

APPENDIX C

[FACILITIES

Guidelines for completing the declaration format

[These declaration formats require information on rooms, laboratories, or other buildings or structures, and on specified activities conducted therein⁷⁰, which in the reporting year met the criteria set out in one or more of the declaration triggers of the Protocol, and which are therefore to be declared as facilities under the Protocol. Such facilities are referred to throughout the format as the “declared facility”.

It is recognized that in most cases the rooms, laboratories or buildings or other structures and the activities therein that satisfy the requirements of one or more triggers may involve only a part of a location, perhaps even only part of a building. That is to say, the facility declarable under the Protocol may be co-located with one or more other facilities the activities of which are not declarable. In other cases, however, the declared facility may cover the entire location. The declaration formats are designed to cover this range of possibilities.

Submit a separate copy of the facility declaration format for each facility satisfying the requirements of a declaration trigger. When scientific/technical activities in different parts of a location, for example in different buildings and/or departments at a university campus or at a commercial installation operated by a single company, jointly satisfy the requirement of a particular clause in a declaration trigger because they are working cooperatively, but would not satisfy it individually, they shall be considered one declarable facility and must be declared on a single copy of the format. When such activities at a location are not connected, and separately satisfy one or more declaration triggers, they shall be considered separate declarable facilities and must be declared on separate copies of the format.]

OR

[The facility declaration format requires information on facilities meeting the criteria set out in one or more of the declaration triggers of the Protocol. Such facilities are referred to throughout the format as the “declared facility”. A common format is to be utilized by declared facilities to report activities captured by each declaration trigger.

70. A view was expressed that it would be better to use the term “facility” and refer to the definition in Article II.

The design of the format takes account of the differing sizes, complexities and scope of facilities satisfying the requirements of one or more of the Protocol declaration triggers. It is recognized that in some cases the rooms, laboratories or structures that satisfy the requirements of the trigger - and that therefore are to be the facility - may involve only part of a building. That is to say, the facility declarable under the Protocol may be co-located with or within one or more other facilities or activities that are not declarable. In other cases, however, the declared facility may be much larger.

The facility declaration format is designed to cover this range of possibilities. The facility to be declared is the combination of room(s), laboratory(ies) or structures which carried out activities during the reporting calendar year that satisfied the requirements of one or more of the declaration triggers.

When a declared facility has been used during the reporting period for the conduct of more than one declarable activity, the facility shall submit a separate format for each of the declared activities conducted therein.]

Declared facilities should answer the questions in sections A and B and, according to the trigger involved, the following questions in section C:

<u>Trigger that applies</u>	<u>Questions to be answered in section (C)</u>
Biological defence facility	[all] [34] [...]
Vaccine production facility	35 [38 and 39] [...]
Maximum biological containment (BL-4 - ...) facility	36 [...]
High biological containment (BL3 - ...) facility	37 [38 and 39] [...]
Work with listed agents and/or toxins	38 and 39 [...]
Other production facility	40 [and 37] [38 and 39] [...]
Other triggers for facility declarations	41 [and 37] [and 40] [...]

Option One

[FORMAT I. DECLARATION OF A BIOLOGICAL DEFENCE FACILITY

Reporting period

This declaration covers the calendar year:

INTRODUCTION

(i) Other declaration trigger(s) that apply to the facility

This facility is being declared because it satisfies the requirements of the declaration trigger for a biological defence facility. Indicate if any of the following declaration triggers also apply, by circling the appropriate trigger(s) [and indicating the approximate percentage of the total work of the declared facility that relates to each trigger]:

	[Approximate percentage (in person-years)]
Vaccine production facility	...
Maximum biological containment (BL-4 - ...) facility	...
High biological containment (BL3 - ...) facility	...
Work with listed agents and/or toxins	...
Other production facility	...
Other triggers for facility declarations	...

[If any of these other triggers apply, estimate the proportion of the total work of the declared facility that relates to the work being declared under the trigger for a biological defence facility:

up to 10 per cent 10 - 50 per cent over 50 per cent]

(ii) Declared facilities should answer the questions in sections A and B, and questions in section C from question 35 to the end.]

