# Germany



This document is a compilation of all questions, justifications, and sources used to determine the 2021 Global Health Security Index scores for Germany. For a category and indicator-level summary, please see the Country Profile for Germany.

# Category 1: Preventing the emergence or release of pathogens with potential for international concern

## 1.1 ANTIMICROBIAL RESISTANCE (AMR)

### 1.1.1 AMR surveillance, detection, and reporting

#### *1.1.1a*

**Is there a national AMR plan for the surveillance, detection, and reporting of priority AMR pathogens?**

Yes, there is evidence of an AMR plan, and it covers surveillance, detection, and reporting = 2, Yes, there is evidence of an AMR plan, but there is insufficient evidence that it covers surveillance, detection, and reporting = 1, No evidence of an AMR plan = 0

**Current Year Score: 2**

Germany has a national antimicrobial resistance (AMR) plan for the surveillance, detection and reporting of priority AMR pathogens. The German Antimicrobial Resistance Strategy (Deutsche Antibiotika-Resistenzstrategie, DART) is outlined in the policy document "DART 2020: Fighting antibiotic resistance for the good of both humans and animals" [1]. DART is aimed at reducing the further development and spread of antibiotic resistance in Germany and contains measures for recognizing, averting, and combating antibiotic resistance. First conceptualized by the federal government in 2008, the strategy has guided concrete changes in relevant laws aimed at better combatting antimicrobial resistance, especially the 2011 Infection Protection Act and the 2013 Medicinal Products Act [1]. The federal government adopted "DART 2020" in 2015, and regular interim reports have been released, to ensure a high level of transparency [1, 2]. In addition, Germany's Antibiotic Resistance Surveillance monitoring system (Antibiotika-Resistenz-Surveillance) in human medicine at the Robert Koch-Institute (RKI) has been in place since 2007. The system forms the central basis for the recording and evaluation of resistance data from the outpatient and inpatient sectors in Germany [1].

[1] The Federal Government of Germany. 2015. "DART 2020: Fighting antibiotic resistance for the good of both humans and animals (DART 2020: Antibiotika-Resistenzen bekämpfen zum Wohl von Mensch und Tier)". [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/D/DART_2020/BMG_DART_2020_Bericht_dt.pdf]. Accessed 20 January 2021.
[2] Federal Ministry of Health. "German Antimicrobial Resistance Strategy (Deutsche Antibiotika-Resistenzstrategie - DART)". [https://www.bundesgesundheitsministerium.de/themen/praevention/antibiotika-resistenzen/antibiotika-resistenzstrategie.html]. Accessed 20 January 2021.

#### *1.1.1b*

**Is there a national laboratory/laboratory system which tests for priority AMR pathogens?**

All 7 + 1 priority pathogens = 2 , Yes, but not all 7+1 pathogens = 1 , No = 0

**Current Year Score: 2**

There is public evidence that Germany's national laboratory system tests for all 7+1 priority pathogens. Germany's Protection against Infection Act (Infektionsschutzgesetz, or IfSG) lists the pathogens that must be monitored by and reported to the authorities. The list includes the majority of the 7+1 priority pathogens (E. coli, S. aureus, S. pneumoniae, Salmonella spp., Shigella spp, N. gonorrheae and Mycobacterium tuberculosis) with the exception of K. pneumonia [1]. The 2017 Annual report of the European Antimicrobial Resistance Surveillance Network (EARS-Net) confirms that Germany tests for E. coli, K.

pneuomniae, S. pneuomiae and S.aureus [2]. The Robert Koch Institute (RKI), a federal government agency and research institute responsible for disease control and prevention, has been running a laboratory-based Antimicrobial Resistance Surveillance System (ARS) since 2007 [3]. The RKI's laboratories have the capacity to test for antibiotic resistance of Salmonella spp., Shigella spp, N. gonorrheae and Mycobacterium tuberculosis [4]. Laboratories submit data from routine testing of clinical samples from hospitals and outpatient care settings to the RKI for central processing [5]. In 2017, 30% of all general hospitals participated in the ARS through the sharing of data with the RKI, with participation continuing to grow according to 2019 Fourth Interim Report on DART 2020 [6].

