

## Biosafety Glossary

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### Allergen

A foreign substance that causes an allergic reaction. Allergens are all around us and are often proteins or chemical compounds presented to the body through touch, ingestion and/or inhalation.

### Allergenicity

Refers to the potential of a substance to be an allergen. The two most important determinants of allergenicity are identity and exposure.

### Allergy

A damaging immune response by the body to a substance; often associated with a particular food, pollen, fur, or dust, to which it has become hypersensitive.

### *Bacillus thuringiensis*

It is a soil bacterium, which produces a crystalline protein (*Bt* Cry protein) that - when ingested by certain types of insects – binds to gut cell receptors and in doing so kill the insect. *Bt* toxin is considered an effective insecticide to a wide variety of pest insects.

### Biodiversity

The wide diversity and complex interactions interrelatedness of earth organisms based on genetic and environmental factors.

### Bioethics

The study of the ethical and moral implications of new biological discoveries, biomedical advances, and their applications as in the fields of genetic engineering and drug research. It considers all living organisms and the environment, from the level of the individual to the biosphere.

### Biosafety

Biosafety refers to the safe handling practices, procedures and proper use of living organisms to prevent accidental harm either directly or indirectly to human health or to the environment.

### Biotechnology

Biotechnology integrates scientific and engineering principles with utility considerations to develop and improve the products and processes of living organisms. Biotech applications can roughly be divided into three different groups based on the level of conceptual complexity:

- The use of living systems/organisms as they are or with minimal modification, e.g. brewing beer using yeast.
- Using specialised, *in vitro* techniques, e.g. embryo rescue to generate new seedless grape cultivars.
- Using molecular techniques, e.g. genetic modification (GM) and marker assisted breeding.

### Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is a supplement to the Convention on Biological Diversity and was adopted by the parties in early 2000, and is open for ratification by those parties. It came into effect on 11<sup>th</sup> September 2003.

It aims to protect biological diversity and human health from the potential risks arising from the import and export of genetically modified organisms (GMO's) developed using modern biotechnology.

### Codex Alimentarius

The Codex Alimentarius is a programme established by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). It provides an international set of standards, best practices codes, guidelines and recommendations relating to food quality and safety, including codes governing hygienic processing practices, recommendations relating to compliance with standards, limits for pesticide residues, and guidelines for contaminants, food additives and veterinary drugs. The Codex Alimentarius has also adopted principles and guidelines to assess food safety of foods derived from GM plants, animals and microorganisms. The Codex Alimentarius aims to protect consumer health and ensure fair trade in the food industry, and promoting co-ordination of all food standards work undertaken by international governmental and non-governmental organisations. It is also referred to as the 'food code'.

### Co-existence

Co-existence is defined as the ability of farmers being to be able to make practical choices between conventional, organic and genetically modified crop production, in compliance with the relevant legislation on labelling rules and purity standards. Co-existence involves the economic implications of "good agricultural practice". Good agricultural practice involves suitable measures during cultivation, harvest, transport, storage and processing which is necessary to ensure sufficient segregation of GM and non-GM crop production hence, good quality standards in a diverse agricultural production environment.

### Containment

Refers to the techniques and systems used to limit the environmental exposure of hazardous or potentially hazardous biological agents or their products. Containment measures aim to eliminate the potential risks associated with exposure to such agents. Laboratory practice and techniques, safety equipment, and facility design requirements are key indicators of the level of containment. These levels range from the lowest biosafety level 1 to the highest at level 4.

### Environmental Impact

Impacts on human beings, ecosystems and man-made capital resulting from changes in environmental quality.

**Environmental impact assessment (EIA)** is a process of evaluating the likely environmental impacts of a proposed activity taking into account inter-related socio-economic, cultural and human-health impacts, both beneficial and adverse.

### Field Trials (also often referred to as confined field trials or CFTs)

When referring to GMOs it involves testing, trying, or putting to proof a new technique or crop variety outside a laboratory but with specific containment requirements, e.g. limited locations, limited plot size, strict operating procedures, preventative measures so that they may not enter the food and feed supply, etc.

### Gene

A hereditary, functional unit consisting of a sequence of DNA that occupies a specific location on a chromosome and encodes a specific functional product (i.e. a RNA molecule and/or protein) which determines a particular characteristic in an organism.

### Gene Flow (also referred to as pollen mediated gene flow in plants)

The movement of genes from one individual or population to another genetically compatible individual or population.

### Genetic Engineering (GE) & Genetic Modification (GM)

Refers to the direct modification of an organism's genome by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.

