

1	2	(3)	4	5	(6)	(7)
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Included into the table (column 7) the comments to the proposed changes submitted by BBP						
BBP	Application	Paragraph 2	Ge	There is no reference to the possibility of having a legal obligation to hire a BSP	In general, a biosafety professional is appointed <u>where required by regulations or, in absence of regulatory obligation.</u>	Comment rejected. The document already refers to laws and regulations and legal requirements in the last paragraph of the "Application". Also in CWA15793 this is mentioned. If a BSP is a legal requirement the comment is already covered by the present wording.
BBP	Application	Paragraph 6	Ge	The wording 'not applicable' and "exclusions' are too strong and should be rephrased.	Replace in the 1 st sentence 'not applicable' by 'out of consideration'; and 'exclusions' by 'exemptions'	Comment rejected. Using wording similar to that used in CWA 15793.
BBP	Terms and definitions	3.2	Te	As animal and plant cells are not likely "to provoke infection, allergy or toxicity" (terms of the definition of a biological agent) by themselves but only through the biological agents they harbour or the substances they produce, I would rather consider them as biological materials	Remove animal and plant cells from the definition of biological agents and include them in the definition of biological materials (3.3).	Comment acknowledged. In the previous comment (no. 27 = Comment accepted. Text modified. Cell cultures are added as human, animal and plant cell cultures.) it was asked to add cell cultures. This is defined as human, animal and plant cell cultures. The plants and animals are added to "biological materials"
BBP	Terms and definitions	3.3	Ed	This is not a real definition	3.6. Biological material <u>Any biologically-derived material or, material which, either by accident or design, contains or may contain, biological agents including bacteria, viruses, micro-organisms, genetically modified organisms / micro-organisms (GMOs, GMMs), or any other biological agents which might pose a</u>	Comment acknowledged. Text is modified.

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					<i>risk to health and safety or the environment.</i>	
BBP	Term and definitions	3.5	Te	The term 'low', 'moderate' and 'high risk should be defined clause 3		Comment rejected. It is very difficult to define these terms, because they are subject to interpretation differences and even contradictory interpretations
BBP	Term and definitions	3.5	Te	A definition of 'biosafety containment' should be added	Containment is the set of measures including biological features, microbiological practices, safety equipment and facility safeguards that protect laboratory workers, the environment, and the public from exposure to biological material when stored or worked with.	Comment acknowledged. A definition for biosafety containment is included
BBP	Term and definitions	3.5	Te	In the description of the levels 1 to 4, animal and plant health is not specifically included or addressed	Correction: "... containment is appropriate to protect human, animal and plant health and the environment ... "	Comment acknowledged. Text modified

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BBP	Term and definitions	3.23 and 3.24	Te	Difference between validation and verification is not clear, more clarification is needed	<p>Either only use verification in the text (validation being considered as a specific type of verification) or find definitions that make the distinction easier to understand.</p> <p>If validation is considered as a specific type of verification (as qualification, commissioning...), then it could be mentioned as a note between the definition</p>	Comment acknowledged, consider that the two definitions to show the difference between the terms
BBP	Term and definitions	3.5 7.2.12	Ge	Contrarily to decontamination and disinfection, sterilization is not defined while it is used	<p>Add:</p> <p><u><i>Sterilization</i></u></p> <p><u><i>The complete destruction or elimination of all living microorganisms, including spores, accomplished by physical methods (saturated steam of dry heat), chemical agents, radiation or mechanical methods</i></u></p>	Comment acknowledged. A definition is included using the proposal of comment 26 (= Sterilization (from ISO 15190:2003) validated process used to render a product free from microorganisms.)
BBP	Term and definitions	3.5	Ge	Add the definition of 'Personnel qualification'	It is proposed to use one of the definitions of CEN Guide 14:2010	Comment rejected. However we added an extra note in 6.1 where we explain the term "Qualification". In 3.5 is the only reference to qualification in the entire document.
BBP	Role	Paragraph 1	Te	<p>What is given here is note the description of a role but some considerations related to a possible role. Moreover, the position in citing CWA is ambiguous: is it a requirement of this document?</p> <p>This would also require to adapt Annex A</p>	<p>Replace paragraph by:</p> <p><u><i>The role of the Biosafety professional is to give advice to management and personnel on biosafety and biosecurity issues and to support the design and implementation of efficient biorisk management programmes or systems.</i></u></p>	Comment acknowledged. Text modified using proposed text. Original text is included as note

