



Verband | **Biologie, Biowissenschaften
& Biomedizin in Deutschland**

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Comments on WS 31 - Laboratory Biorisk Management

Dear Ms Franssen,

Thank you for the mail of Ms Le Gall dated September, 3rd and the invitation of CEN to register for the workshop in order to be a member. We will check whether an expert from our organisation can take part in the November session since it is important that our comments are taken into consideration.

We are surprised, that CEN and EBSA claim the draft CEN Workshop Agreement "Laboratory Biorisk Management Standard" is a document without any long-term consequences. Since the EU Commission has opened the discussion on the "Green Paper on Bio-Preparedness" COM(2007) 399, we are still concerned about the draft CWA, since we assume that it will be the basis of any future regulatory activities in this field. If implemented, the quantity and quality of the standards listed in the draft CWA will result in considerable changes to the infrastructure in the biological and biomedical research community.

Per definition there is no risk associated with GRAS- or RG1-organisms. So we would strongly recommend that the current concept of classifying biological material into Risk Groups (1-4), as well as the corresponding containment levels 1-4, together with the established European recommendations and corresponding national regulations have to be taken into consideration by CWA.

We believe that it is better to differentiate between biosafety aspects and biosecurity demands. External certification is not necessarily the appropriate way for increasing the level of biosecurity. Further EU harmonization of the present national regulations, advanced vocational training and enforced awareness towards bioterrorism will contribute more significantly to minimising access to Biorisk material.

VBIO and its member societies would greatly welcome being able to contribute to these discussions, and development and implementation of appropriate biosafety and biosecurity regulations/ recommendations.

Yours sincerely,


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President

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