OR

Option Two

[FORMAT. DECLARATION OF FACILITIES

Reporting period

This declaration covers the calendar year:

INTRODUCTION

(i) Declaration trigger(s) that apply to the facility

When a facility has engaged in activities meeting the criteria for more than one of the declaration requirements set out in Article III, section D, subsection I, the facility shall submit a separate format for each of the declaration requirements. Indicate which of the declaration triggers is applicable to this copy by ticking one of the triggers below:

Biological defence facility	YES / NO
Vaccine production facility	YES / NO
Maximum biological containment (BL-4 - ...) facility	YES / NO
High biological containment (BL3 - ...) facility	YES / NO
Work with listed agents and/or toxins	YES / NO
Other production facility	YES / NO
Other triggers for facility declarations	YES / NO

Were any other activities conducted within this declared facility that will be declared pursuant to another declaration trigger?

YES / NO

If yes, indicate the relevant declaration trigger(s) (select all applicable):

Biological defence facility	YES / NO
Vaccine production facility	YES / NO
Maximum biological containment (BL-4 - ...) facility	YES / NO
High biological containment (BL3 - ...) facility	YES / NO
Work with listed agents and/or toxins	YES / NO
Other production facility	YES / NO
Other triggers for facility declarations	YES / NO]

OR

Option Three

[FORMAT. DECLARATION OF FACILITIES

Reporting period

This declaration covers the calendar year:

INTRODUCTION

(i) Declaration trigger(s) that apply to the facility

Submit a copy of the facility declaration format for each facility satisfying the requirements of one or more of the declaration triggers identified below. Indicate which of the declaration triggers is applicable to this facility, by ticking the appropriate triggers below [and indicating the approximate percentage of the total work of the declared facility that relates to each trigger]:

	[Approximate percentage (in person-years)]
Biological defence facility	...
Vaccine production facility	...
Maximum biological containment (BL-4 - ...) facility	...
High biological containment (BL3 - ...) facility	...
Work with listed agents and/or toxins	...
Other production facility	...
Other triggers for facility declarations	...]

Common text

SECTION (A) GENERAL INFORMATION

Name and address

1. Name of the declared facility:
2. Address of the declared facility:
3. Postal address of the declared facility, if different:
4. Building details for the declared facility.

State, as appropriate, building name(s):

building number(s):

room number(s):

[floor level(s):]

Diagram/location⁷¹

5. [Fixed facilities. Provide a [scale] [indicative] map of the locality, showing the declared facility:

.....]

OR

[Provide the following:

- (a) An orientation map (with scale, and a key explaining any abbreviations and symbols) of the location of the declared facility, including the following elements:
 - (i) The principal natural and/or man-made topographical features surrounding the declared facility, e.g., major highways or roads, mountain(s), rivers (minimum size of area represented by the map should be approximately [1] square kilometre);
 - (ii) Geographic coordinates of a designated reference point where the declared facility is located, accurate to one second;
 - (iii) Direction of true north;
 - (iv) For current biological defence facilities only: In addition, provide the general boundary of the site within which the declared biological defence facility is located, including all major access routes.

- (b) A facility diagram. The purpose of the facility diagram is to graphically indicate the location of the declared facility (e.g., the area(s) where declared activities took place). The facility diagram can be one or multiple diagrams and should include the entire declared facility, with boundaries of the declared facility building(s), room(s) or other structures, as appropriate, clearly marked. If the declared facility is defined as room(s), or floor(s) within buildings, the diagram must include floor plan(s) with boundaries of the declared facility's spaces clearly marked. The facility diagram shall include the following elements:

71. A view was expressed that the format should state that the locations of animal holding areas may be excluded from such maps.

- (i) Clearly marked boundary of the declared facility (e.g., the area(s) where declared activities took place, which could be building(s), room(s) or other structures);
- (ii) Geographic coordinates of a designated reference point within [100] metres of the declared facility, accurate to one second;
- (iii) Direction of true north;
- (iv) A key with an explanation of all abbreviations and symbols, and with an indication of the scale of the diagram.]

