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Risk Assessment of Genetically Engineered Crops

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There is always an uncertainty regarding persistence, propagation and production of viable offspring by a genetically modified organism(s) (GMOs). The biggest concern is about hazardous impact on environment and living systems. All the events and their outcomes in terms of risk and hazards with respect to duration of their happening are critical to understand the assessment of a problem.

Introduction

Risk is defined as the probability that adverse effects will result from exposure to a substance. It always increases along with the exposure duration to source of risk. The assessment of risk requires the identification of all the possibilities (likelihood and severity) of an adverse effect(s)/ event(s) occurring to living systems as well as environment following exposure under defined conditions to a risk source(s). Before a Genetically modified organism(s) is released into the environment, a determination of the possible associated risks to the environment, including to human health, should be undertaken. The pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis.

Procedure along with safety concerns

The safety assessment of GMOs and their derived products involve 2 steps:

1) comparative analysis with their non-GM counterparts to identify differences, and 2) assessment of the environmental and food/feed safety or nutritional impact of the identified differences. Major concerns involved during safety assessment are:

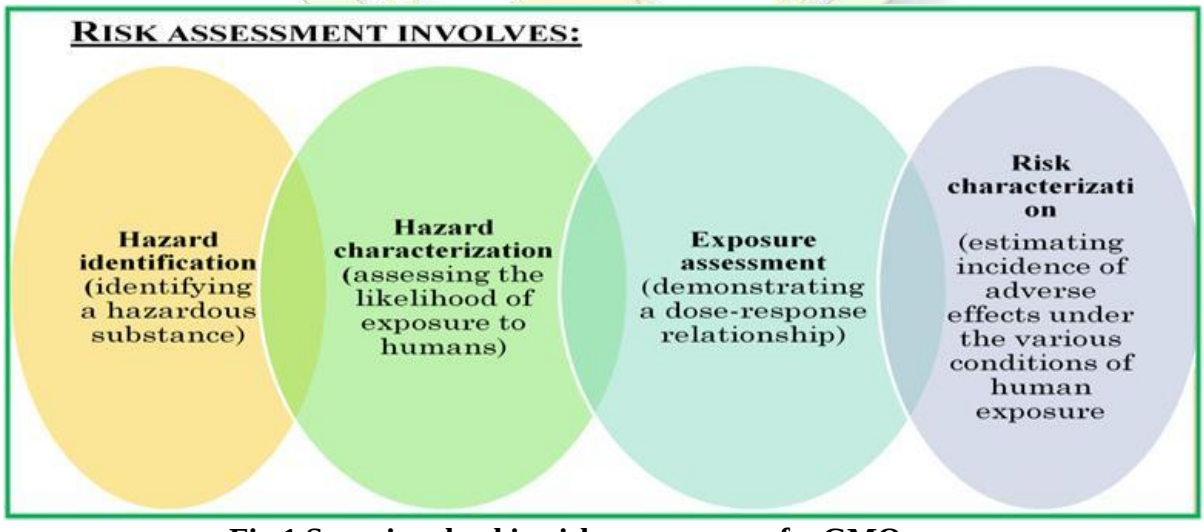

Fig.1 Steps involved in risk assessment of a GMO crop

i) Description of GMO

- characteristics of the donor and recipient organisms
- Genetic modification and its functional consequences

ii) Environmental safety

- Intended and unintended effects due to the modification of the recipient organism
- Agronomic characteristics
- Potential environmental impact

iii) Food/feed safety

- Compositional and nutritional characteristics
- Potential toxicity and allergenicity of gene products, plant metabolites and whole GM plant
- Influence of processing on the properties of food or feed
- Potential for changes in dietary intake
- Potential for long-term nutritional impact

Authorities regulating the assessment

The paradigm that was developed to assess the safety of genetically modified foods is known as "**substantial equivalence**" and was jointly developed in 1991 by the Food and Agriculture Organization and the World Health Organization in order to provide a standardized international methodology for the safety assessment of genetically modified foods (GMFs). Government regulations in the US, Europe, Canada, Japan, and most other countries are based upon the concept of substantial equivalence. It is based on the determination of any differences between a GMF and its traditional counterpart, which has traditionally been regarded as safe. The safety equivalence category involves traditional toxicological and risk assessment methods more than the others. When considering safety equivalence, safety assessors focus on the source of potential hazard in GMFs.

1. **The International Centre for Genetic Engineering & Biotechnology (ICGEB):** It is an international organization dedicated to advanced research and training in molecular biology and biotechnology, with special regard to the needs of the developing world and promotes the safe use of biotechnology. It has biotech labs in: ICGEB- Trieste (Italy), ICGEB- Cape Town (South Africa) and ICGEB- New Delhi (India). Their major roles are to disseminate as widely as possible significant information related to the bio-safety issues raised through the use of products derived from modern biotechnology As well as to assist its Member States in their capacity to identify, regulate, manage, and monitor those products within their own countries.

2. European food safety authority (EFSA): EFSA's remit in the risk assessment of GMOs is very broad encompassing genetically modified plants, microorganisms and animals and assessing their safety for humans, animals and the environment. **Main focus** of EFSA's GMO Panel lies in the evaluation of the scientific risk assessment of new applications for their market authorization of GMOs, and in the development of corresponding guidance for the applicants. Also, the selection of appropriate comparators is central to the comparative approach in the risk assessment of GMOs. The identification and production of such comparators is becoming increasingly challenging due to the increasing complexity of breeding schemes and the GM plants themselves, e.g. those developed by combining (stacking) events through conventional breeding, or those in which compositional changes are targeted. EFSA's guidance on the selection of comparators (EFSA Panel on Genetically Modified Organisms (GMO), 2011a) develops options for a more flexible and workable framework.

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