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**CBD Notification 2017-087, relating to Decision BS-VIII/17 on Contained Use (Article 6)**

**Reference SCBS/SPS/DC/MM/DA/86806**

**Contribution from Spain on practical guidance on specific measures for contained use of living modified organisms**

In Spain, European rules on GMOs has been transposed into the national legislation. Depending on the type and level of containment, the specific requirements are regulated by Law 9/2003 of 25 April, which establishes the legal regime of the confined use, voluntary release and commercialization of genetically modified organisms. It is also developed by Royal Decree 178/2004, of 30 January, approving the General Regulations for the Development and Implementation of the Law. Article 3 of the Law establishes the competences of the General Country Administration and Article 4 establishes the competences of the Autonomous Communities.

The second additional provision of the Law contemplates the responsible collegiate bodies at the national level, in the exercise of regulated activities:

- **Interministerial Council of Genetically Modified Organisms (CIOMG)**. CIOMG is the competent Authority to provide authorizations for GMOs notifications, when its object is the possible incorporation to medicines for human and veterinary use, when funding is obtained from the State Plan for Scientific and Technical Research and Innovation, and in those cases in which notifications are related to National Registers of Varieties. In all other cases, the Autonomous Communities will grant the authorizations. They shall inform the CIOMG and the CNB must conduct the risk assessment.

Also, there is a Committee of Participation in which stakeholders, professional agricultural organizations, agribusiness cooperatives, consumer organizations and users and conservation organizations are represented. This Committee is attached to the CIOMG to whom provides advice and support, ensuring public participation and information.

- **National Biosafety Committee (CNB).** The CNB is a collegiate consultative body whose role is to report to both the General State Administration and the Autonomous Communities on applications for authorization contained use, deliberate release and marketing of GMOs presented to, and to carry out risks assessments.

Our legislation has a broader scope of application. Spanish legislation on contained use is not only limited to microorganisms. Activities with GM plants or mice are also regulated in the Spanish legislation.

At national level, all the information about practical guidance on specific measures for contained use of living modified organisms, is published on the website of the Ministry of Agriculture and Fisheries, Food and Environment. Also, the national register of activities with GMO is published on the Ministry website. This register includes updated information on approved facilities and specific information about activities providing an overview of the facilities and activities with living modified organism under contained use in Spain. There is registered in the following link:

<http://www.mapama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/notificaciones-y-autorizaciones/uso_confinado.aspx>

In order to facilitate the work of notifiers, the CNB has published a practical Guidance to unify access to documentation, and facilitate the procedure of submitting applications for registration of facilities to carry out the contained use activities on genetically modified organisms. It is based on practical experience and tips on the contained use of living modified organisms:

[http://www.mapama.gob.es/es/calidad-y-evaluacion ambiental/temas/biotecnologia/guiadeutilizacionconfinadaversion9\_tcm7-472421.pdf](http://www.mapama.gob.es/es/calidad-y-evaluacion%20ambiental/temas/biotecnologia/guiadeutilizacionconfinadaversion9_tcm7-472421.pdf)

In addition, there is a section with all the information concerning risk assessment bodies and decision making authorities, as well as applications and communications that has been presented. The containment measures will depend on the classification of the activity according to the preliminary risk assessment to human health and environment provided by the CNB. This classification is described in Article 11 of Royal Decree 178/2004 of 30 January. The actions regarding activities with GMOs are based on the precautionary principle and on "step by step" and "case by case" evaluation. Furthermore, scientific opinions issued by the European Food Safety Authority are always considered.

According to European standards, some requests for contained use must first be submitted to public information for a period of 30 days. This information is also available on the national website:

<http://www.mapama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/participacion-publica/uso-confinado/default.aspx>

Finally, we have implemented the electronic way to submit applications via telematics when the competence in matters of authorization lies with the General State Administration:

<https://sede.mapama.gob.es/portal/site/se/ficha-procedimiento?procedure_id=10&procedure_suborg_responsable=79&by=theme>