Dear Executive Secretary,

Referring to Notification No. 2016-041, please find below the Hungarian response relating to the “Information on existing mechanisms and requirements regarding the contained use of living modified organisms”.

The Hungarian national regulations on contained use of GMOs are in line with the EU legislation. Besides, there are numerous national regulations on the abovementioned topic.

The Gene Technology Authority decides on the applications for authorisations taking into account the opinion of the Gene Technology Advisory Committee (GTAC). The Head of the National Gene Technology Authority nominates the members to the GTAC. The GTAC consists of representatives of various scientific fields, such as agriculture, microbiology, human health, law, education, veterinary etc. The GTAC holds meetings regularly, depending on the number of applications.

The relevant legislation on contained use of GMOs is the following:

DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 on the contained use of genetically modified micro-organisms Article 4 (3) specify the four containment levels Annex III. : the procedure of the final classification of the contained use. This part of the Directive was implemented by Hungary as national regulation (Regulation 132/2004. (IV. 29.)). It contains the classes as follows:

* Class 1: activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health and the environment.
* Class 2: activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health and the environment
* Class 3: activities of moderate risk, that is to say activities for  which level 3 containment is appropriate to protect  human health and the environment.
* Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human  health and the environment

Due to the recommendations by the Committee, the National Gene Technology Authority uses the following practical criteria of GMOs in contained use:

* Class 1: is unlikely to cause disease to humans, animals or plants, and/or not able to survive in the environment
* Class 2: likely to cause disease to animals or plants, and/or able to survive and reproduce in the environment
* Class 3: likely to cause disease to humans, and/or able to survive and reproduce in the environment
* Class 4: likely to cause disease to humans, animals or plants and/or able to survive and reproduce in the environment and can cause contagious disease

Best regards,

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GMO and Biodiversity Expert



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