[1] Federal Ministry of Health. “Law for the Prevention and Control of Infectious Diseases in Humans - Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG.” Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 20 January 2021.
[2] The European Centre for Disease Prevention and Control (ECDC). November 2018. "Surveillance of antimicrobial resistance in Europe 2017." [https://ecdc.europa.eu/sites/portal/files/documents/EARS-Net-report-2017-update-jan-2019.pdf]. Accessed 20 January 2021.
[3] The Federal Government of Germany. 2015. "DART 2020: Fighting antibiotic resistance for the good of both humans and animals (DART 2020: Antibiotika-Resistenzen bekämpfen zum Wohl von Mensch und Tier)". [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/D/DART_2020/BMG_DART_2020_Bericht_dt.pdf]. Accessed 20 January 2021.
[4] Robert Koch Institute. 2019. "National Reference Centers and Consulting Laboratories (Nationale Referenzzentren und Konsiliarlabore)". [www.rki.de/DE/Content/Infekt/NRZ/nrz_liste.pdf?__blob=publicationFile]. Accessed 20 January 2021.
[5] Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2012. "Antimicrobial resistance in Germany. Four years of antimicrobial resistance surveillance (ARS)". Published November 2012. [www.ncbi.nlm.nih.gov/pubmed/23114435]. Accessed 20 January 2021.
[6] The German Federal Government. 2019. "DART 2020. Fourth Interim report 2019". [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Praevention/Broschueren/DART2020_4-Zwischenbericht_2019_EN.pdf]. Accessed 20 January 2021.

## *1.1.1c*

**Does the government conduct environmental detection or surveillance activities (e.g., in soil, waterways) for antimicrobial residues or AMR organisms?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no publicly available evidence that the government conducts environmental detection or surveillance activities for antimicrobial residues or AMR organisms. The websites of the Federal Ministry of Health and the Federal Ministry for Environment, Nature Conservation and Nuclear Safety do not include information that suggests such surveillance activities exist [1,2]. Furthermore, in 2018 the Federal Environment Agency published a background paper confirming that a systematic monitoring system for antibiotics and antibiotic-resistant bacteria in the environment was still missing in Germany. Antibiotic substances have, however, been found in various environmental media [3]. The Federal Environment Agency is currently working on drawing up policy recommendations for a European Union strategy against AMR in the environment [4].

[1] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 20 January 2021.
[2] Federal Ministry for Environment, Nature Conservation and Nuclear Safety. 2021. Website. [https://www.bmu.de/en/]. Accessed 20 January 2021.
[3] Federal Environment Agency. 2018. “Antibiotics and Antibiotic Resistances in the Environment: Background, Challenges

and Options for Action (Antibiotika und Antibiotikaresistenzen in der Umwelt: Hintergrund, Herausforderungen und Handlungsoptionen)"
[https://www.umweltbundesamt.de/sites/default/files/medien/479/publikationen/181012_uba_hg_antibiotika_bf.pdf]. Accessed 20 January 2021.
[4] Federal Environment Agency. 2019. "Combating the development of antimicrobial resistance (AMR) in the environment (Bekämpfung der Entstehung von Antimikrobieller Resistenz (AMR) in die Umwelt)".
[https://www.umweltbundesamt.de/en/das-uba/was-wir-tun/foerdern-beraten/verbaendefoerderung/projektfoerderungen-projekttraeger/bekaempfung-der-entstehung-von-antimikrobieller]. Accessed 20 January 2021.

