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EUROPEAN COMMISSION

Dr. Ahmed Djoghla
Executive Secretary
CBD Secretariat
413 rue Saint Jacques, suite 800
Montréal QC H2Y 1N9
Canada

Stockholm, Brussels, 21 September 2009

Subject: EU response to Notification 2009-056

Dear Dr. Djoghla,

On behalf of the European Community and its Member States, please find enclosed the response to Notification 2009-056 in which Parties, other governments and relevant international organisations were invited (according to the COP-MOP/4 decision BS-IV/11) to submit scientifically sound information regarding the identification of Living Modified Organisms (LMOs) or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Yours sincerely,

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EU coordinated response to Notification 2009-056: Submission of scientifically sound information regarding the identification of Living Modified Organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health:

According to Decision BS-IV/11, paragraph 8, Parties are invited to submit scientifically sound information available at that time, on the identification of LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Parties are also invited in paragraph 5 of the same decision to submit information relevant to the work of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management. According to its terms of reference in the Annex to Decision BS-IV/11 (Paragraph 1) e) (iv)), the AHTEG is instructed to consider possible *modalities for cooperation* in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Environmental risk assessments of GMOs in the European Community are carried out according to the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

Directive 2001/18/EC introduced propositions calling for a phase-out of LMOs harbouring certain antibiotic resistance marker genes, which may have adverse effects on human health and the environment. It is taken into account that these traits are not essential with regard to the purpose of the respective LMOs and that alternatives for these marker genes are available for newly-developed LMOs.

In some risk assessments prior to the authorization of insect-resistant GM maize events in the EU, the potential for adverse effects, i.e. for promoting the occurrence of resistance against Bt-proteins in pest species, is taken into account by means of a requirement for case-specific monitoring to further investigate this issue after placing on the market of these LMOs.

Regarding the fact that risks of LMOs can differ in different geographical areas, general guidance documents concerning risk assessment procedures also seem relevant in this

context. Most of the documents in the following list have already been mentioned in the European coordinated response to Notification 2008-140 submitted to the Secretariat of the Convention on Biological Diversity on 26 February 2009. The European Food Safety Authority will further develop and update in 2010 its guidance on environmental risk assessment as currently included in the guidance document of 2006 on the risk assessment of genetically modified plants (see fourth indent below).

A. Information on how to determine whether a LMO is potentially dangerous.

- Directive 2001/18/EC of 12 March 2001 on the deliberate release of genetically modified organisms and repealing Council Directive 90/220/EEC, including Annex II (Principles for environmental risk assessment)
- Regulation (EC) No 1829/2003 on genetically modified food and feed (principles for human and animal health).
- [Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II \(Principles for environmental risk assessment\) to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.](#)
- [Guidance document of the Scientific Panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed. EFSA Journal \(2006\) 99,1-100, updated in 2008.](#)
- [Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use by the Scientific Panel on Genetically Modified Organisms \(GMO\) EFSA Journal \(2006\) 374, 1-115.](#)
- FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA Animals, World Health Organization, Headquarters Geneva, Switzerland, 26 February – 2 March 2007 (http://www.who.int/entity/foodsafety/publications/biotech/report_biotech_07_en.pdf)
- Codex Alimentarius. Codex principles and guidelines on foods derived from biotechnology(2003):
[Principles for the risk analysis of foods derived from modern biotechnology, CAC/GL 44-2003.](#)
[Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms, CAC/GL 46-2003.](#)

[Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants CAC/GL 45-2003, including Annex 1 \(Assessment of possible allergenicity\), Annex 2 \(Food safety assessment of foods derived from recombinant-DNA plants modified for nutritional and health benefits\) and Annex 3 \(Food safety assessment in situations of low-level presence of recombinant-DNA plant material in food\), \(2003, Annexes 2 and 3 adopted 2008\).](#)

[Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals, CAC/GL 68-2008.](#)

http://www.fao.org/ag/agn/agns/biotechnology_detection_en.asp

- [Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organisation: Rome.](#)
- Communication from the Commission on the Precautionary Principle, COM (2000)1 final.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52000DC0001:EN:HTML>
- An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology No. 32, 2005, [ENV/JM/MONO\(2005\)5](#)
- OECD, 1993. [Safety Considerations for Biotechnology: Scale-up of Crop Plants](#)
- Van den Eede et al. (2004): [The relevance of gene transfer to the safety of food and feed derived from genetically modified \(GM\) plants.](#) Food and Chemical Toxicology 42, 1127-1156
- Nelson, K.C.; Banker, M.J. [Problem formulation and options assessment handbook.](#) 2007, A publication of the GMO ERA Project
- Cellini et al. (2004): [Unintended effects and their detection in genetically modified crops.](#) Food and Chemical Toxicology 42, 1089-1125
- [Guidance Document for the risk assessment of genetically modified plants containing stacked transformation events by the Scientific Panel on Genetically Modified Organisms \(GMO\) EFSA Journal \(2007\) 512,1-5.](#)
- Final report. Long-term effects of genetically modified (GM) crops on health and the environment (including biodiversity): Prioritisation of potential risks and delimitation of uncertainties.

http://ec.europa.eu/environment/biotechnology/pdf/beetle_report.pdf

B. Information on risks related to specific traits

- [Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants" and the Scientific Opinion of the GMO Panel on "Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants, EFSA Journal \(2009\) 1108, 1-8.](#)
- Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants No. 25, 2002, [ENV/JM/MONO\(2002\)14](#)
- Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Phosphinothricin Herbicide No. 11, 1999, [ENV/JM/MONO\(99\)13](#)
- Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide No. 10, 1999, [ENV/JM/MONO\(99\)9](#)
- Consensus Document on General Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection No. 5, 1996, [OCDE/GD\(96\)162](#)
- Consensus Document on Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis* - Derived Insect Control Protein No. 42, 2007, [ENV/JM/MONO\(2007\)14](#)