃO PARA AVALIAÇÃO DE RISCO DE PLANTAS GENETICAMENTE MODIFICADAS

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RESUMO: Um passo essencial no desenvolvimento de produtos baseados em plantas geneticamente modificadas (PGM) é a avaliação da sua segurança, incluindo a avaliação do seu impacto potencial, e das práticas relacionadas ao seu cultivo, no meio ambiente, na saúde humana e animal, de modo comparativo com variedades convencionais, sem a modificação genética. Apesar da importância da avaliação de risco, o GMP-RAM é a primeira ferramenta eletrônica de suporte à decisão para a avaliação do risco relacionado ao uso dos transgênicos. Comparado com a siatuação atual de análise dos transgênicos, o uso deste software pode resultar num processo menos subjetivo e mais transparente para a avaliação de risco como apoio a tomada de decisão.

PALAVRAS-CHAVE: biossegurança, transgênicos, avaliação de risco, suporte à decisão.

GMP-RAM V1.1: A PROPOSED SOFTWARE TOOL LIKE A DECISION SUPPORT SYSTEM FOR RISK ASSESSMENT OF TRANSGENIC PLANTS

ABSTRACT: An essential step in the development of products based upon genetically modified plants (GMP) is an assessment of safety, including an evaluation of potential impact on the crops and the practices related to their cultivation on the environment, human or animal health, in a comparative way with its parental or reference crop. Despite the importance of the evaluation being currently done by risk assessment, the "GMP-RAM" is the first electronic tool for decision support at the evaluation of potential risks related to the use of genetically modified plants. The Software GMP-RAM is provided as a tool that may help to evaluate the safety of the genetically modified plants. The use of this software could represent a less subjective and more transparent process for risk assessment.

KEY-WORDS: biosafety, transgenic, risk assessment, decision support system.

1. INTRODUCTION

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; 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.

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This paper introduces a risk analysis method as a decision support system, 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 in 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.

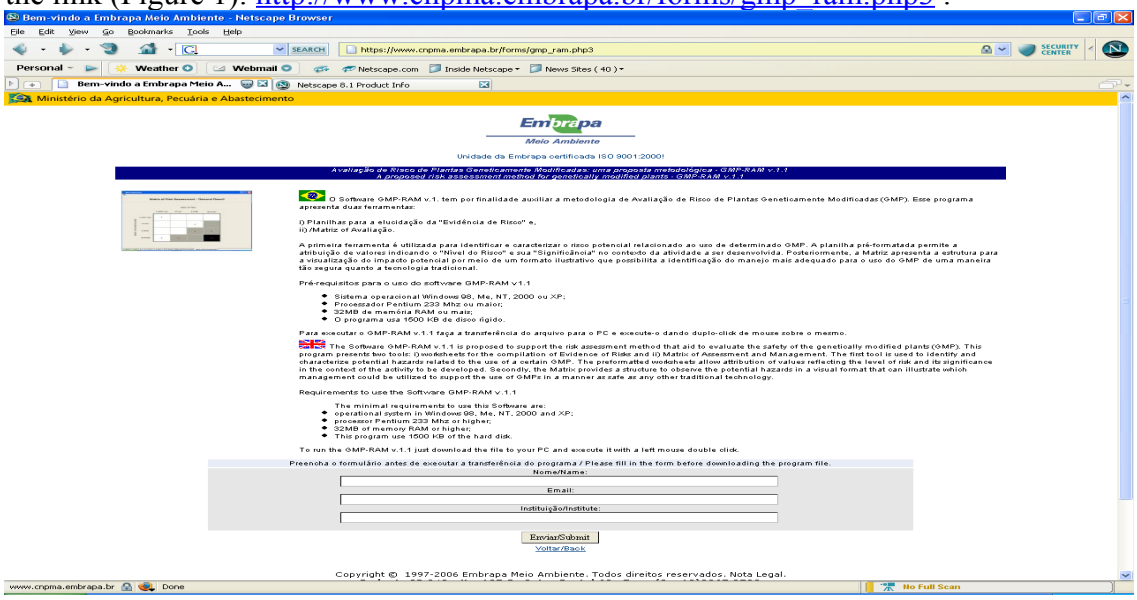
The uniqueness of this risk assessment as a decision support is the eletronic format to fill all the worksheets and to show the results in the matrix. The GMP-RAM software (JESUS et al., 2006) provides to add parameters to the tool according to the specificity of the technology and on a case-by-case basis. Likewise, it is possible complete only the parameters that are related to the object under analysis.