## 1.1.2 Antimicrobial control

### *1.1.2a*

**Is there national legislation or regulation in place requiring prescriptions for antibiotic use for humans?**

Yes = 2 , Yes, but there is evidence of gaps in enforcement = 1 , No = 0

**Current Year Score: 2**

Germany has legislation requiring prescriptions for antibiotic use for humans, and there is no evidence of gaps in enforcement. In Germany antibiotics are listed as medicinal products requiring prescriptions in the Ordinance on Prescription-Only Medicines ("Arzneimittelverschreibeverordnung - AMVV"), and therefore must be prescribed by a practising doctor or dentist, as outlined by section 48 of the Medicinal Products Act (Arzneimittelgesetz, AMG) [1,2]. According to section 95 of the Medicinal Products Act, dispensing prescription-only medicine to a consumer without a prescription is punishable by a fine or a prison sentence of up to 3 years [2]. A survey conducted in 2016 suggests that 95% of German patients who use antibiotics acquire their medicine legally through a medical practitioner [3].

[1] Federal Ministry of Health. Law of 12 December 2005, last amended 9 December 2020, "Medicinal Products Act (Arzneimittelgesetz - AMG)". [http://www.gesetze-im-internet.de/amg_1976/index.html]. Accessed 19 January 2021.
[2] Federal Ministry of Health. Law of 21 December 2005, last amended 21 October 2020, "Ordinance on Prescription-Only Medicines (Arzneimittelverschreibeverordnung - AMVV)". [https://www.gesetze-im-internet.de/amvv/BJNR363210005.html]. Accessed 19 January 2021.
[3] European Commission, Directorate-General for Health and Food Safety. April 2016. "Special Eurobarometer 445 - April 2016 'Antimicrobial Resistance'".
[https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/eb445_amr_generalreport_en.pdf]. Accessed 19 January 2021.

### *1.1.2b*

**Is there national legislation or regulation in place requiring prescriptions for antibiotic use for animals?**

Yes = 2 , Yes, but there is evidence of gaps in enforcement = 1 , No = 0

**Current Year Score: 2**

Germany has legislation requiring prescriptions for antibiotic use for animals, and there is no evidence of gaps in enforcement. Antibiotics used to treat animals are listed in the in the Ordinance on Prescription-Only Medicines (Arzneimittelverschreibeverordnung, AMVV) and require a prescription from a practising veterinarian [1, 2]. Moreover, according to section 56 of the Medicinal Products Act (Arzneimittelgesetz, AMG), veterinarians may only prescribe medicated feeding stuffs for animals that they are personally treating [3]. In addition, since 2018, throughout the European Union it has been forbidden to give animals antibiotics for any reason other than medical treatment, due to article 107 of the Regulation

on Veterinary Medicinal Products [4].

[1] Federal Ministry of Health. Law of 21 December 2005, last amended 21 October 2020, "Ordinance on Prescription-Only Medicines (Arzneimittelverschreibeverordnung - AMVV)". [https://www.gesetze-im-internet.de/amvv/BJNR363210005.html]. Accessed 19 January 2021.
[2] Federal Veterinarians Association. "Guidelines for the careful handling of antibacterial veterinary medical products (Leitlinien für den sorgfältigen Umgang mit antibakteriell wirksamen Tierarzneimitteln)". 2015. [https://www.bundestieraerztekammer.de/tieraerzte/leitlinien/]. Accessed 19 January 2021.
[3] Federal Ministry of Health. Law of 12 December 2005, last amended 9 December 2020, "Medicinal Products Act (Arzneimittelgesetz - AMG)". [http://www.gesetze-im-internet.de/amg_1976/index.html]. Accessed 19 January 2021.
[4] European Parliament and Council of the European Union. Regulation (EU) 2019/6. Adopted 11 December 2018. "Regulation of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC." [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019R0006]. Accessed 19 January 2021.