[6. Mobile facilities.

- (a) List the locations at which the declared facility is usually operated:

.....

- (b) Indicate where the declared facility was normally kept, if different from above:

.....

- (c) List the locations at which the declared facility was operated:

.....]

Owner

- 7. Name:

.....

- 8. Affiliation (tick all that apply):

9	Ministry/Department/Agency of Defence	9	wholly	9	partially
9	Other government ministry/department/ agency	9	wholly	9	partially
9	Non-government	9	wholly	9	partially

Operator(s) (Only provide details if different from the owner)

- 9. Name(s):

.....

- 10. Affiliation(s) (tick all that apply):

9	Ministry/Department/Agency of Defence	9	wholly	9	partially
9	Other government ministry/department/ agency	9	wholly	9	partially
9	Non-government	9	wholly	9	partially

[Funding]

[11.⁷² Estimate the funding levels for the current biological defensive programme work at the declared facility:
]

12. Affiliation of sources of funding (tick all that apply):

9	Ministry/Department/Agency of Defence	9	wholly	9	partially
9	Other government ministry/department/ agency	9	wholly	9	partially
9	Non-government	9	wholly	9	partially
9	International organization	9	wholly	9	partially

[(a) Identify the primary sponsor of or source of funding for declared activities at the declared facility (tick all that apply):

9	Ministry/Department/Agency of Defence	9	wholly	9	partially
9	Other government agency or department	9	wholly	9	partially
9	International body (e.g. WHO, UN, etc.)	9	wholly	9	partially
9	Other non-government	9	wholly	9	partially

(b) Identify the type of primary purchaser or recipient of the product or services of declared activities at the declared facility (tick all that apply):

9	Ministry/Department/Agency of Defence	9	wholly	9	partially
9	Other government agency or department	9	wholly	9	partially
9	International body (e.g. WHO, UN, etc.)	9	wholly	9	partially
9	Other non-government	9	wholly	9	partially]

Personnel

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

13. [Estimated number of personnel. Do not include personnel who make minor contributions to the declared activity. Examples may be administrative or health and safety personnel.]

	Total personnel			Scientific personnel including engineers			Technical assistance/support personnel		
	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]
[Military] personnel									
[Civilian personnel]									
Contract employees who have worked for more than 6 [person] months in the reporting calendar year									

SCIENTISTS

	Military	Civilian	Contract*
Microbiologists			
Pathologists			
Molecular biologists			
Epidemiologists			
Entomologists			
Plant pathologists			
Others			

* Contract employees who have worked for more than 6 months in the reporting calendar year.

ENGINEERS

	Military	Civilian	Contract*
Mechanical engineers			
Chemical engineers			
Electronics/instrumentation engineers			
Others			

* Contract employees who have worked for more than 6 months in the reporting calendar year.

OR

[13. Estimate the person-years of technical and scientific staff directly involved in the declared activities at the declared facility (include on-site contractors):

___ 0 - 10 ___ 11 - 25 ___ 26 - 50 ___ greater than 50

(a) Estimate the percentage of these personnel who hold, as their highest qualification, a diploma, bachelors degree or technical degree in the life sciences, chemistry, engineering or physics:

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(b) Estimate the percentage of these personnel who received a higher or advanced degree in the life sciences, chemistry, engineering or physics:

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(c) Estimate the percentage of person-years that are full-time active duty military:

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(d) Estimate the percentage of person-years that are full-time civilian ministry/department/agency of defence employees (include on-site contractors):

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent]

SECTION (B) SCIENTIFIC AND TECHNICAL INFORMATION

[14. State the aims and objectives of the work at the declared facility ([10 lines or less] [... words or more]):

.....
.....
.....]

[15. Describe the work at the declared facility in the reporting year ([10 lines or less] [... words or more]):

.....

