

APPENDIX C

[FACILITIES

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[16. Fields of activity at the declared facility

Did the work include research and development, testing and evaluation, or ~~{production}~~
~~{manufacturing}~~ **for distribution, sale or storage** in any of the following areas (tick all that apply)?

	Research and development	Testing and evaluation	{Production} {Manufacturing} for distribution, sale or storage
Detection, identification and diagnosis techniques			
Decontamination, disinfection and pest control techniques			
Prophylaxis techniques			
Physical protection techniques			
Medical or veterinary treatment techniques			
Genetic modification			
{Maintaining culture collection/ repository}			n.a.?
Insect/pest control techniques for use in agriculture/horticulture			
Studies of Characteristics of biological agents and or toxins:			
pathogenicity/virulence		n.a.	n.a.?
toxicity			n.a.?
toxiology		n.a.	n.a.?

	Research and development	Testing and evaluation	{Production} {Manufacturing} for distribution, sale or storage
environmental stability		n.a.	n.a. ⁴⁷
{production}			n.a. ⁴⁷
antimicrobial resistance		n.a.	n.a. ⁴⁷
Aerobiology studies, including open air release			n.a. ⁴⁷
Vector (insect) ecology studies			n.a.
Plant pathology studies			n.a.
n.a. = not applicable			

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[26.⁴⁷ If the facility conducted work with agents and/or toxins listed in Annex A, whether or not it satisfied the declaration trigger for work with listed agents and/or toxins, provide the following information:

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)		
	up to x	x to y	above y

Toxin	Estimated amount produced (dry or wet packed weight in grams)

47. Only the delegations which saw this format I as the format for biodefence facilities wanted to retain this question in this place.

For larger scale production?	YES / NO
For downstream processing?	YES / NO
For animal studies?	YES / NO
For aerobiology studies?	YES / NO

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30. ~~Were declared activities at~~ **Was the declared facility supported at the same location or elsewhere by:**

A fixed outdoor site or fixed grid that is designed, intended and used for outdoor studies of biological aerosols?	YES / NO}
An experimental facility for animals, or an animal holding facility?	YES / NO
A waste decontamination facility?	YES / NO
A facility for larger scale production, or for downstream processing?	YES / NO

[31. ~~Were any agents and/or toxins listed in Annex A transferred between the declared facility and any other areas at the same location or at a different location (indicate which)?~~

Same location _____	YES / NO
Different location _____	YES / NO

~~If yes, were any of these other areas at the same location:~~

Laboratories _____	YES / NO
Animal houses _____	YES / NO
Production areas _____	YES / NO
Areas involved in downstream processing, formulation or packaging _____	YES / NO
Waste treatment areas _____	YES / NO
Areas involved in field testing or evaluation _____	YES / NO }

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35. Vaccine production

If the declared facility satisfied the requirements of the declaration trigger for vaccine production, provide the following information:

Provide the following information for the production of microorganisms or substances causing a [specific] [protective] immune response as an ingredient of a vaccine at the facility declared in accordance with paragraph 10 of Article III, section D, subsection I:

Ingredient	Level of containment		Amount of ingredient produced (in ranges)		
	BL3	BL4	up to x	x to y	above y

OR

{(a)

Ingredient	Vaccine	Disease against which the vaccine is directed	Production objectives

*** Production objectives: A - Public health applications; B - Ministry/Department/Agency of Defence applications; C - Both**

(b) Estimate the total quantity of ingredients produced, as a ~~single total number~~ **totals** of dose equivalents of the corresponding vaccine(s), in ranges (**tick the appropriate box**):

{ ~~up to 25,000~~ ~~25,000 to 1,000,000~~ ~~above 1,000,000~~ }

Type of vaccine	Level of containment		Aggregate dose equivalents*		
	BL3	BL4	up to 100,000	100,000 to 5,000,000	above 5,000,000

Human					
Animal					

OR

Human or type of animal	Aggregate dose equivalents*		
	up to 25,000	25,000 to 1,000,000	above 1,000,000
Human			
Animal 1			
Animal 2			
...			

