

BBP Position Paper

Emergency planning for contained use of genetically modified micro-organisms

In December 2005 a circular letter by Minister Dewael of Internal Affairs was published addressing new requirements and procedures for establishing emergency plans and accident reporting for contained use activities with genetically modified micro-organisms.

In order to keep the new requirements focused on activities that could pose a significant risk and to avoid confusion in cases of emergency, BPP proposes the following clarifications:

- **Small scale activities up to risk class 2 do not require a specific emergency planning or procedure**
- **The general internal emergency plan should be the starting point for the authorities to set up their emergency plans for special assistance.**
- **Notification of the internal emergency plan to SBB and the relevant municipal and provincial authorities instead of complex administrative procedures**
- **Avoiding conflicting indications on emergency reporting between different legal requirements.**

1. Background

1.1. Circular letter on emergency planning

The circular letter¹ on emergency planning by Minister Dewael of Internal Affairs implements article 14 of EU-directive 98/81/EC concerning the contained use of genetically modified micro-organisms. This article prescribes that:

- a) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment, except where such an emergency plan has been drawn up under other Community legislation;
- b) information on such emergency plans, including the relevant safety measures to be applied, is supplied in an appropriate manner, and without their having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

In line with the indications of the circular letter any user needs to submit a specific form to the SBB to confirm the need for and validity of the emergency plans. The information required in this form is largely overlapping with the information already provided in existing contained use notifications. There is a concern with regard to the requirement to provide adequate information and the possible confidentiality of this information.

Although decided on a case-by-case basis, all class 4, class 3 and large scale class 2 activities will lead to special emergency plans to be established at the municipal and provincial level. It is not excluded that also for certain small scale class 2 activities a special emergency plan will be required.

1.2 GMO emergency planning in regional legislation

In the actual regional implementation of the EU Directive 98/81 there are already provisions on emergency planning and response. The legislation in the Brussels Capital Region describes that before the start of a class 2, 3 or 4 activity the authority consults with the minister responsible for civil protection in order to establish the emergency plan. In the other two regions there are fewer requirements, but in all cases it is required to include in the notification information allowing the competent authority to evaluate any emergency response plans if required.

1.3. Other legislation concerning emergency planning

The circular letter specifically addresses emergency planning for contained use of GMMOs. BBP realizes that there are general requirements for emergency planning resulting from different other legislations as well, such as the CODEX, COMAH (Control of Major Accident Hazards), and legislations specific for hospitals and nursing homes, etc. There may therefore be more reasons to develop an emergency plan than only following from the EU Directive 98/81 and the circular letter, and all organizations should follow these other regulations as appropriate.

¹ MB/BS 21.12.2005, p. 54623 – 54626

2. BBP Position

2.1. General

BBP clearly subscribes to the need for emergency planning for activities where failure of the containment measures could lead to serious danger to humans outside the premises and/or the environment outside the premises of the establishment, as set out in article 14 of the EU-directive 98/81/EC.

2.2. Need for emergency planning

BBP is of the opinion that there is a need for emergency planning for risk class 3 and 4 and large scale class 2 activities. BBP sees no need for emergency planning for small scale class 2 activities. BBP is of the opinion that such a clear division is in line with the international consensus in this area. It also makes time consuming case-by-case assessments for small scale class 2 activities redundant.

2.3. Difference between emergencies and smaller incidents

A clear distinction should be made between emergencies and minor incidents. Emergencies may lead to serious danger to human health and/or the environment outside the premises. Smaller incidents may occur when failure of the containment measures for instance results in a spill of GMMOs but have no consequences for the outside environment. Such small incidents should be dealt with following internal procedures such as for the decontamination of accidental spills, or accidental prick- or cutting accidents. These internal procedures may be part of biosafety manuals or other written instructions, but are not part of emergency planning.

2.4. Internal emergency planning

Article 14 (a) and (b) of EU-Directive 98/81/EC clearly relate to internal emergency planning and the communication of these plans to the relevant authorities. It is therefore the internal emergency planning that should be the starting point of any GMMO specific alterations to municipal and provincial emergency planning. As already stated, establishments performing risk class 3 and 4 and large scale class 2 activities with GMMOs should set up such an internal emergency plan.

2.5. Administrative procedure

BBP sees no need for additional administrative forms or procedures for the establishment of GMMO specific emergency plans. BBP is of the opinion that establishments could send in their internal emergency plans to SBB and the municipal and provincial authorities and make reference to the notification files in which the contained use activities with GMMOs have been described in detail. SBB can then forward its opinion on the adequacy of the internal emergency plan back to the notifier and the relevant municipal and provincial authorities. On the basis of the internal emergency plan the municipal and provincial authorities can then adjust, if necessary, their emergency plans for special assistance, in consultation with the establishment concerned. In this way specific forms are redundant.

2.6. Avoiding conflicting indications on emergency reporting

The circular letter describes who should be contacted in case of an emergency. Yet, the regional Decrees implementing the EU Directive 98/81/EC also provide indications on who should be contacted and what information should be provided. BBP's analysis concludes that these indications are not in line, which leaves the user at the critical moment of an emergency in confusion.

In order to avoid this confusion, the different authorities are called upon to clarify the unique way for reporting in case of emergency.

Belgian Biosafety Professionals (BBP) is a professional association representing the interests of practitioners of biological safety in Belgium and providing a forum for the continued and timely exchange of biosafety information.

<http://www.ebsa.be/regional/bbp>