### Genetically Modified Organism (GMO)

An organism whose genome has been altered through genetic engineering and as a result may have one or more novel genetic traits not normally associated with the organism. Similar to Living Modified Organism (LMO).

### Genome (& Genotype)

The full complement of an organism's genetic material, which is unique for every individual except clones, e.g. plants grown from cuttings and identical twins. The human genome contains an estimated 20 to 25 thousand protein coding genes.

### GM event (& GM line)

Refers to a unique GMO – generated from a unique DNA recombination event that took place in a single cell during transformation, which was subsequently regenerated into a complete GMO.

#### **Guidelines**

Are documents that accompany regulations and acts and are produced by regulatory authorities. They provide the steps an individual should follow with respect to a given act or regulation. They are mandatory, but failure to follow them may result in actions contrary to an act or regulation, which is enforced by law.

#### **Hazard**

A hazard is any potential source of harm.

#### **Herbicide**

Herbicides are chemicals that are toxic to a particular group of plants and are used to manage weeds. The molecular mechanism of the toxicity is highly specific for every group of herbicides, e.g. inhibition of protein synthesis, and allows a basis for the engineering of herbicide tolerance.

#### **Herbicide Tolerance**

Herbicide tolerance refers to a plant's ability to survive the activity of a particular herbicide and is based on a molecular mechanism that somehow neutralises the activity of a herbicide; e.g. via deactivation or substitution reactions. It is the most common GM trait in commercial agriculture because it enables more effective weed control and the use of low or no tillage agricultural practices.

#### **Identity Preservation**

Identity preservation refers to a system of production, handling and marketing practices that preserves the identity of the source or the nature of the materials for separate trade of grains and seeds in order to meet customer demands. Identity preservation is an important feature in markets where GM and non-GM products co-exist (see co-existence).

#### **Indigenous Population**

Refers to communities of natural inhabitants in a defined geographical area. Indigenous people are typically a minority population that has maintained distinct cultural, language and social characteristics.

#### **Insect Resistance**

The development or selection of heritable traits (genes) in an insect population that allow individuals expressing the trait to survive in the presence of levels of an insecticide (biological or chemical control agent) that would otherwise debilitate or kill this species of insect. The presence of such resistant insects makes the insecticide less useful for managing pest populations.

#### **Insect Resistant**

Usually refers to a crop plant that contains substances (e.g. bio-active proteins or hard fibres) that kill or deter plant-eating insects. Insect resistance is the second-most common commercial GM trait for crop plants after herbicide tolerance and is predominantly obtained through the use of *Bt* toxin proteins originating from the soil bacterium *Bacillus thuringiensis*.

#### **Intellectual Property**

Intellectual property often refers to the exclusive rights that developers of GM technology have to their intellectual or creative contribution. Copyrights, patents and trademarks are common types of intellectual property.

#### **Living Modified Organism**

Living modified organism (LMO) refers to any living organism that possesses a novel combination of genetic material obtained through the use of genetic engineering.

#### **Novel Foods**

Novel foods are products that have never been used as a food; foods which result from a process that has not previously been used for food; or, foods that have been modified by genetic manipulation. This last category of foods has been described as genetically modified foods.

#### **Novel Trait**

Novel traits are genetic characteristics in an organism that have been developed either through the use of traditional or modern biotechnology.

#### **Permits issued by the South African regulatory authority**

- **Contained Use Permit**

Refers to a permit that allows activities involving work with GMOs within a facility where a number of barriers, such as chemical, physical and biological containment methods, limit the contact between the GMO and the external environment. This would include work conducted in greenhouses and laboratories. Certain activities for research and academic purposes conducted under containment level 1 and 2 are exempt from permit requirements, however these facilities still need to be registered in terms of the GMO Act.

- **Field Trials Permit**

Refers to a permit issued which allows the testing of a specific GMO in a designated, limited area under strictly regulated, confined conditions to monitor the performance of the GMO and to generate necessary biosafety data in the field for a specified period of time.

- **Export Permit**

Refers to the permit issued for the intentional transboundary movement of living GMOs (also referred to as LMOs) for use in countries outside South Africa.

- **Import Permit**

Refers to permit issued for the import of living GMOs (LMOs), including relatively small amounts of seed to be used for experimental purposes (e.g. contained use or field trials) and use as a commodity in South Africa.

- **Commodity Clearance Permit**

Refers to the permit to use a specific event in large quantities (typically 1000s of tons) of imported GM grain for use in food/feed – NOT for propagation.

