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|  | CBD Secretariat |
|  | Biosafety Clearing House Mechanism |
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**Submission of information requested in decision on Contained Use (Article 6) Response to CBD Notification 2016 – 009**

*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.*

## Competent authorities for the contained use of living modified organisms

The Swedish Work Environment Authority and the Swedish Board of Agriculture have has provided the following information on contained use of genetically modified micro-organisms (GMM) and genetically modified organisms (GMO) for this response to CBD Notification 2016 – 009.

Three Swedish authorities have responsibility for authorization, supervision, and inspection of contained use of genetically modified organisms;

* The Swedish Work Environment Authority has the responsibility for authorization, supervision and inspection of contained use of genetically modified micro-organisms (GMM) according to the Swedish Environmental Inspection Regulation[[1]](#footnote-1). All use of genetically modified micro-organisms is by law required to be reported to the Swedish Work Environment Authority[[2]](#footnote-2),
* The Swedish Board of Agriculture is responsible for authorization, inspection and control of contained use of genetically modified macro-organisms, plants and animals, with the exception of water-living organisms and cell cultures[[3]](#footnote-3),
* The Swedish Agency for Marine and Water Management is the competent authority for genetically modified water-living organisms[[4]](#footnote-4) and their contained use.

Detailed information on the areas of responsibilities regarding genetically modified organisms is given on the Internet site common to all government authorities with responsibility for genetically modified organisms [www.gmo.nu](http://www.gmo.nu). These three competent authorities have issued legal provisions for the contained use of genetically modified organisms (see Table 1).

Table 1. Competent Authorities for contained use of living modified organisms

|  |  |  |
| --- | --- | --- |
| **National Agency** | **Area of responsibility for contained use of:**  | **Provisions on contained use** |
| Swedish Work Environment Authority | genetically modified micro-organisms | AFS 2011:2 |
| Swedish Board of Agriculture | genetically modified macro-organisms, plants and animals, with the exception of water-living organisms and cell cultures | SJVFS 2007:29[[5]](#footnote-5), SJVFS 1995:33[[6]](#footnote-6) |
| Swedish Agency for Marine and Water Management | genetically modified water-living organisms | HVMFS 2011:5 |

## European Union and National legislation on contained use of genetically modified organisms

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 its member states. Member states may have stricter regulations than those specified in the directive.

The provisions in Directive 2009/41/EG have been included in the Swedish Environmental Code (1998:808) Chapter 13, paragraph 5, the Swedish Ordinance (SFS 2000:271) on the contained use of genetically modifiedorganisms and the Swedish Work Environment Provisions (AFS 2011:2) on the contained use of genetically modified microorganisms. The legal provisions for enabling the competent authorities to inspect and control activities using genetically modified organisms in contained use are in the Environmental Inspection Ordinance (2011:13). Animal welfare regulations for animal testing also apply for genetically modified animals in contained use.

The Swedish Work Environment Authority is required to report its experiences with implementing Directive 2009/41/EG every third year to the European Commission. The latest report was in 2014. The European Commission then compiles all of the member state reports. The Swedish Work Authority is also required to annually report on the permits granted for contained use of GMM in risk classes 3 and 4, to the European Commission.

The European Directive 2000/54/*EC on the protection of workers from risks related to exposure to biological agents at work* is also applicable to work places with contained use of GMM, especially when the GMMs are human pathogens. Directive 2000/54/EC also contains obligations to notify the use of biological agents (human pathogens), whether or not they are genetically modified, and certain safety measures must be taken at different levels, as well as the safety measures specified in the Contained Use Directive 2009/41/EC.

### Risk classes for contained use of genetically modified micro-organisms

According to Directive 2009/41/EG Article 4.3, the risk classes for contained use of genetically modified micro-organisms are defined and requirements pertaining to the level of protection are given. This risk classification does not apply to contained use of genetically modified animals and plants that are not genetically modified micro-organisms. The classes are;

* Class 1 covers activities with no risk or negligible risk. According to Swedish regulations, this class is the same as Class F and includes the premises where the activity takes place. The use of GMMs in this class must be notified before the activity may start. The necessary information that must be notified is found in the Swedish Work Environment Authority (SWEA) Provision AFS 2011:2 Annex 3. Activity in this class may be carried out without further notification to authorities, until the user notifies that the activity is ended, but the authorities can decide that activities in this class may no longer be continued.
* Class 2 covers activities of low risk. In Swedish regulations this class is the same as Class L and includes the premises where the activity takes place. The user must notify the authorities of their use of GMM before the activity can start. The necessary information that must be notified is found in the SWEA Provision AFS 2011:2 Annex 4. New use of GMMs must also be reported to the authorities. Activity in this class may be carried out without further notification to authorities, until the user notifies that the activity is ended, but the authorities can decide that activities in this class may no longer be continued.
* Class 3 covers activities of moderate risk. Class 3 and Class 4 are the same as Class R according to Swedish regulations and include the premises where the activity takes pace. The user is not permitted to begin their activities with GMM until permission is received from the Swedish Work Environment Authority. The necessary information that must be notified is found in the Swedish Provision AFS 2011:2 Annex 5. New use of GMMs may not start until permission is received. A permit is valid for a maximum of five years.

Permits that are granted for activities in risk group 3 and 4 (according to Biological Agents directive 2000/54/EC) are to be reported to the European Commission annually according to Directive 2009/41/EG, Article 17.1.

