**CBD Notification 2016-009 (14 January 2016)**

**Submission of information, tools, practical experience and guidance related to existing mechanisms and requirements regarding the contained use of living modified organisms, including any specific requirement relating to the type and level of containment.**

**Contribution from Belgium**

Introduction

Belgium is a federal state, composed of communities and regions. To avoid disparities between the different entities sharing competencies in the field of biosafety a harmonised implementation of the regulatory framework on biosafety has been necessary. As a result, decisions by different administrative bodies representing different institutional levels are based on a single science-based biosafety advisory system. The legal basis for this centralised biosafety advisory system is the “*Cooperation Agreement of 25 April 1997 between the Federal State and the Regions on the administrative and scientific coordination concerning biosafety*”. According to the Cooperation Agreement, biosafety-related expertise is carried on in Belgium by two complementary bodies: the Biosafety Advisory Council and the Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health.

Belgium has maintained in its biosafety legislation the distinction introduced at EU level between the use of GMOs in a contained environment on the one hand and, on the other hand, their deliberate release into the environment.

In Belgium, contained use is defined as *any activity in which organisms are genetically modified or in which genetically modified and/or pathogenic organisms are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment*. Contained use refers therefore to activities involving genetically modified and/or pathogenic micro-organisms, as well as genetically modified plants or animals, in a "closed environment" such as laboratories, animal units, greenhouses and production units. They mainly include diagnostics, R&D and large-scale activities. Manipulating and administering GMOs in clinical trials is also considered "contained use".

Regulatory and procedural requirements

Contained use activities are regulated at regional level as a part of the environmental laws for classified installations. The contained use regional legislations are based on the implementation of the European Directive 2009/41/EC (see <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2009.125.01.0075.01.ENG&toc=OJ:L:2009:125:TOC>). However the scope of the Belgian regional legislation is broader than the scope of the EU Directive since it includes, in addition to genetically modified microorganisms (GMMs), genetically modified organisms (GMOs) and pathogenic organisms. Since contained use also includes activities involving pathogens, a close relationship with the federal regulation on workers protection exists.

Any contained use activity is subject to a preliminary written authorisation from the relevant regional competent authority on the basis of a specific notification and decision procedure. During the procedure, the risk assessment made by the notifier is submitted for advice to the Biosafety and Biotechnology Unit (SBB), who acts as technical expert for the Regions.

The whole information that has to be given to notify a contained use activity represents the biosafety dossier. In order to facilitate the information and notification procedures and to limit at the minimum the administrative constraints for the notifiers, the SBB has, in collaboration with the regional authorities, developed notification forms and a user guide, on the basis of the requirements of the regional decrees but also of the experience gained of implementing the regulation.

The main element of a biosafety dossier is the technical dossier. It provides a detailed description of the contained used activities (including confidential information), the infrastructure, the containment measures, the laboratory practices and any other information allowing the SBB to assess whether the installations and containment measures comply with the intended contained use. In two of the three Regions a public dossier should also be provided. It is a non-confidential summary of the technical dossier that can be submitted to public hearing.

The procedural requirements vary according to the risk class of the contained use (from 1 to 4) and whether premises are to be used for the first time for contained uses. Some slight differences also exist between the three Regions. More information is available on the “Belgian Biosafety Server”:

* Brussels Region: <http://www.biosafety.be/CU/EN/ProceduresRBEN.html>
* Wallonia: <http://www.biosafety.be/CU/EN/ProceduresRWEN.html>
* Flemish Region: <http://www.biosafety.be/CU/EN/ProceduresVGEN.html>

Risk assessment and containment levels

The risk assessment of contained use activities involving pathogens and/or GMOs is carried out according to the general methodology and principles adopted at international level. It is performed on a case-by-case basis (meaning that it depends on the GMO or pathogen concerned, the introduced genes, and the intended use), based on established science (known scientific facts, results published in recognised scientific journals). It is conducted in six steps, in an integrated process and in an iterative manner, as follows:

1. Identification of any characteristics of the GMO or pathogen which may cause adverse effects (hazards) to human health or the environment, of the nature of these effects, and of pathways of exposure through which the GMO or pathogen may adversely affect the human health or the environment.;
2. Hazard characterisation, i.e. the evaluation of the potential consequences of each adverse effect;
3. Exposure characterisation, i.e. the evaluation of the likelihood of the occurrence of each identified potential adverse effect;
4. Risk characterisation, which is an estimation of the risk posed by each identified characteristic of the GMO or pathogen which has the potential to cause adverse effects;
5. Application of management strategies to reduce potential identified risks associated with the GMO or pathogen to a level of no concern, and to address the uncertainties;
6. Determination of the overall risk of the GMO or pathogen, taking into account the results of the risk assessment and associated levels of uncertainty and the risk management strategies proposed.

