Dr. Braulio Ferreira de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, Quebec, Canada
H2Y 1N9

Copenhagen, Brussels, 14 May 2012

Subject: EU response to Notification 2012-016

Dear Dr. Ferreira de Souza Dias,

On behalf of the European Union and its Member States, please find enclosed the response to Notification 2012-016 in which Parties, other Governments and relevant organizations were invited (according to the COP-MOP/5 decision BS-V/12, paragraph 12) to submit to the Executive Secretary (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms that *are not likely* to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and (ii) the criteria that were considered for the identification of such living modified organisms.

Yours sincerely,

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EU submission in response to CBD Notification 2012-016 - Submission of information on identification of living modified organisms that are not likely to have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health

The EU regulatory framework foresees a case-by-case risk assessment of LMOs (recital 18, art 4.3 and Annex II of Directive 2001/18/EC) conforming to the principles of Annex III of the Cartagena protocol. These risk assessments are based on what is required in the EU legislative framework (Annex II of Directive 2001/18/EC) and on detailed guidance developed by the European Food Safety Authority[1] (EFSA).

Information on the risk assessments carried out to date within the framework of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms are publicly available on both the website of EFSA[2] and the Joint Research Center[3] (JRC) of the European Commission.

While the risk assessments referred to above include consideration of the receiving environment for a specific LMO (art 4.3 and Annex II of Directive 2001/18/EC) there is no specific assessment in respect of identifying LMOs that are *not likely* to have adverse effects on the environment or public health. From the existing evidence, the EU cannot come to the unambiguous conclusion that in any environment and under any condition a certain LMO will have no adverse effects (direct or indirect), leading to full exclusion from the scope of the Advanced Informed Agreement procedure.

[1] http://www.efsa.europa.eu/en/gmo/gmoguidance.htm
[2] http://www.efsa.europa.eu/en/gmo/gmoscdocs.htm
[3] http://gmoinfo.jrc.ec.europa.eu/gmc_browse.aspx