

High Consequence Bio Labs: Growing Risks and Lagging Governance

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Global BioLabs Report 2023



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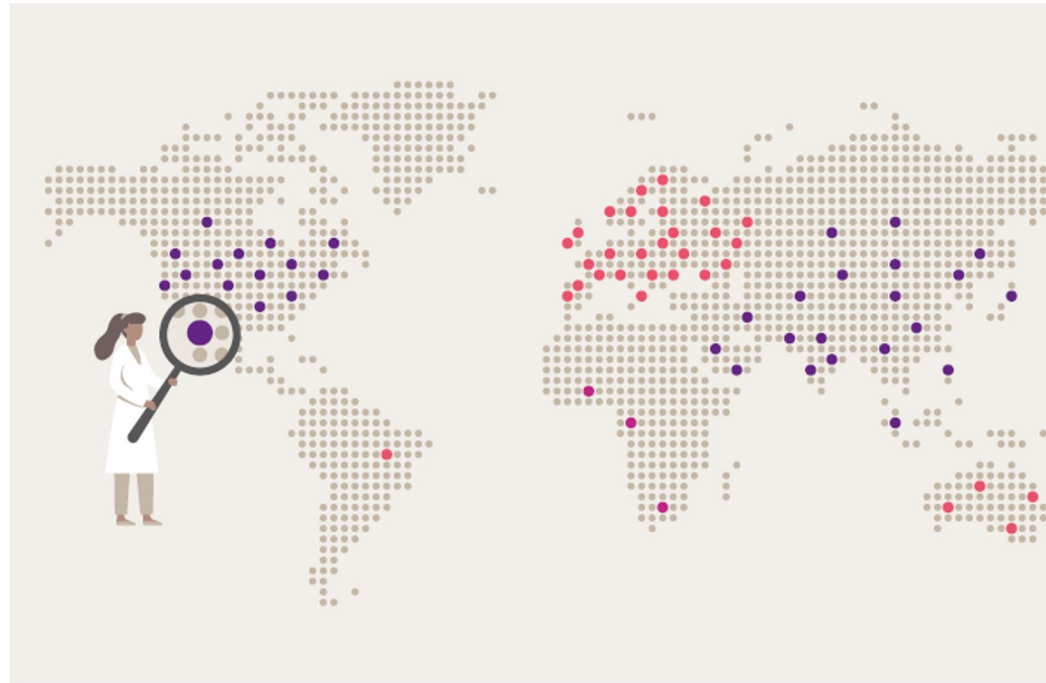
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69 BSL4 Labs

Today, there are at least 69 BSL4 labs in operation, under construction or planned around the world, significantly more than 10 years ago.

Europe has 26 BSL4 labs, Asia 20, North America 15, Oceania 4, Africa 3 and South America 1.

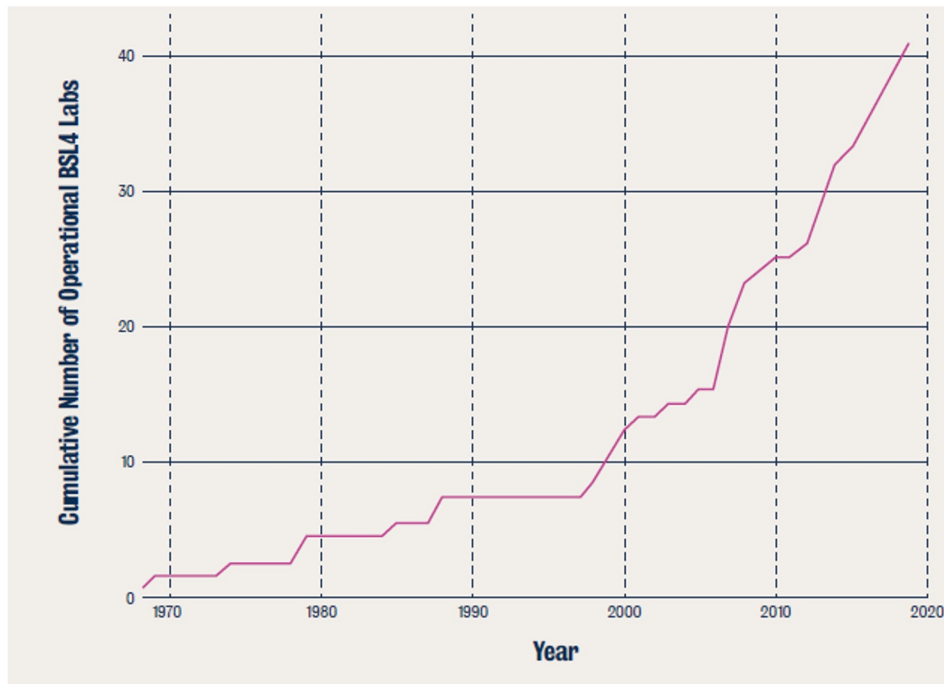
75% of BSL4 labs are in/planned for urban centres.