]

[16. Fields of activity at the declared facility

Did the work include research and development, testing and evaluation, or [production] [manufacturing] in any of the following areas (tick all that apply)?

	Research and development	Testing and evaluation	[Production] [Manufacturing]
Detection, identification and diagnosis			
Decontamination, disinfection and pest control			
Prophylaxis			
Physical protection			
Medical or veterinary treatment			
Genetic modification			
[Maintaining culture collection/ repository]			n.a.?
Insect/pest control techniques for use in agriculture/horticulture			
Characteristics of biological agents and toxins:			
pathogenicity/virulence			n.a.?
toxicity			n.a.?
toxinology			n.a.?
environmental stability			n.a.?
[production]			n.a.?

	Research and development	Testing and evaluation	[Production] [Manufacturing]
antimicrobial resistance			n.a.?
Aerobiology studies, including open-air release			n.a.?
Vector (insect) ecology			
Plant pathology			
n.a. = not applicable			

[17.⁷³ Indicate whether high biological containment (BL3 - ...), as defined by the Protocol, was used for declared activities within the declared facility:

YES / NO

18. If [yes] [the declared activities took place in any area designated as high biological containment (BL3 - ...) for human pathogens], specify the floor area of the working areas by indicating which range applies:

up to 30 sq.m. 30 to 100 sq.m. 100 to 500 sq.m. over 500 sq.m.]

[19. Did declared activities at the declared facility utilize outlet air vents and/or exhaust paths equipped with filters that removed or captured particles as small as 0.3 micrometres in diameter?

YES / NO]

[20. Was waste from declared activities at the declared facility, whether solid, air or liquid, rendered safe by decontamination or sterilization prior to release or removal from the facility?

YES / NO]

[21. If the declared facility included room(s) for holding and/or working with live animals under maximum biological containment (BL-4 - ...) or high biological containment (BL3 - ...), indicate which applies:

73. If high biological containment (BL3 - ...) is agreed as a declaration trigger, this question may not be necessary.

Maximum biological containment (BL-4 - ...) YES / NO

High biological containment (BL3 - ...) YES / NO]

OR

[21. If the declared facility included room(s) for holding and/or working with live animals under maximum biological containment (BL-4 - ...) or high biological containment (BL3 - ...), specify the floor area of the holding/working areas, excluding shower areas, by indicating which range applies:

Type of animal	Floor area			Indicate biological containment level that applies	
	up to 30 sq.m.	30 - 100 sq.m.	over 100 sq.m.	Maximum	High

22. Answer the questions about equipment at the declared facility, to be found in the attached Annex ...⁷⁴

[23. Indicate whether tissue culture media was used:

YES / NO

If yes, [indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres]

[estimate the amount used, to an accuracy of +/- 20 per cent:]]

[24. Indicate whether other complex culture media was used:

YES / NO

74. The list as developed in the rolling text, Annex A, section II should be used.

If yes, [indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres]

[estimate the amount used, to an accuracy of +/- 20 per cent:]]

[25. Indicate whether embryonated eggs were used to culture microorganisms:

YES / NO

If yes, [indicate which range applies:

[up to 1,000 eggs 1,000 - 15,000 eggs over 15,000 eggs]
 [1 - 10,000 eggs 10,000 - 100,000 eggs over 100,000 eggs]
 [up to 10,000 eggs over 10, 000 eggs]]

[estimate the number used, to an accuracy of +/- 20 per cent:]]

[26.⁷⁵ 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)		
	up to x	x to y	above y

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

Rickettsia	YES / NO
Toxins	YES / NO
Fungi	YES / NO]

[28. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

If yes, list the vaccines that applied:

.....]

OR

[28. Were any declared facility personnel vaccinated against any agents or toxins listed in question ... in connection with declared activities at the declared facility?

YES / NO

28 bis Were any declared facility personnel vaccinated against any other agents or toxins in connection with declared activities at the declared facility?

YES / NO]

[29. Did any declared activities of the declared facility involve aerobiological work (excluding nasal and oral inhalers intended for personal prophylactic use)?

