

 **1 Aout 2016**

 **SCBD/BS/MPM/DA/85215**

**A :** Monsieur le Secrétaire Exécutif de La Convention de la Diversité Biologique

**Objet :** Communication par La Mauritanie pour suggérer des sujets supplémentaires pour des guides sur l’évaluation des risques.

Suite à votre notification ci-référenciée ; j’ai l’honneur de vous faire parvenir la communication de la Mauritanie attachée ici



Sincèrement,

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**Submission by Mauritania for suggestions on Risk assessment guidance on additional topics**

**Suggested topic:**

Environmental application of in vitro nucleic acid techniques that overcome natural physiological reproductive or recombination barriers, e.g., for use in pest management.

This suggestion follows closely the wording of Article 3(i) “’Modern biotechnology’ means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection”

**Rationale:**

Until recently, the introduction of nucleic acids into organisms was done entirely in laboratories. Emerging biotechnologies now allow the creation of LMOs at environmental scales, created in the environment. Several patents and soon to be released products are based on this new capacity. The new capacity is often referred to as types of “Biologicals” or “Agricultural Biologicals”.

The nucleic acids are introduced into cells using chemicals that lower the barriers to uptake of nucleic acids. For example, in patent “Formulations and methods for control of weedy species” WO 2014167514 A1

<http://www.google.com/patents/WO2014167514A1?cl=en>

“A method of inhibiting or impairing plant growth and development is also provided. The method comprises delivering a formulation to a host plant, by spraying, imbibing, irrigating, or injecting the formulation, the formulation comprising an interfering Ribonucleic Acid (RNAi) payload, an at least one of a liquid carrier, a surfactant, a binder and tackifier, a thickener, a colorant, a spreader, an anti-freezing agent, a sticker, an anticaking agent, a stabilizer, a disintegrator, an emulsifier, a synergistic compound, an abrasive, an emulsifier, a penetrating agent and a preservative, thereby inhibiting or impairing growth and development.”

The nucleic acids most often mentioned are RNA, as per this quote from the literature:

**- *Novel herbicides***

* ***RNAi technology***

RNA interference (RNAi) technology (branded BioDirect™ by Monsanto) may help combat weed resistance to glyphosate and potentially other herbicides. Using this technology, which is in the early stages of development, a mirror copy is made of a weed's DNA in which targeted genes can be turned on or off. Monsanto utilizes precise RNA segments directly able to inhibit the normal production of the enolypyruvyl-shikimate-3-phosphate synthase (EPSPS) protein in plants. Particularly interesting and important is that under experimental conditions it appears that BioDirect™, when combined with a herbicide, can reverse resistance. It would certainly rank as a ‘game-changer’ if a POST spray application of a xenobiotic developed with this technology could make HR weeds susceptible to glyphosate or other herbicides” (Shaner and Beckie. The future for weed control and technology. Pest Manag Sci 2014; 70: 1329–1339).

However, this emerging technology is not limited to the use of RNA. As described in US Patent 9121022 B2 “Method for controlling herbicide-resistant plants” (assignee: Monsanto Technology) <http://www.google.com/patents/US9121022>, the technology applies equally to DNA:

"In other aspects the invention provides a plant with exogenous DNA or RNA for suppressing an endogenous gene, where the exogenous DNA is not integrated into a chromosome of the plant, the exogenous RNA is not transcribed from DNA integrated into a chromosome of the plant, and the endogenous gene is suppressed by topical application of a polynucleotide to the plant. These and other aspects of the invention are described in greater detail in the following sections.”

Other patents also make the claim to use either RNA or DNA, e.g. patent “Formulations and methods for control of weedy species” WO 2014167514 A1

<http://www.google.com/patents/WO2014167514A1?cl=en>

“RNAi Inducer means at least one specific nucleic acid sequence or analogue sequence that, when introduced into the body of a plant, will trigger or initiate an RNAi cascade. This can be, for example, but is not limited to DNA, dsRNA, ssRNA, siRNA, and miRNA sequences.”

At least one product, called BioDirect (<http://www.monsanto.com/products/pages/biodirect-ag-biologicals.aspx>) and produced by the Monsanto Company, is based on this technology.

These methods are claimed by some developers to be outside the coverage of genetic engineering regulations because the intent is not to create genetically modified organisms. For example

* “**Stem Shock™** is a programmable non-GMO herbicide platform to aid managers of towns, forests, farms, and parks in their fight against invasive or herbicide-resistant weeds.” “Uses natural, biodegradable, non-replicating and non-integrating RNA technology. Sprays or other products containing Stem Shock will be non-GMO. RNA is natural, present in all cells, and non-toxic.” http://stem-shock.com
* “Pesticides that work by tinkering with gene expression in the pest without modifying crop genes could get around regulations on genetic modification. The technology is based on a process called RNA interference and may be ready within the next five years.” <https://www.newscientist.com/article/dn28066-big-farmer-firms-plan-pesticides-to-manipulate-gene-expression/>

Despite these assertions by non-regulatory sources, the Protocol is specific to the methods for the creation of living modified organisms and these are organisms that involve nucleic acid techniques that result in the uptake of nucleic acids.

When it comes to pest management, the intention is to kill some of those organisms that take up the nucleic acids. In which case, they might not create “living” modified organisms. However, this is not clearly the case for several reasons.

1. Non-target organisms, e.g., the crop plants, are equally susceptible to taking up the nucleic acid even if the nucleic acid does not cause the intended adverse effect. These exposed plants, animals and microbes will live, potentially experiencing a recombination between their genomes and the active DNA or reverse transcribing the active RNA ingredient.
2. Not all target organisms may die, with the potential that they too may experience a recombination event with the introduced nucleic acid (or its derivative) and their genomes.

Subjecting these emerging biotechnologies to risk assessment is consistent with the Protocol, and would be appropriate to its Strategic Objective 1.3 to “further develop and support implementation of scientific tools on common approaches to risk assessment and risk management for Parties” outcome to provide guidance “on risk assessment and risk management including guidance on new developments in modern biotechnology.”

Agricultural biologicals have a unique potential to cross national and regional boundaries in the form of spray drift and runoff.

For these reasons and others, we ask that the Secretariat include “Environmental application of in vitro nucleic acid techniques that overcome natural physiological reproductive or recombination barriers, e.g., for use in pest management” as a topic for future guidance.

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