Global proliferation of BSL4 labs.

12 New

BSL4 labs planned
across nine countries
since the start
of the pandemic



3 out of **5**

BSL4 labs are government-run public health institutions.

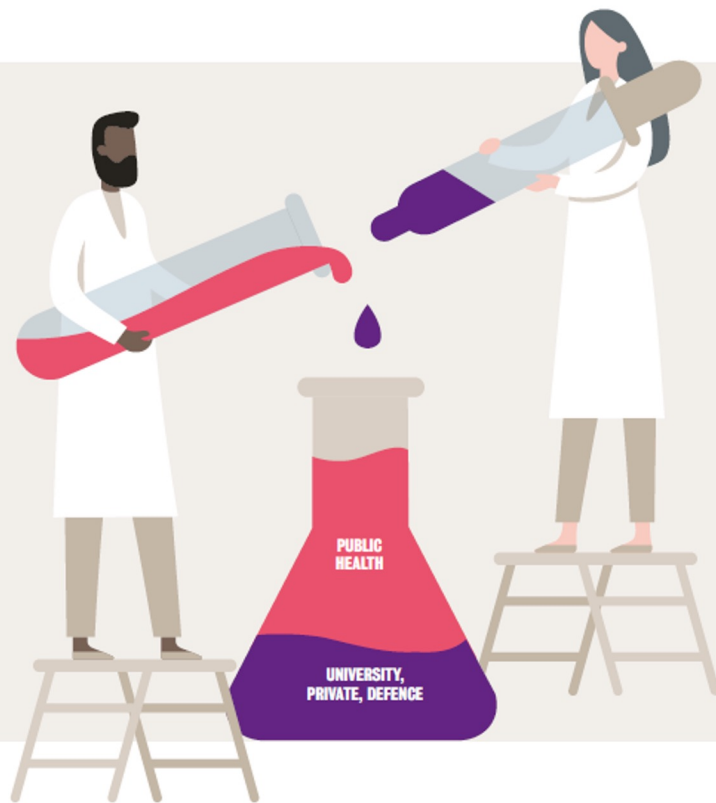
Less than 1/5 are university labs.

Less than 1/5 are defence labs.

Only 2 labs are wholly privately owned.

The vast majority focus on human health.

Sample size:
66 labs.



BSL4 Lab Attributes

Containment Type	Suit	41
	Glove box	7
	Both	1
BSL4 with arthropod (ACL4) facility	N°	2
BSL4s with animal (ABSL4) facility	N°	15
Lab Size	>1,000 sq m	9
	200-1,000 sq m	15
	<200 sq m	22