YES / NO

30. Were declared activities at the declared facility supported by a fixed outdoor site or fixed grid that is designed, intended and used for outdoor studies of biological aerosols?

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]

32. Indicate the publication policy for work at the declared facility:

Publishing in the open literature and/or at open scientific/technical meetings	YES / NO
Scientific/technical reports on limited distribution only	YES / NO
No publications or reports	YES / NO

33. Attach a list of the papers that were published in the open literature and/or at open scientific/technical meetings by personnel involved in the declared activities, during the reporting calendar year, in scientific/technical/medical/veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

.....
.....
.....

SECTION (C) ADDITIONAL INFORMATION

[34.⁷⁷ Facility declared as a biological defence facility

77. Delegations which saw this format I as the format for biodefence facilities did not want to keep this paragraph.

- (a) Name of site if different from name of facility:
- [(b) Estimate the funding levels for the current biological defensive programme work at the declared facility:

.....]
- (c) Indicate the average person-years spent on the current biodefence activities [in ranges]:

[.....] [up to x x to y above y]
- (d) State the aims and objectives of the current biological defensive programme work at the declared facility (10 lines or less):

.....
.....
.....]

OR

[If the declared facility satisfied the requirements of the declaration trigger for biological defence facilities in accordance with Annex ..., answer the following:

- (a) Did declared activities at the declared facility include work on pathogenicity?

YES / NO

If yes, summarize the aims and objectives of biological defence work on pathogenicity at the declared facility (10 lines or less):

.....
.....
.....

- (b) Did declared activities at the declared facility include work on virulence?

YES / NO

If yes, summarize the aims and objectives of biological defence work on virulence at the declared facility (10 lines or less):

.....

(c) Did declared activities at the declared facility include work on aerobiology?

YES / NO

If yes, summarize the aims and objectives of biological defence work on aerobiology at the declared facility (10 lines or less):

.....

(d) Did declared activities at the declared facility include work on toxinology?

YES / NO

If yes, summarize the aims and objectives of biological defence work on toxinology at the declared facility (10 lines or less):

.....

]]

35. Vaccine production

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

(b) Estimate the total quantity of ingredients produced, as a single total number of dose equivalents of the corresponding vaccines, in ranges:

[up to 25,000 25,000 to 1,000,000 above 1,000,000]]

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 any units 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:]

[37. High biological containment (BL3 - ...)

If the facility included a high biological containment (BL3 - ...) facility, provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

[up to 30 sq.m. 30-100 sq.m. over 100 sq.m.]

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 sq.m.]

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

(c) 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

(d) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....

]

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	x to y	above y
-------	---------	--------	---------

	Estimated amount produced (dry or wet packed weight in grams)		
Toxin	up to x	x to y	above y

OR

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

* 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:

.....

(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:

.....

(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:

.....
.....
.....

- (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:

.....
.....
.....]

- [39. Did the declared facility engage in genetic modification of any agent and/or toxin listed in Annex A?

YES / NO]

40. Other production

Did the facility produce any products for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging?

YES / NO

If yes,

- (a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

Medicine
[Antimicrobial]

- Pesticides
- Plant inoculants
- Enzymes
- Fine chemicals
- Proteins other than enzymes
- Peptides or amino acids
- Nucleic acids or genetic elements
- Microorganisms for use in biotransformation processes
- Other, specify:

(b) State if any of these products were produced in areas protected by high biological containment:

YES / NO

(c) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight x to y kg dry weight above y kg dry weight

[(d) If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.]

[(e) Did the facility produce plant inoculants and/or biological control agent(s) inside a plant quarantine capability?

YES / NO

If yes,

(i) Indicate which was produced:

.....
.....
.....

(ii) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight x to y kg dry weight above y kg dry weight]

41. Other triggers for facility declarations

(a) Possession of aerosol chambers.

Did the facility possess aerosol chambers?

YES / NO

(b) Possession of aerosol generation equipment.