* State the dose equivalent as an aggregate value for all vaccine ingredients intended for use with humans or for each type of animal, as appropriate, in terms of the estimated dose for adults even if a vaccine is intended for use with children or immature animals.

36. Maximum biological containment (BL-4 - ...)

If the declared facility satisfied the requirements of the declaration trigger for maximum biological containment (BL-4 ...), provide the following information:

- (a) Estimate the total floor area of the BL4 containment area, by indicating which range applies:

up to 40 sq.m. 41 to 100 sq.m. 100 to 500 sq.m. over 500 sq.m.

- [(b) Indicate the number of units: . . .]

- [(c) Indicate whether **the contained area includes** any unit(s) are for the management and/or treatment of patients:

YES / NO]

- [(d) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
[Zoonotic pathogens	YES / NO
Other] animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO]

[(e) Method/system of decontamination of the biocontainment area(s) (check all that apply):

- | | |
|-------------------------------|----------|
| Formaldehyde/paraformaldehyde | YES / NO |
| Ultraviolet light | YES / NO |
| Steam | YES / NO |
| Chlorine/perchlorate | YES / NO |
| Hydrogen peroxide | YES / NO |
| Washdown | YES / NO |
| Other, specify: |] |

(f) **Indicate all biological agents on which genetic modification was conducted to enhance pathogenicity, virulence, stability or resistance to antibiotics or chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis, within a high biological containment facility (BL3):**

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38. Work with listed agents and/or toxins

Did the declared facility satisfy the requirements of the declaration trigger for work with listed agents and or toxins?

YES / NO

If yes, indicate which activities it has conducted:

- (a) Production [with the purpose of recovery] of [one or more] [any single] agent[s] and/or toxin[s] listed in Annex A, using:
- (i) Any fermenter(s)/bioreactor(s) with a total internal volume of [10] [25] [50] [100] litres or more YES / NO
 - (ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] litres an hour YES / NO
 - (iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of [10] [50] [100] litres or more YES / NO
 - (iv) More than [1,000] [2,000] embryonated eggs on an annual basis YES / NO

- (v) More than 1,000 litres of tissue culture or other medium on an annual basis YES / NO

- (b) Intentional aerosolization of any agent and/or toxin listed in Annex A in:
 - (i) A static aerosol test chamber YES / NO
 - (ii) An explosive aerosol test chamber YES / NO
 - (iii) A dynamic aerosol test chamber that has a total volume exceeding 5 m³ YES / NO

If yes, provide the following information:

Estimated amount produced
(litres of culture or of working suspensions of agents)

Agent	[up to x] [a to b]	[x to y] [b to c]	[above y] [above c]
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Estimated amount produced (dry or wet packed weight in grams)

Toxin	[up to x] [a to b]	[x to y] [b to c]	[above y] [above c]
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OR

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)			Level of containment		Field of activities*
	up to x	x to y	above y	BL3	BL4	

* With reference to question 16.

Toxin	Estimated amount produced (dry or wet packed weight in grams)			Level of containment		Field of activities*
	up to x	x to y	above y	BL3	BL4	

* With reference to question 16.						

[(c) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor or for any toxin or subunit of any toxin, into an agent listed in Annex A?

YES / NO

If yes, name the agent(s) and the toxin(s) and give a short description of the purpose:

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(d) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor from an agent or toxin listed in Annex A, or for a subunit of such toxin into any microorganism, resulting in a genetically modified organism with disease-causing or toxic properties?

YES / NO

If yes, name both organisms or toxins and give a short description of the purpose:

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(e) Did the facility conduct intentional aerosolization of any agent and/or toxin listed in Annex A or any work with aerosolized agents and/or toxins listed in Annex A?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

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- (f) Did the facility conduct the administration of any agent and/or toxin listed in Annex A to animals via the respiratory tract?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

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