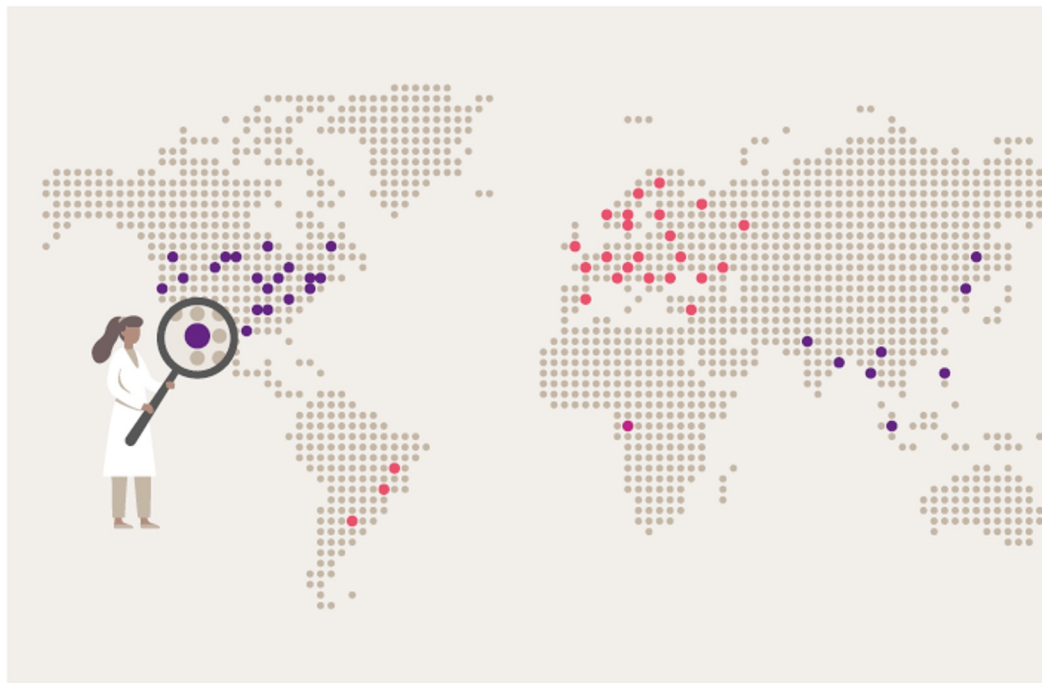
57

BSL3+ Labs

Today, there are at least 57 BSL3+ labs around the world. These labs are all operational except for one in the United States which is still under construction and one in Brazil which is planned.

Europe has 21 BSL3+ labs, North America 19, Asia 10, South America 4, Africa 2, and Oceania 1.

80% of BSL3+ labs are in/planned for urban centres.



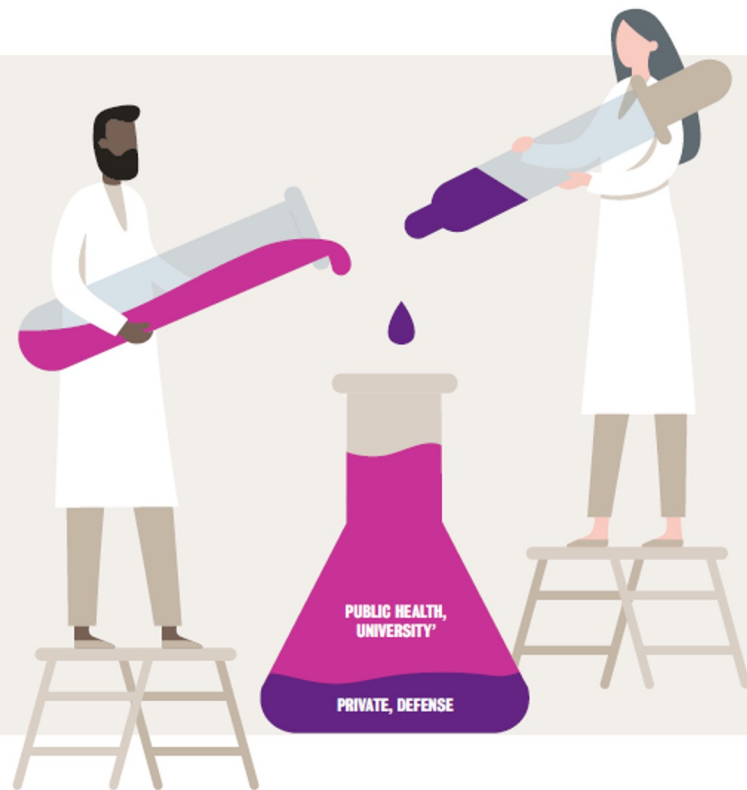
1 of 4

BSL3+ labs deal exclusively with threats to animal health

The 57 BSL3+ labs are evenly divided between government-run public health labs and university-based research labs, with 40 percent, or 25 labs, in each category.

Less than 1/5 are defense labs or privately owned labs.

Sample size:
57 labs.



Global distribution of BSL4 and BSL3+ labs



	BSL-4			BSL-3+			Total
	Per Region	Operational	Planned/Under Construction	Per Region	Operational	Planned/Under Construction	
Europe	26	24	2	21	21	0	47
Asia	20	9	11	10	10	0	30
Africa	3	2	1	2	2	0	5
North America	15	12	3	19	18	1	34
Oceania	4	4	0	1	1	0	5
South America	1	0	1	4	3	1	5
Total	69	51	18	57	55	2	126

Measuring Biorisk Governance



- **Biorisk Management**
 - Biosafety
 - Biosecurity
 - Dual-use Research Oversight
- **National Context**
 - Governance
 - Stability

Biorisk Management Research Methodology



- **Metrics based on international standards**
 - WHO, GHSA, JEE, ISO 35001, NTI
- **Open source research**
- **Scored on legally binding governance measures**