Did the facility possess aerosol generation equipment?

YES / NO

(c) Conducting genetic modification.

Did the facility conduct genetic modification?

YES / NO

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL-4 - ...) level

[FORMAT II. DECLARATION OF A FACILITY DECLARED OTHER THAN AS A BIOLOGICAL DEFENCE FACILITY

Reporting period

This declaration covers the calendar year:

Declaration trigger(s) that apply to the facility

The facility being declared may satisfy the requirements of more than one declaration trigger.
Circle the trigger(s) that apply:

- Vaccine production facility
- Maximum biological containment (BL-4 - ...) facility

- High biological containment (BL3 - ...) facility

- Work with listed agents and/or toxins

- Other production facility

- Other facility

(A) GENERAL INFORMATION

Name and address

1. Name of the declared facility:
2. Address of the declared facility:
3. Postal address of the declared facility, if different:
4. Building details for the declared facility.

State, as appropriate, building name(s):

building number(s):

room number(s):

Diagram/location

5. Fixed facilities. Provide an indicative map of the locality, showing the declared facility:

.....

6. Mobile facilities.

(a) List the locations at which the declared facility is usually operated:

.....

(b) Indicate where the declared facility was normally kept, if different from above:

.....

(c) List the locations at which the declared facility was operated:

.....

Owner

7. Name:

.....

8. Affiliation (tick all that apply):

9	Ministry/Department/Agency of Defence	9	wholly	9	partially
9	Other government ministry/department/ agency	9	wholly	9	partially
9	Non-government	9	wholly	9	partially

Operator(s) (Only provide details if different from the owner)

9. Name(s):

.....

10. Affiliation (tick all that apply):

9	Ministry/Department/Agency of Defence	9	wholly	9	partially
9	Other government ministry/department/ agency	9	wholly	9	partially
9	Non-government	9	wholly	9	partially

Funding

11. Affiliation of sources of funding (tick all that apply):

- | | | | | | |
|---|---|---|--------|---|-----------|
| 9 | Ministry/Department/Agency of Defence | 9 | wholly | 9 | partially |
| 9 | Other government ministry/department/
agency | 9 | wholly | 9 | partially |
| 9 | Non-government | 9 | wholly | 9 | partially |

Personnel

[12. Estimated number of personnel. Do not include personnel who make minor contributions to the declared activity. Examples may be administrative or health and safety personnel.

	Total personnel			Scientific personnel including engineers			Technical assistance/support personnel		
	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]
[Military] personnel									
[Civilian personnel]									
Contract employees who have worked for more than 6 [person] months in the reporting calendar year									

(B) SCIENTIFIC AND TECHNICAL INFORMATION

[13. Describe the work at the declared facility in the reporting year ([10 lines or less] [... words or more]):

.....

]

[14. Fields of activity at the declared facility

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

	Research and development	Testing and evaluation	[Production [for distribution, sale or storage]]
Detection, identification and diagnosis			
Decontamination, disinfection and pest control			
Prophylaxis			
Physical protection			
Medical or veterinary treatment			
Genetic modification			
[Maintaining culture collection/ repository]			n.a.?
Insect/pest control techniques for use in agriculture/horticulture			
Characteristics of biological agents and toxins:			
pathogenicity/virulence			n.a.?
toxicity			n.a.?
toxinology			n.a.?
environmental stability			n.a.?
[production]			n.a.?
antimicrobial resistance			n.a.?
Aerobiology studies			n.a.?
Vector (insect) ecology			
Plant pathology			
			n.a. = not applicable

]

15. Trigger: Vaccine production⁷⁸

Provide the following information for the production of vaccines [against listed agents and/or toxins] at the facility declared in accordance with paragraph 10 of Article III, section D, subsection I:

[

Vaccine	Estimated number of doses produced (in ranges)			
	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 33%;">up to x</td> <td style="text-align: center; width: 33%;">x to y</td> <td style="text-align: center; width: 33%;">above y</td> </tr> </table>	up to x	x to y	above y
up to x	x to y	above y		

]

OR

[

Vaccine	Level of containment		Estimated number of doses produced (in ranges)		
	BL3	BL4	up to x	x to y	above y

]

OR

[(a) List these vaccines:

.....

