Executive Secretary

Convention on Biological Diversity

*Regarding:* **SUBMISSION OF INFORMATION REQUESTED IN DECISION ON CONTAINED USE (ARTICLE 6) - RESPONSE TO CBD NOTIFICATION 2016 – 009**

**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 (LMOs, hereafter referred to as genetically modified organisms, GMOs), including any specific requirement relating to the type and level of containment.

The Board for Gene Technology, which is the national competent authority of Finland for the Biosafety Clearing House, provides the following information on contained use of genetically modified organisms (GMO) as a response to CBD Notification 2016 – 009:

**Finnish national authorities for the contained use of GMOs**

The Board for Gene Technology is responsible for the authorization of the contained use of GMOs Finland in Finland. It is also functioning as a national Competent Authority for the EU directive 2009/41/EC on the contained use of genetically modified micro-organisms. The supervision and inspection of contained use of GMOs is performed by another authority: the National Supervisory Authority for Welfare and Health (Valvira). Both authorities have their own internet sites (<http://geenitekniikanlautakunta.fi> and <http://valvira.fi>, respectively) which contain information on the legislation, authorizing procedures, supervision and guidance on various GMO-related topics.

**European Union and national legislation on the contained use of GMOs**

The requirements in the Directive 2009/41/EG of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms are minimum requirements that are to be implemented through the legislation of the EU Member States. Hence, the Member States may have stricter regulations than those specified in the directive. This is the situation in Finland, where in addition to the GM micro-organisms (GMMs), provisions of the use of genetically modified (GM) plants and animals are included in the national Gene Technology Act (377/1995) and various Decrees.

The legal provisions for enabling the supervisory authorities to inspect and control contained use of GMOs are included in the Gene Technology Act. There are also additional provisions for the supervision in the Decree of the Ministry of Social Affairs and Health on Inspection Procedures under the Gene Technology Act (198/2007).

Any animal welfare or test animal regulations apply for GM animals in contained use. The same situation applies for the occupational safety regulations, eg. on the protection of workers of the hazards caused by exposure to biological agents at work.

The Board for Gene Technology is required to report its experiences with implementing Directive 2009/41/EC every third year to the European Commission, which compiles the Member State reports.

**Classification of GMOs in contained use**

Directive 2009/41/EC specifies in its Article 4.3 the risk classes for contained use of GMMs as well as required level of protection. This Directive does not apply to the contained use of GM animals and plants, but its classification system is applied in Finland also for such GM plant and animal cell cultures that can be considered as GM micro-organisms. The classification is as follows:

* **Class 1** covers activities with no risk or negligible risk. A notification on class 1 GMO use must be made before the activity may start. The notification includes the premises where the activity takes place. Unless changes later take place, class 1 activity may be carried out without further notification to authorities until the user notifies that the activity has been terminated.
* **Class 2** covers activities of low risk. Class 2 activity may only be started 45 days after making a notification, unless isolation level 2 premises to be used have been notified before. A new notification is required for taking into use new class 2 organisms, unless certain conditions are met. Otherwise class 2 activity may be carried out without further notification until the user notifies that the activity has been terminated.
* **Class 3** covers activities of moderate risk. Class 3 activity cannot be initiated until the Board for Gene Technology has made a positive decision on the application. Any new use of GMMs may not start either until permission is received.
* **Class 4** covers activities of high risk. The application procedures are the same as for class 3.

The classification and notification/application procedures of GM-plants are similar to those for GMMs (four risk classes), whereas the GM-animals are classified to two risk classes only. The notification procedures for GM-animal in the lower risk Class 1 are similar to those for Class 1 GMMs. For Class 2 GM-animal use, the same procedures apply as for Class 3 or 4 GMM use.

Should there be indications of risk to human or animal health or environment, the Board can restrict or prohibit the notifier from continuing their GMO activities regardless of the risk class.

**Gene technology register:**

The notifications and applications of contained use of GMOs as well as any Board decisions or supervision documents on them are collected in a national register which is used by the authorities. There are currently approximately 380 contained use operators having valid notifications/applications listed in the gene technology register. The vast majority of these are university research groups doing basic research, with very few biotechnology companies. 80-90 % of the GMO work is made with GMMs, and a majority of that work is medical research by nature. Annually the Board handles 30-40 new notifications/applications; minor changes and updates for the notifications/applications are not included in this number. The number of different recipient organisms in contained use is more than 250, most of them micro-organisms.

**Experiences with contained use of genetically modified organisms**

*GM micro-organisms (GMMs):*

The licensing process of the contained use of GM plants depends on the risk class as assigned in the risk assessment which the operator must perform *a priori*. In addition to the EU directive 2009/41 /EC, various EU regulations, EFSA guidelines and national regulations on contained use, there is ample international material for both risk assessment and risk management procedures of GMMs in contained use. The most challenging issue is often assignment of the appropriate risk class, as the classification may differ from the initial risk classification of the host organism due to the genetic modification and/or earlier attenuation of the host strain.

*GM plants:*

As for GMMs, the licensing process of the contained use of GM plants depends on the risk class as assigned in therisk assessment which the operator must perform *a priori*. The Board provides guidelines for the risk assessment on its internet page, including recommendations for the use or certain plant species or waste management procedures for GM plants. As the final risk class is determined by a combination of different factors (e.g. of the GM plant species, the modified trait, premises to be used, nature of the work, relevant environment, and seasonal variation), the isolation procedures and other requirements for the contained use must often be tailored case-by-case. There have not been any cases of unintended release of GM-plants or their reproductive organs into the environment from contained use.

*GM animals:*

As for GMMs or GM plants, the licensing process of the contained use of GM animals depends on the risk class as assigned in the risk assessment which the operator must perform a priori. The requirements for the risk assessment are stated in the *Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified animals, on classification of the contained use, and on containment and other protective measures (771/2014)*. Further guidance on GM-animals is being planned, however, providing general rules for the classification of GM-animals or giving detailed recommendations on the isolation measures has proven challenging due to the hugely variable nature of animal kingdom. Test animal regulations cover also GM-animals, although with a more narrow scope, as GM regulations cover all invertebrates. Almost all GM-animal work in Finland is made with few well-known model organisms, such as mice, zebra fish, *Caenorhabditis* and *Drosophila*. There have not been any cases of unintended release of GM animals or their reproductive tissues into the environment from contained use.

Secretary General Kirsi Törmäkangas