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BBP	Role (clause 5)	Paragraph 2	Ed	The second paragraph is not a requirement (no “shall” but “may”)	The second paragraph should be a Note	Comment accepted. Text modified
BBP	Qualification (clause 6)	6.2	Ed	A bit weird to see relevant experience and established network at the same level, as something that a BSP “has”	“...and <i>shall build or establish a network</i> to enable him/her to properly perform his day to day work	Comment acknowledged. Text modified. You should have a network before you are going to oversee a higher containment level without having experience at this level
BBP	Competences (clause 7)	7.2	Ge	Order of the different core competences. If the current order is not a priority ranking, nor ‘weight’ ranking, place the competences into alphabetical order.	Put the core competences in alphabetical order	Comment rejected. The competences are grouped according to subject.
BBP	Competences (clause 7)	7.2.1 and 7.2.2	Ge	Why are competence 7.2.1 and 7.2.2. separated? No clear justification.	Combine 7.2.1 and 7.2.2 in one core competence	Comment rejected. People can come from different backgrounds, making it inapplicable to combine the 2 competences.
BBP	Competences (clause 7)	7.2.5.	Te	Considering under human factors that it is only “providing tools to...” seems to be somewhat reductive.	The sentence could either be deleted or be more complete, such as for instance: <i><u>The biosafety professional shall be able to influence behaviours and be persuasive in promoting good biosafety and biosecurity practices</u></i>	Comment accepted. Text modified according proposed text
BBP	Competences (clause 7)	7.2	Te	Missing competences: 1. Environmental issues: these are not explicitly present in on the listed 22 competences while others as “Occupational health” are (7.2.4 2. The correct use of equipment 3. The correct use of disinfectants	1. Add: <i><u>Environmental safety:</u></i> <i><u>The biosafety professional shall be able to:</u></i> <i><u>- understand the risks for the environment associated with working with biological agents;</u></i> <i><u>- design suitable measures and surveillance to prevent biological hazards to the environment;</u></i> <i><u>- decide when expert help is needed to address a specific issue.</u></i>	1. Comment accepted and added to the Competences

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					<p>2. add to e.g. § 7.2.9</p> <p><i>“The biosafety professional shall be able to understand the biosafety and biosecurity implications of equipment and shall be able to advise on choice and the correct use, installation, validation, certification and maintenance.</i></p> <p>and § 7.2.12 “</p> <p><i>The biosafety professional shall be able to describe the most important elements of infection control, disinfection, decontamination and sterilization, as well as their efficacy. The biosafety professional shall be able to advise on choice and the correct use of all methods.</i></p>	2. Comment accepted. Text modified in both cases
BBP	Competences (clause 7)	7.2.8	Te	The title is too long, describe too much the competence and gives the impression that the BSP should be a qualified architect and engineer	<p>New title: <i>“Facility design and management”</i></p> <p>The biosafety professional shall be <i>able to identify, facility design and construction issues that are relevant to biosafety and biosecurity. He/she shall be able to read technical drawings and understand the basic systems (Heating Ventilation Air Conditioning (HVAC), etc.); understand the construction, commissioning and validation processes; and shall have knowledge on basic (re)design features of the most important types of facilities.</i></p> <p>The biosafety professional shall <i>also</i> be able to identify and describe the biosafety issues in preventive and corrective maintenance, operations and decommissioning.</p>	<p>Comment rejected. The present title covers more than design and management.</p> <p>The text is modified also taking comment 79 into account</p>
BBP	Competences (clause 7)	7.2.8	Te	Shouldn't part of the competences described under 7.2.8 be considered as specialised competences (7.3) rather than core competences?	To be evaluated in WS	As a BSP you need to have a basic understanding of these subjects. For BCL3 and 4 specialised knowledge is needed. Therefore these subjects are also

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						incorporated for these levels in the curriculum
BBP	Competences (clause 7)	7.2.22	Te	Bioethics is not seen as a 'core competence' but remains an item the BSP should be aware of and therefore it is proposed to integrate § 7.2.22 into 7.2.21	Integrate § 7.2.22 into 7.2.21	Comment rejected. Bioethics is kept as a separate item, because of the nature of the subject compared to other legislation.
BBP	Annex B	B.15		Change according to remark at 7.2.8	Replace by "Facility design and management"	Comment rejected. The present title covers more than facility design and management.
BBP	Annex C	C.2.1.1 and C.2.1.2 C.3.1.1.1 and C.3.1.1.2		No reason to separate into 2 topics cfr. 7.2.1 and 7.2.2	Combine C.2.1.1 and C.2.1.2 Combine C.3.1.1.1 and C.3.1.1.2	Comment rejected. People can come from different backgrounds, making it inapplicable to combine the 2 competences.
BBP	Annex C	C.2.2.6 and C.3.1.2.6		Change according to remark at 7.2.8	Replace by "Facility design and management"	Comment rejected. The present title covers more than facility design and management.
BBP	Annex C	C.2.2.10 and C.3.1.2.10			Replace "sterilization" by "inactivation"	Inactivation has a meaning that is less precise in this context we prefer to keep the word sterilization
BBP	Annex C	C.2.2 C.3.1.1		Add environment cfr. Remark at 7.2	Add: <u>C.2.2.x Environmental safety</u> Add: <u>C.3.1.1.x Principals of Environmental safety</u> ... <u>animal and plant pests: mode of transmission; dispersal, survival structures, ...</u> <u>gene flow</u> <u>protection goals</u>	Accepted

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					...	
BBP	Annex C	C 2.3.3. and C 3.1.3.3		Bioethics to be integrated, in agreement with the core of the text (normative part), see also previous comment	Delete C.2.3.3 as it is part of C.2.3 (but add bioethics to the title. Integrate C 3.1.3.3. into C.3.1.3.1.	Comment rejected. Bioethics is kept as a separate item, because of the nature of the subject compared to other legislation.
BBP	Annex C	C.3.1.2.4		'Working practices' is missing	Add: - <i>Safe working practices</i>	Accepted
BBP	Competences (clause 7)	7.2.22	Te	If bioethics is to be considered a core competence, considering the competence as related to legislations and codes of conduct only is somewhat reductive	<i>The biosafety professional shall be aware of bioethic issues applicable to his/her field of activities and be familiar with the applicable regulations and codes of conduct.</i>	Comment accepted. Text modified according the proposal.

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