In the case of a contained use activity, the procedure ends with the identification of the risk level associated with the GMO or pathogen used. On this basis, containment and other protection measures (working practices, safety equipment, management of biological waste) to be adopted are determined. The analysis carried out leads to the classification of the contained use into one of the four existing risk classes (level of risk increasing from 1 to 4). The final stage consists of definitively classifying the contained use activity, which will be confirmed by a re-assessment of the whole procedure.

The contained use classes are defined 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.

The technical requirements and other protective measures necessary for each level of containment (for laboratories, animal units, greenhouses and large-scale production units) are specified in the regional decrees. An annotated version (providing extra information) is also available on the Belgian Biosafety Server (<http://www.biosafety.be/CU/EN/Tools_RA_RM.html>, in French and in Dutch).

Practical experience and tools for risk assessment and risk management

The implementation at regional level of the regulatory framework relating to the contained use of GMOs and/or pathogens has unquestionably heightened awareness of the biosafety aspects at user level. Even though safety measures were already adopted most of the time in the concerned facilities, the implementation of regional legislation helped to formalise and standardise the risk assessment of activities and the application of containment measures and work practices adapted to the identified biological risk. This was already common practice in the industrial sector but was an innovation for many universities and public bodies. The implementation of biosafety measures in laboratories has also been greatly facilitated by the appointment of a biosafety officer, the setting up of local biosafety committees, staff training and monitoring, the drafting of manuals so that biological material can be used in complete safety, the reorganisation, where appropriate, of the infrastructure and the creation of large databanks of biological material, etc.

In particular the appointment of a biosafety officer and the setting up of a biosafety committee became compulsory at the end of the 1990’s. Belgium was one of the first Member States that included this obligation in its legislation, drawing its inspiration from the UK where the tasks and duties of the "biosafety officer" had already been defined by the Health and Safety Executive (HSE).

The SBB plays a central role in the scientific expertise related to the application of the regional decrees on contained use of GMOs and/or pathogens. Between 1994 – the first year that legislation was applied – and the end of 2015, no fewer than 4,550 motivated advices on activities relating to 1,935 biosafety dossiers were issued in total by the SBB to the regional authorities. Almost half of these activities involved GMOs, the other involving non-GM pathogens only.

The SBB provides on its website (<http://www.biosafety.be/CU/EN/Tools_RA_RM.html>, mostly in French and in Dutch) several tools (guidelines, recommendations, technical notes, Web links) to help people involved in contained use activities to assess the health and environmental risks of their activities and implement the appropriate risk management measures.

With regards to the contained use of GMOs, these tools relate to the following topics:

* Criteria for certification and exemption of GMOs from the contained use legislation
* Criteria for the classification of GMM into class of risk 1
* Criteria for the classification of genetically modified animals into class of risk 1
* Criteria for the classification of genetically modified plants into class of risk 1
* Practical examples of risk assessement and biosafety recommendations for the contained use of genetically modified (micro-)organisms
* Containment criteria and other protective measures
* Biological Safety Cabinets
* Negative air pressure in L3 laboratories
* Biological waste treatment and inactivation methods
* Respiratory protection
* Validation and control of autoclaves within the framework of the waste inactivation resulting from contained uses of genetically modified and/or pathogenic organisms
* Biosafety in laboratory animal facilities: A practical approach
* Effluent decontamination systems: Design, operation and safety

Additional reference

*The Scientific Institute of Public Health, Belgian focal point for Biosafety. 1990-2010: 20 years of risk assessment of GMOs and pathogens*

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Available in English, French and Dutch (see http://www.biosafety.be/Book/BookSBB\_EN.html)