**Ref.: SCBD/BS/CG/MPM/DA/85327 (notification 2016-009) issued on 14 January 2016**

**Submission of information requested in decision on Contained Use (Article 6)**

**In decision BS-VII/4, the COP-MOP invited Parties and other Governments to submit to the Executive Secretary information, tools, practical experience and guidance related to their existing mechanisms and requirements regarding the contained use of living modified organisms, including any specific requirement relating to the type and level of containment.**

The legislative framework in Slovakia has been harmonised with the EU legislation. The basic national legal instrument concerning the use of genetically modified organisms (hereinafter GMOs) is the Act No. 151/2002 Coll. on the use of genetic technologies and genetically modified organisms, as amended, with its implementing Decree No. 399/2005 Coll. The Act and its implementing Decree transpose the Directive 2009/41/EU on the contained use of genetically modified micro-organisms (hereinafter GMMs).

All these laws are available in the Biosafety Clearing-House (record ID 47485, 47486 and 101047).

Contained use shall mean any activity by means of which organisms and microorganisms are genetically changed or when GMOs and GMMs are grown, kept, replaced, disposed of, destroyed or used in another manner and upon application of protective measures.

Laboratories, greenhouses, growing premises and other enclosed facilities equipped with safety appliance preventing release of GMOs and GMMs in research, development or production facilities of the user are considered containment.

Specific requirements relating to the type and level of containment are set in the Decree.

Prior to new contained use, the user is obliged to

1. assess the risks resulting from the planned contained use, especially to identify potential harmful effects to humans and the environment,

2. classify the prepared used of genetic technology into a risk class on the basis of risk assessment results,

a) risk class 1 – activities of no or only negligible risk, where protection level 1 is suitable,

b) risk class 2 – activities of low risk, where protection level 2 is suitable,

c) risk class 3 – activities of moderate limited risk, where protection level 3 is suitable,

d) risk class 4 – activities of high risk, where protection level 4 is suitable.

3. ensure protection level corresponding to the risk class, as well as requirements for the enclosed facilities and the consequent individual protective measures,

4. take measures in order to prevent possible harmful effects to humans and the environment that might result from it,

5. elaborate emergency plan and to publish the listed measures for human and environmental protection by Internet, or by additional appropriate means,

6. make available substantial information on the emergency plan content to the bodies that could be impacted by the accident, and when the activities are classified as class 3 or 4 also to the local authority and municipality,

7. announce the planned contained use or to apply for permit for contained use.

The Competent Authority handling the notifications and applications on the contained use of GMO/GMM is the Ministry of the Environment of the Slovak Republic with its advisory body - the Biosafety Committee and its Panel of Experts. The Committee produces recommendations for the ministry on the basis of its members' specific areas of expertise.

Slightly different procedures are applied to announcement/notification and to application for permit, which is a more formal one. It depends mainly on the level of risk.

To date, all contained uses so far have concerned activities classified as risk class 1 and 2, there are no cases of class 3 nor 4 in Slovakia.

In Slovakia, the most commonly used organisms in contained use are viruses, bacteria, yeasts, drosophila, fly, laboratory mouse, laboratory rat, rabbit, pig (feeding studies), blueberries, raspberries, rapeseed, poplar, flax, tobacco, maize, hypericum, broomrape, pine and fir.

In line with our national law, the transit and domestic transport of GMO/GMM is not a genetic technology, it is merely a transfer of GMO/GMM unchanged from one place to another that means it does not fall under the scope of contained use and no consent is required from the ministry. The transit and transport of GMO/GMM shall be carried out under the rules applicable to the transport of dangerous goods. For the purposes of all modes of transport the GMOs/GMMs are considered as a threat and therefore their classification into risk class is not relevant.

Obligations for carriers and shippers are set down in international treaties - European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) and the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID), appearing as Appendix to the Convention concerning International Carriage by Rail (COTIF). The European Directive 2008/68/EC on the inland transport of dangerous goods extends the application of international rules to domestic transport by road, rail or inland waterway.

According to the European Economic Area agreement, the terms "transit", "export" and "import" mean crossing the customs border of the European Economic Area which is formed by the Member States of the European Union, Iceland, Norway and Liechtenstein. Crossing the border within the European Economic Area does not constitute a transboundary movement.