2. METHODS

The Software GMP–RAM v. 1.1 is an eletronic format of the worksheets that was created in Delphi. This program presents two tools: i) worksheets for the compilation of Evidence of Risks and ii) Matrix of Assessment and Management. The first tool is used to identify and characterize potential hazards related to the use of a certain GMP. The preformatted worksheets allow attribution of values reflecting the level of risk and its significance in the context of the activity to be developed. Secondly, the Matrix provides a structure to observe the potential hazards in a visual format that can illustrate which management could be utilized to support the use of GMPs in a manner as safe as any other traditional technology. The software GMP-RAM provides an easy way to use this method. Using this electronic format is possible to attribute the values for the factors of moderation and the results of the indexes (Risk and Significance) will be calculated and plotted in the Matrix automatically.

Software GMP-RAM v1.1

Aiming to optimize and provide an easy way to perform the "RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS" was built the Software GMP-RAM v. 1.1 (Genetically Modified Plants - Risk Assessment Method). The software can be accessed via the link (Figure 1): http://www.cnpma.embrapa.br/forms/gmp_ram.php3 .



Figue 1: The internet interface to download the GMP-RAM Software. 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. Figure 2 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 (risk evaluated) are grouped according to their source of exposure (mainly concerned under evaluation), 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. 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. 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 Figure 2 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.

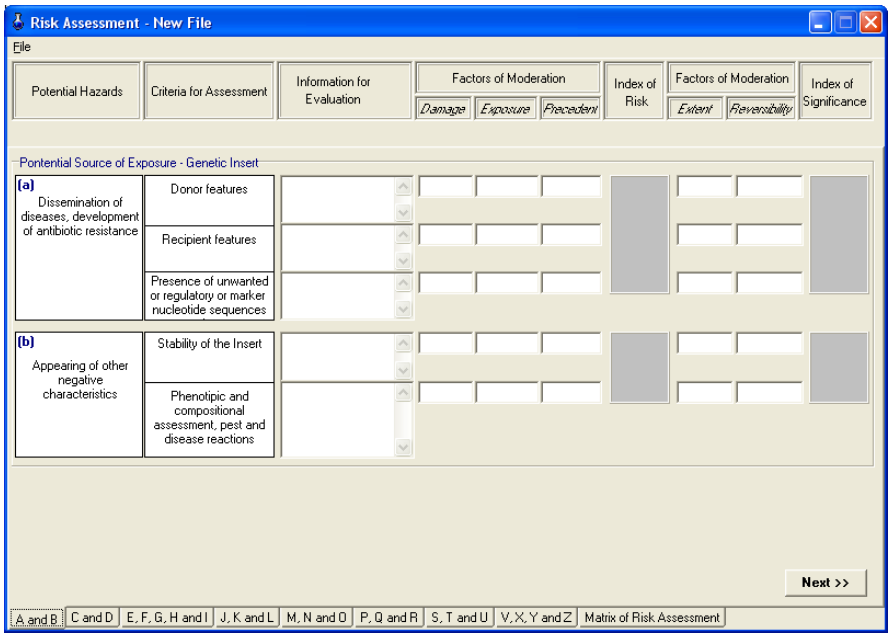


Figure 2. Worksheets for the Compilation of the Evidence of Risk

3. RESULTS

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 Matrix (Figure 3) 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).

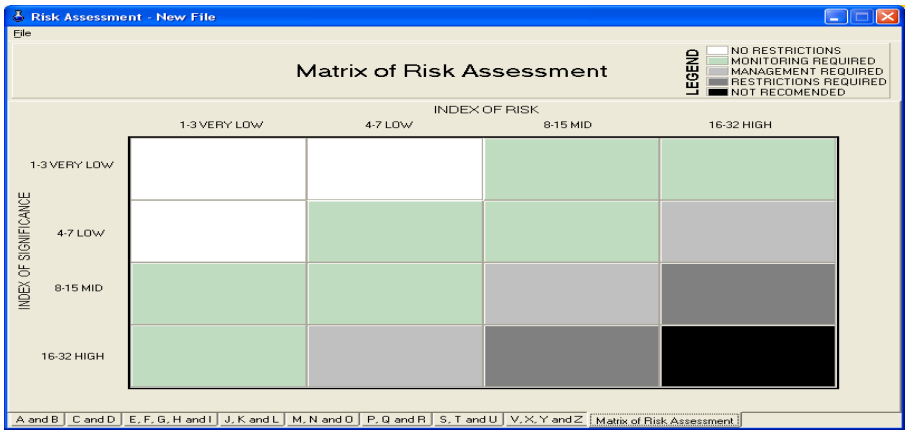


Figure 3: Matrix of Risk Assessment. The main tool to overview all indexes and to support decision makers.

4. CONCLUSIONS

Aiming the GMP-RAM v. 1.1 as a decision support system the result of these method are organized in a way that provides to the user to have the recommendations organized in the level of mitigation from the less restriction management to the higher one, in the specific case that the method indicates a dangerous associated with the GMP. Concluding the evaluation it is sugested to built the list of recommendation specific to the GMP under assessment, based on the results that is showed in the matrix.

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

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