

Republic of Bulgaria MINISTRY OF ENVIRONMENT AND WATER

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Dr Cristiana Paşca Palmer Executive Secretary Secretariat of the Convention on Biological Diversity United Nations Environment Programme 413 Saint-Jacques Street, Suite 800 Montreal, QC, H2Y 1N9 Canada

Subject: Reply of Bulgarian Ministry of Environment and Water to Notification 2017-087

Ref.: SCBD/SPS/DC/MM/DA/86806

Dear Dr Paşca Palmer,

This submission supplements the reply to Notification 2017-087 by the European Union and its Member States (BCH Record ID 112931).

Bulgarian legislation uses the term genetically modified organisms (GMO) and it includes all living modified organisms (LMOs) as defined in the Cartagena Protocol on Biosafety.

EU Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMMs) is implemented through the Bulgarian GMO Act (BCH Record ID 8409) and the Regulation on the contained use of GMOs (BCH Record ID 40262). In addition to GMMs, those two legal instruments regulated the contained use of all other GMO. Contained uses of GMOs other than GMMs are classified as class A or B according to the risks they present to human health and the environment. In each case, risk assessment is carried out by the user. Those assessments are based on principles similar for all GMOs.

The rules for control over the contained use of GMOs by the Bulgarian Competent Authorities are set in the Instruction for the control of contained use and release into the environment of GMOs (available in Bulgarian only at <u>http://www5.moew.government.bg/wp-content/uploads/filebase/Nature/Biodiversity/Tatiana/Instrukcia_za_kontrol_na_GMO.doc</u>).

Yours sincerely,

KRASIMIR ZHIVKOV