Revision of the EU biological agents directive 2000/54/EC
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Considerations by EBSA

1. Risk assessment

One of the main provisions of the current directive is the requirement to perform a risk assessment and take appropriate safety measures where necessary. EBSA is of the opinion that this is the core provision of the directive and should be upheld.

2. Community classification of biological agents

The current directive contains in annex III a list that specifies the community classification of biological agents. This list is currently not kept up-to-date. In practice many EU member states are working with their own classification lists and do not use annex III. In some countries different authorities have their own classification lists. There are sometimes small but relevant differences in the classification of biological agents on these lists. EBSA is favor of harmonized lists that take scientific progress into account as much as possible.

3. Overlap with other legislation that applies to biological agents

There is overlap between EU Directive 2000/54/EC on biological agents and EU Directive 2009/41/EC on the contained use of genetically modified micro-organisms. Biological agents that have been genetically modified are subject to both types of legislation. This sometimes means that for one and the same activity, based on one risk assessment, different administrative procedures must be followed, resulting in a duplication of administrative efforts. EBSA would want to urge authorities to, wherever possible, avoid any unnecessary duplication of administrative procedures and keep administrative procedures as simple as possible. EU member states can avoid unnecessary duplication of administrative procedures by having the same competent authorities deal both with EU Directive 2000/54/EC and EU Directive 2009/41/EC, or have a good coordination between the competent authorities responsible for these two types of legislation.

4. Containment measures and containment levels

The current directive contains in annex V and VI indicative descriptions of containment measures, defined per containment level. At the international level, such as the WHO, there are voices heard that would like to get rid of such indicative containment levels. This is mostly motivated by the difficulty for developing countries to implement the requirements of very prescriptive containment

measures for work with medium to high risk pathogens. But the biological agents directive specifically applies to Europe where this is not a real problem, and EBSA is of the opinion that it is very beneficial to have indicative descriptions of containment levels on the condition that the final choice of measures is dependent on the outcome of the risk assessment.

Because of the overlap between the biological agents and the contained use legislation EBSA is of the opinion that the description of the containment levels in these two pieces of legislation should be in good harmony, avoiding any conflicts or contradictions in the requirements.

European Biosafety Association (EBSA) unites biosafety professionals from 24 countries in Europe, as well as other regions. EBSA establishes and communicates best biosafety and biosecurity practices amongst its members and encourages dialogue and discussions on developing issues. EBSA represents and defends the collective interests of its members in all areas relating to biosafety and biosecurity.

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