78. A view was expressed that the unit “dose” as used in the tables below may need further elaboration for the declaration of facilities producing specific immunogenic components of vaccines as opposed to finished vaccine products.

- (b) Estimate the total quantity of all vaccines produced, as a single total number of doses, in ranges:

[up to 25,000 25,000 to 1,000,000 above 1,000,000]

Was any of this produced under:

High biological containment? YES / NO

Maximum biological containment? YES / NO]

16. Trigger: Maximum biological containment (BL-4 - ...)

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

- (a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

[up to 30 sq.m. 30-100 sq.m. over 100 sq.m.]

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 sq.m.]

- (b) 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

17. Trigger: High biological containment (BL3 - ...)

If the facility satisfied the requirements of the declaration trigger for high biological containment (BL3 - ...), provide the following information:

- (a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

[up to 30 sq.m. 30-100 sq.m. over 100 sq.m.]

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 sq.m.]

(b) 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

18. Trigger: Work with listed agents and/or toxins

If the facility satisfied the requirements of the declaration trigger work with listed agents and/or toxins, provide the following information:

[

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

	Estimated amount produced (dry or wet packed weight in grams)		
Toxin	up to x	x to y	above y

]

OR

[

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

]

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

* With reference to question 14.

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

* With reference to question 14.

OR

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

(a) List the agents worked with:

.....

(b) Estimate the quantity of human, animal or plant pathogen agents produced, as a single total for all agents, in ranges of litres of culture or of working suspensions of agents from solid media:

up to x x to y above y

- (c) Estimate the quantity of toxins produced, as a single total, in ranges of dry weight or wet packed weight, in grams:

up to x x to y above y]

19. Trigger: Other production

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

- (a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

Medicine
[Antimicrobial]
Pesticides
Plant inoculants
Enzymes
Fine chemicals
Proteins other than enzymes
Peptides or amino acids
Nucleic acids or genetic elements
Microorganisms for use in biotransformation processes
Other, specify:

- (b) State if any of these products were produced for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging:

YES / NO

- (c) If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

20. Trigger: Other facilities

(a) Possession of aerosol chambers

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol chambers:

YES / NO

(b) Possession of aerosol generation equipment

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol generation equipment:

YES / NO

(c) Conducting genetic modification

If the facility satisfied the requirements of the declaration trigger for conducting genetic modification, provide the following information:

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL-4 - ...) level

21. Answer the questions about equipment at the declared facility, to be found in the attached Annex ...⁷⁹

[22. Indicate whether tissue culture media was used:

YES / NO

79. The list as developed in the rolling text, Annex A, section II should be used.

If yes, [indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres]

[estimate the amount use, to an accuracy of +/- 20 per cent:]

23. Indicate whether other complex culture media was used:

YES / NO

If yes, [indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres]

[estimate the amount use, to an accuracy of +/- 20 per cent:]

24. Indicate whether embryonated eggs were used to culture microorganisms:

YES / NO

If yes, [indicate which range applies:

[up to 1,000 eggs 1,000- 15,000 eggs over 15,000 eggs]
[1 - 10,000 eggs 10,000 - 100,000 eggs over 100,000 eggs]
[up to 10,000 eggs over 10,000 eggs]]

[estimate the number use, to an accuracy of +/- 20 per cent:]

25. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

If yes, list the vaccines that applied:

.....

26. 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

27. Indicate the publication policy for work at the declared facility:

Publishing in the open literature and/or
at open scientific/technical meetings YES / NO

Scientific/technical reports on limited distribution only YES / NO

No publications or reports YES / NO

28. Attach a list of the papers that were published in the open literature and/or at open scientific/technical meetings by personnel involved in the declared activities, during the reporting calendar year, in scientific/technical/medical/ veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

.....
.....
.....]]