* Class 4 covers activities of high risk. This class is also considered a Class according to Swedish regulations and the same regulations as stated for Class 3 apply also for Class 4.

There are approximately 650 enterprises with contained use of GMM listed in the Swedish Work Environment Authority’s register. The number of active GMM activities varies considerably, but is clearly greater at universities than biotechnology companies. Nearly all contained use of GMM is for research. Annually the Swedish Work Environment Authority handles about 120 administrative cases for new activities, new useage and updates.

### Experiences with contained use of genetically modified organisms that are not micro-organisms in Sweden

Genetically modified animals in contained use can be animals used for experimental purposes. In addition to requirements for contained use, there may be other requirements to be met before use can be allowed, such as animal welfare regulations. Animal testing must be approved by an animal testing ethical board before the test may be started. These requirements are not described in this document.

### Guidance on the contained use of genetically modified micro-organisms

The European Food and Safety Agency has published guidance on the risk assessment of genetically modified micro-organisms and their derived products intended for food and feed[[7]](#footnote-7). It provides guidance for the risk assessment of GMM as well as guidance to assist in the preparation of applications to market GMMs and their products for food and feed. Information on risks with genetically modified micro-organisms is also given in this guidance.

**Table 2. Number of GMM activities and employers in June 2012. Reports for the period 2013 -2015 are not available**

|  |  |  |  |
| --- | --- | --- | --- |
| **GMM Activity** | **F-activity Class 1** | **L- activity Class 2**  | **R-activity Class 3 & 4** |
| Total number of activities | 364 | 183 | 19 |
| Government sector | 250 | 152 | 9 |
| Cities and County Council Boards | 15 | 2 | 0 |
| Private Sector | 99 | 29 | 0 |
|  |  |  |  |
| **Laboratory activity** | 320 | 135 | 14 |
| GMM in animal testing activities | 14 | 43 | 4 |
| GMM in plant activities  | 6 | 4 | 0 |
| Large scale activities | 18 | 0 | 0  |
| Other activities | 6 | 1 | 1 |
|  |  |  |  |
| **Employers (Users)** | Number |  |  |
| Total number employers | 102 |  |  |
| Government sector | 24 |  |  |
| City and County Council Boards  | 13 |  |  |
| Private Sector | 68 |  |  |

The Swedish Work Authority provides guidance on the web page “Gene technique”[[8]](#footnote-8) (only in Swedish) for people and enterprises involved in contained use of genetically modified organisms. This web page provides information on the requirements for contained use of genetically modified micro-organisms and how to notify and apply for permission for use and updating GMM activities and enterprises. Information is provided to help the user in writing a notification or an application for contained use, and to inform about the process of considera-tion of the application and assessment of the type of GMM use. This web page also contains information on the risks that may be involved in the use and handling of GMM’s and the necessary measures and requirements for providing a safe working environment, as well as other useful information on *i.e*. inspection procedures. Guidance is also given for applying legal provisions and recommendations for contained use of genetically modified micro-organisms (in English and Swedish). [[9]](#footnote-9)

The Swedish Board of Agriculture does not have specific guidance for contained use of plants and animals. The assessment process for granting permission for contained use of plants is influenced by a combination of factors; the locale, planned protective measures, routines and the plant species involved and its characteristics, such as if it flowers. Because all of these aspects interact and affect the level of risk, the assessment is to a high degree specific for each case. It is therefore difficult to write and use standards or guidance. For this reason, a guidance written by a working group within the Cartegena Protocol would not be helpful.

For assessment of applications for permission for contained use of genetically modified animals, the goal should be that no animal can come outside of containment and the premises. The assessment is more focused on the requirements of the technical form of the premises. There are however, ideas about developing guidance for risk assessment of the animals.

For the Swedish Environmental Protection Agency,

Focal Point of the BCH

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1. https://www.av.se/globalassets/filer/publikationer/foreskrifter/engelska/contained-use-of-genetically-modified-micro-organisms-provisions-afs2011-2.pdf [↑](#footnote-ref-1)
2. https://www.av.se/halsa-och-sakerhet/sjukdomar-smitta-och-mikrobiologiska-risker/innesluten-anvandning-av-gmm/?hl=genteknik [↑](#footnote-ref-2)
3. http://www.jordbruksverket.se/amnesomraden/odling/genteknikgmo/inneslutenanvandning.4.4eea2b6311f3b931ba48000131.html [↑](#footnote-ref-3)
4. http://www.gmo.nu/gmoenglish.4.778a5d1001f29869a7fff935.html [↑](#footnote-ref-4)
5. Board of Agricultures Provisions (SJVFS 2007:29) on contained use of genetically modified plants [↑](#footnote-ref-5)
6. Provisions on changes in the Swedish Board of Agriculture’s provisions (SJVFS 1995:33) on the use of genetically modified animals. [↑](#footnote-ref-6)
7. EFSA, 2006**.** Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified micro-organisms and their derived products intended for food and feed use. Adopted on 17 May 2006. The EFSA Journal (2006) 374, 1-115. <http://www.efsa.europa.eu/en/scdocs/doc/374.pdf> [↑](#footnote-ref-7)
8. https://www.av.se/halsa-och-sakerhet/sjukdomar-smitta-och-mikrobiologiska-risker/innesluten-anvandning-av-gmm/ [↑](#footnote-ref-8)
9. https://www.av.se/globalassets/filer/publikationer/foreskrifter/engelska/contained-use-of-genetically-modified-micro-organisms-provisions-afs2011-2.pdf [↑](#footnote-ref-9)