# 1.2 ZOONOTIC DISEASE

## 1.2.1 National planning for zoonotic diseases/pathogens

### *1.2.1a*

**Is there national legislation, plans, or equivalent strategy documents on zoonotic disease?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has legislation and policies on zoonotic disease. The "General Administrative Regulation for Zoonoses in the Food Production Chain", adopted in 2012, regulates the surveillance of zoonoses and zoonotic pathogens, surveillance of antimicrobial resistance among zoonotic pathogens and exchange of information related to zoonotic diseases [1]. Section 3 of the law defines zoonoses as "diseases and/or infections that can naturally be transmitted directly or indirectly between animals and humans" [1]. The Federal Office of Consumer Protection and Food Safety and the Federal Institute for Risk Assessment draw up a Zoonoses Sampling Plan every year to identify the risks of zoonotic disease. The annual plan "contains specific standards about the zoonotic agents to be tested for, the animal populations to be monitored, the stages of the food chain to be monitored, the number of samples to be tested, the sampling methods and the analysis procedures to be used" [2]. The findings ensuing from this research are published in publicly available reports which include recommendations on how to tackle zoonotic risks [3]. In addition, the 2014 Animal Health Act aims to prevent and control animal diseases with a focus on minimizing the risk of zoonotic diseases to human health. It outlines general duties of animal owners, such as the obligation to report dangerous diseases to the authorities. The Federal Ministry for Food and Agriculture's list of notifiable dangerous animal diseases includes the zoonotic diseases Salmonella spp.; Listeria monocytogenes; Verotoxin forming Escherichia coli and Campylobacter spp. [4].

[1] German Federal Government. "General Administration Regulation for Zoonoses in the Food Production Chain. (Allgemeine Verwaltungsvorschrift Zoonosen Lebensmittelkette)". Adopted 10 February 2012. Last amended 18 November 2020. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_10022012_3289026230009.htm]. Accessed 21 January 2021.
[2] Federal Office of Consumer Protection and Food Safety. "Zoonoses monitoring". [https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/02_OfficialFoodControl/06_ZoonosesMonitoring/ZoonosesMonitoring_node.html;jsessionid=F707D412297EDB999B927B1064E07058.2_cid369#doc11007428bodyText3]. Accessed 21 January 2021.

[3] Federal Office of Consumer Protection and Food Safety. "BVL-Report 12.2: Report on Food Safety Zoonoses Monitoring 2016 (Berichte zur Lebensmittelsicherheit Zoonosen-Monitoring 2016)". 2016. [www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/04_Zoonosen_Monitoring/Zoonosen_Monitoring_Bericht_2016.pdf?__blob=publicationFile&v=4]. Accessed 21 January 2021.
[4] Federal Ministry of Food and Agriculture. 2021. "Notifiable Animal Diseases/Epidemics (Anzeigepflichtige Tierseuchen). [https://www.bmel.de/DE/themen/tiere/tiergesundheit/tierseuchen/meldepflichtige-tierkrankheiten.html]. Accessed 20 January 2021.

## *1.2.1b*

**Is there national legislation, plans or equivalent strategy document(s) which includes measures for risk identification and reduction for zoonotic disease spillover events from animals to humans?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has legislation and policies to identify and reduce risk of zoonotic disease spillover events from humans to animals. The General Administrative Regulation for Zoonoses in the Food Production Chain, adopted in 2012, regulates the surveillance of zoonoses and zoonotic pathogens, surveillance of antimicrobial resistance among zoonotic pathogens and exchange of information related to zoonotic diseases [1]. Section 3 of the regulation defines zoonoses as "diseases and/or infections that can naturally be transmitted directly or indirectly between animals and humans" [1]. The Federal Office of Consumer Protection and Food Safety and the Federal Institute for Risk Assessment draw up a Zoonoses Sampling Plan every year to identify the risks of zoonotic disease. The annual plan "contains specific standards about the zoonotic agents to be tested for, the animal populations to be monitored, the stages of the food chain to be monitored, the number of samples to be tested, the sampling methods and the analysis procedures to be used" [2]. The findings ensuing from this research are published in publicly available reports, which include recommendations on how to tackle zoonotic risks. For example, the 2016 Zoonoses Monitoring report suggests that poultry slaughterhouses should be held to higher standards of hygiene and be given technical guidance on how to reduce zoonotic risks [3]. The Federal Office of Consumer Protection and Food Safety also shares findings on its website in a more accessible format with the view of informing and protecting consumers [4].