- **General Release Permit**

A permit issued for a particular GMO event that allows its commercial production for food, feed, fibre or fuel in South Africa.

#### **Precautionary Principle**

The precautionary principle is an approach to risk management that has been developed in circumstances of scientific uncertainty, emphasising the need for action in the face of potentially serious risk to humans or their environment.

#### **Resistance development**

Usually refers to the development of resistance against some sort of treatment. Pathogenic bacteria can for example develop resistance against antibiotics, plants/weeds can develop resistance against herbicides and insects can develop resistance against insecticides. Resistance development is possible because all these treatments are based on highly specific molecular mechanism, which in turn are based on the variable genetics of the respective organisms. Natural genetic variation and continued molecular evolution over time could therefore generate alternative mechanisms unaffected by the treatment. When these genetic traits are passed on to new generations it will result in resistant populations.

#### **Resistance development management**

Refers to the techniques and mechanisms used to prevent resistance development in targeted populations. These could include high-dose treatments, integrated/combination management practices, alternate treatments, population genetic management, etc.

#### **Risk**

Risk is the probability of a harm occurring under defined circumstances. Risk is estimated by considering both the likelihood and consequence of a harm occurring (risk = likelihood x consequence).

#### **Risk Analysis**

Risk analysis integrates the contextualisation, assessment, management and communication of risk posed by, or as a result of activities with GMOs.

#### **Risk Assessment**

Risk assessment is defined as a formalised basis for the objective quantitative or qualitative evaluation of risk in a manner in which assumptions and uncertainties are clearly considered and presented.

#### **Segregation**

In a GMO context it is the physical separation of GM and non-GM components to allow for two distinct product offerings. Requires record-keeping, testing, separate value chains, etc. (also see co-

existence and identity preservation).

**Socio-economic Impacts**

Socio-economic impacts refer to all social and economic impacts that result or potentially can result due to a change in amongst others, the environment, industry or policy when adopting a technology. Changes might impact positively or negatively on a range of issues including production, employment, income, way of life, culture, political systems, environment, health, well-being, personal and property rights, and fears and aspirations.

**Species**

It is one of the basic units of biological classification. They are comprised of reproductive communities and populations that are distinguished by their collective variation with respect to many different characteristics and qualities.

**Stakeholder**

An institution, organisation, or group that has some interest in a particular sector or system.

**Substantial Equivalence**

The concept of substantial equivalence is used as a guide in the safety assessment of genetically modified foods by comparing the novel food to its unmodified counterpart which has a history of safe use. This approach allows regulatory authorities to include in their consideration, the substantial history of information related to foods which have long been safely consumed in the human diet to aid in the identification of potential safety and nutritional issues.

**Sustainability/ Sustainable Development**

The ability to meet present needs without compromising those needs of future generations. It relates to the continuity of economic, social, institutional and environmental aspects of human society, as well as the non-human environment.

**Toxicity**

The degree to which something is toxic or poisonous, or a substances potential to exert a harmful effect on humans, animals, or plants and a description of the effect and the conditions or concentration under which the effect takes place.

**Toxin**

A complex and poisonous organic substance, often a protein, that is produced by living cells or organisms and is capable of causing disease when introduced into the body tissues or cells of certain organisms at a specified dose.

**Traceability**

Codex Alimentarius defines traceability as "the ability to follow the movement of a food through specified stage(s) of production, processing and distribution". Traceability is the underlying principal used by regulatory agencies and industry in product recall, removing potentially harmful food products once they are in distribution. Traceability is particularly important in markets where GM and non-GM foodstuffs co-exist.

**Transboundary Movement**

Transboundary movement refers to the movement of living modified organisms (LMOs) across boundaries of countries and includes intended as well as unintended movement.

**Transgene**

Transgene refers to a gene(s) or genetic material that is isolated and transferred from one organism and incorporated by another organism, either naturally or through genetic engineering techniques. The process is known as **transgenesis**. The transgene introduces novel traits to the new host. A **transgenic** organism is any living organism containing a transgene and it is able to transmit the new transgenic trait to its offspring.

**Unintended Effects**

Unintended effects refer to the outcomes that are not (or not limited to) the results originally intended in a particular situation. The unintended results may be foreseen or unforeseen.

**Variety**

A subdivision of a species for taxonomic classification also referred to as a 'cultivar.' A variety is a group of individual plants that are uniform, stable, and distinguishable from other groups of individuals in the same species by distinct genetic and phenotypic characteristics.

**Willingness to pay**

The amount an individual is willing to pay to acquire a product or service. This may be obtained from stated or revealed preference approaches.