Verband | Biologie, Biowissenschaften & Biomedizin in Deutschland

CEN WS 55 Secretariat
CEN Management Center
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***- via e-Mail -***

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**Comments on WS 55 – Guidance Document for**
**CWA 15793:2008 Laboratory Biorisk Management Standard**

Dear Ms Le Gall,

Thank you your mail 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 February session since it is important that our comments are taken into consideration.

VBIO and its member organisations are more than willing to bring their collective practical experience into the consultation process. It is our intention to balance reasonable approaches and those that attempt overregulate and seriously hinder work in Life Science Research. Therefore we strongly recommend that in this CEN-Workshop-Procedure the points we raise are taken into account prior to the beginning of the workshop:

1. You claim that there is a need for an additional document assisting in the understanding of the CWA 15793:2008 and helping end-users in the actual implementation. We think it is better to skip the whole CWA 15793:2008 and to build up a totally new standardization process involving all interested AND affected parties as well as referring to the CBRN-Action plan and European commissions "Green book on Bio-Preparedness" rather than trying to further adjust and correct an inappropriate paper like the CWA 15793:2008. There is very little time to get a helpful Guidance Document formulated within 6 months and acceptance will not be raised by the present rushed procedure.
2. Per definition there is no risk associated with GRAS or RG1 (BSL1) organisms. We 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 the CWA.
3. There are good reasons for standardisation of processes - as far as it means adaptation of existing regulations – and not the establish-ment of new, additional ones, which bring more bureaucracy with

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hardly any security advancement. On the other hand advanced research itself is not suitable to standardisation at all.

Consequently external certification is not helpful to improve Biosecurity in university or other research labs. As has been emphasised in the “CBRN-Action plan” it is important that this becomes part of an actively practiced culture, rather than a formally certified exercise.

4. We believe that it is better to differentiate strictly 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.
5. VBIO is very critical about a kind of “awareness check” for Life Scientists, as proposed by CEN. However, for VBIO and its members the question is whether one can verify anyone's attitude at all?
   In our view “professional” terrorism implies a significant amount of criminal energy and any potential offender will be able to mask themselves easily. It is important to note, that in the European Commission there are already discussions to link EU funding with those kinds of procedures.
6. Standardized handling of bio-risks is useful, where risks might occur. However, for VBIO there is an urgent need to differentiate between low and high risk potential. In particular the CEN paper seems to make an elaborated process of certification mandatory for all laboratories regardless of their safety level. If certification will include laboratories with low or even no risk potential, the efforts will provide further impediments to work in Life Science Research. Neither public nor private institutions will be able to finance the implementation of the measures that are necessary

VBIO and its member societies would greatly welcome being able to contribute to these discussions, and the development and implementation of appropriate biosafety and biosecurity regulations/ recommendations that would contribute positively to the establishment of an appropriate, workable biosafety and biosecurity awareness culture.

Yours sincerely,

Carsten Roller, Manager

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