[1] German Federal Government. "General Administration Regulation for Zoonoses in the Food Production Chain. (Allgemeine Verwaltungsvorschrift Zoonosen Lebensmittelkette)". Adopted 10 February 2012. Last amended 18 November 2020. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_10022012_3289026230009.htm]. Accessed 21 January 2021.
[2] Federal Office of Consumer Protection and Food Safety. "Zoonoses monitoring". [https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/02_OfficialFoodControl/06_ZoonosesMonitoring/ZoonosesMonitoring_node.html;jsessionid=F707D412297EDB999B927B1064E07058.2_cid369#doc11007428bodyText3]. Accessed 21 January 2021.
[3] Federal Office of Consumer Protection and Food Safety. "BVL-Report 12.2: Report on Food Safety Zoonoses Monitoring 2016 (Berichte zur Lebensmittelsicherheit Zoonosen-Monitoring 2016)". 2016. [www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/04_Zoonosen_Monitoring/Zoonosen_Monitoring_Bericht_2016.pdf?__blob=publicationFile&v=4]. Accessed 21 January 2021.
[4] Federal Office of Consumer Protection and Food Safety. 21 November 2016. "Pork continues to be a major source of Salmonella Infection in humans (Schweinefleisch ist nach wie vor eine bedeutende Infektionsquelle des Menschen mit Salmonellen)". [https://www.bvl.bund.de/SharedDocs/Pressemitteilungen/01_lebensmittel/2016/2016_11_21_PI_Zoonosen_Monitoring.html?nn=11019972]. Accessed 21 January 2021.

### *1.2.1c*

**Is there national legislation, plans, or guidelines that account for the surveillance and control of multiple zoonotic pathogens of public health concern?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has regulations in place that account for the surveillance and control of multiple zoonotic pathogens of public health concern. The General Administrative Regulation for Zoonoses in the Food Production Chain (Adopted 10 February 2012. Last amended 18 November 2020) provides legal basis for zoonosis monitoring, while the European Council and European Parliament's "Directive on the monitoring of zoonoses and zoonotic agents provides key guidance [1, 2]. The regulations cover all zoonoses, including zoonotic agents along the food chain. Examples of monitored zoonoses are Salmonella spp., Campylobacter spp; Listeria monocytogenes, Verotoxin-forming Escherichia coli (VTEC), Methicillin-resistant Staphylococcus aureus (MRSA). Findings are published annually in the form of reports by the Federal Office of Consumer Protection and Food Safety (BVL) [3]. These reports determine the prevalence of zoonotic pathogens of public health concern, assess the efficacy of current control measures and make recommendations for further measures to be taken. For example, the 2018 report underlines the importance of slaughterhouses compliance with process hygiene criteria according to Regulation (EC) No. 2073/2005 for Salmonella in poultry carcasses and that appropriate measures should be taken to ensure compliance [3]. The report also mentions precise hygiene standards for slaughterhouses introduced in January 2018 to control the spread of Campylobacter spp. The 2019 report recommends that measures to curb the prevalence of methicillin-resistant Staphylococcus aureus (MRSA) in cow's milk should cover calves as well as dairy cows as both animal groups have been found with the pathogen [4]. The General Administrative Regulation for Zoonoses in the Food Production Chain governs the approach to the coordination and implementation of zoonotic monitoring and for the subsequent reporting, and forms the foundation of zoonotic monitoring. [3] This general administrative regulation is based on Directive 2003/99/EC on the monitoring of zoonoses, which obligates the member states of the European Union to share representative data pertaining to zoonoses as well as antibiotic resistance in foodstuffs, feed and live animals. [5].