Biosafety

Scoring metric	Number of countries
Governance Framework	
1. National biosafety legislation	23
2. National biosafety oversight entity	22
3. National list	22
4. Whistleblower protections	15
Implementation	
5. Physical/engineering controls	22
6. Good microbiological practices	20
7. Biosafety risk assessments	21
8. Administrative controls	21
9. Training	20
10. Personal protective equipment	19
11. Occupational health	22
12. Inventory	17
13. Transportation safety	22
14. Decontamination	21
15. Incident response plan	20
16. Incident reporting	21
17. Biosafety Association	
National	16
Regional	8
None	3
18. International Engagement	
Participation in 3 groups	7
Participation in 1 or 2 groups	14
No participation	6

Scoring metrics on biosafety

Principles, technologies, measures and practices of containment that can be used to prevent inadvertent release or unintentional exposure to biological agents or biological material

Biosafety scores by country



Biosafety (score out of 20)

Country	Score
Australia	20
Canada	20
France	19
Germany	19
Japan	19
United States	19
Brazil	18
China	18
Italy	18
Singapore	18
Spain	18
Taiwan	18
United Kingdom	18
Sweden	17

Biosafety (score out of 20)

Country	Score
Kazakhstan	16
South Africa	16
Switzerland	16
Hungary	15
Republic of Korea	15
Russian Federation	15
Belarus	14
Czech Republic	11
Philippines	7
India	5
Côte D'Ivoire	3
Gabon	3
Saudi Arabia	1

Biosecurity	
Scoring metric	Number of countries
Governance Framework	
1. National biosafety legislation	17
2. National biosafety oversight entity	16
3. National list	22
4. Whistleblower protections	15
Implementation	
5. Physical security	17
6. Information and cyber security	11
7. Personnel reliability	14
8. Biosecurity risk assessments	12
9. Inventory	15
10. Export controls	24
11. DNA screening	2
12. Training	16
13. Transportation security	20
14. Incident response plan	15
15. Incident reporting	16
International Engagement	
16. BWC	
Ratified and public CBM	9
Ratified and private CBM	16
Ratified but no CBM	2
Signed but not ratified	0
Not signed	0

Biosecurity	
Scoring metric	Number of countries
17. UNSCR 1540	
Part 1: Implementation of national legislation and domestic control measures: 66-100%	20
Part 1: Implementation of national legislation and domestic control measures: 34-65%	2
Part 1: Implementation of national legislation and domestic control measures: 0-33%	3
Part 2: National report and action plan	8
Part 2: National report but no action plan	16
Part 2: No national report	1
18. Membership in International Biosecurity Initiatives	
Member of 5 groups	6
Member of 4 groups	3
Member of 3 groups	4
Member of 2 groups	7
Member of 1 group	4
Member of 0 groups	3

Scoring metrics on biosecurity

Principles, technologies, measures and practices that can be used to prevent unauthorized access to or loss, theft, misuse, diversion or intentional release of a biological agent or biological material

Biosecurity scores by country



Biosecurity (score out of 18)

Country	Score
France	18
United States	18
Australia	17
Canada	17
Japan	17
United Kingdom	17
China	15
Taiwan	14
Kazakhstan	13
Republic of Korea	13
Singapore	13
Taiwan	13
Spain	13
Sweden	13
Hungary	12

Biosecurity (score out of 18)

Country	Score
Russian Federation	12
Sweden	12
Czech Republic	11
Belarus	9
Brazil	9
Germany	9
Italy	6
Switzerland	6
India	5
Philippines	4
South Africa	4
Saudi Arabia	2
Côte D'Ivoire	1
Gabon	1

Scoring metrics on dual-use

Dual-Use Research	
Scoring metric	Number of countries
Governance Framework	
1. National dual-use legislation	1
2. National dual-use research oversight	
Entity with national oversight responsibility	2
Funding agency review process	3
No oversight	22
3. Awareness-raising	3
4. Whistleblower protections	15
Stakeholder Management and Oversight	
5. Self governance measures	11

Life sciences research conducted for peaceful and beneficial purposes that could provide knowledge, information, methods, products or technologies that could also be intentionally misused to endanger the health of humans, animals, or the environment

Dual-use research scores by country



Dual-Use Research (score out of 10)		Dual-Use Research (score out of 10)	
Country	Score	Country	Score
Canada	9	India	1
United Kingdom	5	Kazakhstan	1
United States	5	Republic of Korea	1
Germany	4	South Africa	1
Australia	3	Sweden	1
Taiwan	3	Belarus	0
Hungary	2	China	0
Italy	2	Czech Republic	0
Japan	2	Gabon	0
Switzerland	2	Philippines	0
Brazil	1	Russian Federation	0
Côte D'Ivoire	1	Saudi Arabia	0
France	1	Singapore	0
		Spain	0

Overall biorisk management scores by country



Many of the countries building new labs, some for the first time (marked in bold), score poorly on biorisk management.

Overall Score (out of 48)	
Country	Score
Canada	46
United States	42
Australia	40
United Kingdom	40
France	38
Japan	38
Taiwan	35
China	33
Germany	32
Singapore	31
Spain	31
Kazakhstan	30
Sweden	30
Hungary	29

Overall Score (out of 48)	
Country	Score
Republic of Korea	29
Brazil	28
Russian Federation	27
Italy	26
Switzerland	24
Belarus	23
Czech Republic	22
South Africa	21
India	11
Philippines	11
Côte D'Ivoire	5
Gabon	4
Saudi Arabia	3

Table 13: Governance and Stability composite scores by country

Country	Governance	Stability
Australia	83	68
Belarus	12	26
Brazil	26	23
Canada	86	66
China	25	26
Côte d'Ivoire	16	18
Czech Republic	56	80
France	63	52
Gabon	9	45
Germany	81	72
Hungary	40	67
India	30	15
Italy	50	52
Japan	74	79
Kazakhstan	22	42
Philippines	22	10
Republic of Korea	57	67
Russian Federation	9	17
Saudi Arabia	29	25
Singapore	77	79
South Africa	34	36
Spain	56	58
Sweden	94	80
Switzerland	91	82
Taiwan	71	75
United Kingdom	76	63
United States	60	35

Table 14: Distribution of lab types and status by percentile cutoff in countries with BSL4 labs that are operational, under construction or planned

Lab Type and Status	Metric	Number of Labs in Countries with Percentile Score	
		Less than 50	Greater than/equal to 50
Operational BSL4	Governance	12	39
	Stability	20	31
Planned and Under Construction BSL4	Governance	10	8
	Stability	12	6

Putting Biorisk Management Implementation in Context



Key Recommendations

Labs

- Adopt ISO 35001: Biorisk management for laboratories and other organizations (2019)

States

- Develop whole-of-government national biorisk management system
- Develop national standards for field biosafety
- Encourage and support the creation of a national biosafety association
- Submit public CBMs to BWC and comply fully with UN Security Council Resolution 1540

WHO

- Develop criteria and guidance for BSL3+ labs
- Provide guidance on field biosafety
- Establish collaborating centers for biorisk management in every region
- World Health Assembly should require Director-General to provide annual progress reports on strengthening biorisk management

BWC

- Add BSL-3+ labs and adoption of international biorisk management standards to CBM forms

Minilateral Strategy

- Leverage existing informal biorisk management groups to promote adoption and compliance with ISO 35001

Global Architecture for Biorisk Management

International Organizations

- Biological Weapons Convention (BWC)
- World Health Organization (WHO)
- World Organization for Animal Health (WOAH)
- Food and Agriculture Organization (FAO)
- Interpol

Informal Groups and Networks

- Australia Group (AG)
- Global Partnership's Biological Security Working Group (BSWG)
- BSL4 Zoonotic Laboratory Network (BSL4ZNET)
- European Risk Infrastructure on Highly Pathogenic Agents (ERINHA)
- Global Health Security Agenda Action Package Prevent-3 (GHSA APP-3)
- International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR)
- International Federation of Biosafety Associations (IFBA)
- International Organization for Standardization (ISO)

A Multilateral Approach to Global Biorisk Management

WHO

- Develop criteria and guidance for BSL3+ labs
- Provide guidance on field biosafety
- Establish collaborating centers for biorisk management in every region
- World Health Assembly resolution requiring Director-General to submit annual progress reports on strengthening of global biorisk management

BWC

- Add BSL-3+ labs and adoption of international biorisk management standards to CBM forms

A Minilateral Approach to Global Biorisk Management

- “Coalition of the willing” approach
- Multiple objectives: information-sharing, standard-setting, policy-coordination, capacity-building, confidence-building
- Complement existing multilateral regimes
- Expand mission, membership, and/or role of IFBA, GHSA APP3, BSWG, BSL4ZNET, and ERINHA to promote widespread adoption of ISO 35001: *Biorisk management for laboratories and other related organizations* (2019).
- Establish international mechanism based on IEGBBR for auditing compliance with ISO 35001



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Lab Research Methodology

- Collate a list of BSL3+ and BSL4 labs from previous studies and reports
- Analyse institutional websites for information such as lab construction dates, publications, type of lab, research focus, affiliation, and ongoing research
- Undertake literature and internet searches on reported BSL3+ and BSL4 labs for additional data
- Contact labs directly to verify and complete the information
- Consult with an international group of experts to review the dataset