[1] German Federal Government. "General Administration Regulation for Zoonoses in the Food Production Chain. (Allgemeine Verwaltungsvorschrift Zoonosen Lebensmittelkette)". Adopted 10 February 2012. Last amended 18 November 2020. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_10022012_3289026230009.htm]. Accessed January 20, 2021.
[2] European Council and European Parliament. Published 2003. "Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC". Accessed January 20, 2021.
[3] Federal Office of Consumer Protection and Food Safety. 2018. "Zoonoses Monitoring 2018: Summary of Findings and Conclusions".
[https://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/04_Zoonosen_Monitoring/Zoonosen_Monitoring_Bericht_2018_en-summary.pdf?__blob=publicationFile&v=3]. Accessed 20 January 2021.
[4] Federal Office of Consumer Protection and Food Safety. 2019. "Zoonoses Monitoring 2019".
[https://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/04_Zoonosen_Monitoring/Zoonosen_Monitoring_Bericht_2019.pdf?__blob=publicationFile&v=5]. Accessed 22 February 2021.
[5] Federal Office of Consumer Protection and Food Safety. "Zoonoses monitoring".
[https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/02_OfficialFoodControl/06_ZoonosesMonitoring/ZoonosesMonitoring_node.html;jsessionid=F707D412297EDB999B927B1064E07058.2_cid369#doc11007428bodyText3]. Accessed 20 January 2021.

### *1.2.1d*

**Is there a department, agency, or similar unit dedicated to zoonotic disease that functions across ministries?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no publicly available evidence that Germany has a department, agency or similar unit dedicated to zoonotic disease that functions across ministries. The agency leading zoonoses monitoring in Germany is the Federal Office of Consumer Protection and Food Safety (BVL) [1]. The BVL is an agency of the federal government and comes under the Federal Ministry of Food and Agriculture (BMEL). The BVL does not function across ministries, though it cooperates with other ministries and agencies and the federal states. The states report their monitoring results to a central BVL notification point. The BVL analyses the data and publishes an annual report on zoonoses monitoring. The Federal Institute for Risk Assessment, a separate institution, assesses the results. Other ministries or institutions involved in zoonoses monitoring are the Federal Ministry of Food and Agriculture, the Friedrich-Loeffler Institute and the Robert Koch Institute. The BVL is Germany's national contact point for the European Rapid Alert System for Food and Feed [1]. The websites of the Federal Ministry of Health, Federal Ministry of the Interior, Building and Community, Federal Ministry of Food and Agriculture as well as local and international media do not include information on a department, agency or similar unit dedicated to zoonotic disease that functions across ministries [2, 3, 4].

[1] Federal Office of Consumer Protection and Food Safety. “Zoonoses monitoring”. [https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/02_OfficialFoodControl/06_ZoonosesMonitoring/ZoonosesMonitoring_node.html;jsessionid=F707D412297EDB999B927B1064E07058.2_cid369#doc11007428bodyText3]. Accessed 20 January 2021.
[2] Federal Ministry of the Interior, Building and Community 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 21 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 21 January 2021.
[4] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 21 January 2021.

## 1.2.2 Surveillance systems for zoonotic diseases/pathogens

### *1.2.2a*

**Does the country have a national mechanism (either voluntary or mandatory) for owners of livestock to conduct and report on disease surveillance to a central government agency?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has a mandatory mechanism for owners of livestock to conduct and report on disease surveillance. Section 4 of the Animal Health Act (adopted 2014, last amended 2019) states that animal owners (such as livestock owners) are obliged to immediately inform the relevant authorities, typically the local Veterinary Office, if they identify or suspect a case of a notifiable animal disease [1,2]. A list of the notifiable dangerous diseases for livestock (anzeigepflichtige Tierseuchen) and the notifiable diseases for pets (meldepflichtige Tierkrankheiten) is maintained by the Federal Ministry of Food and Agriculture and can be found on their website [2,3]. The German state has a comprehensive zoonosis surveillance system in place, coordinated by the Federal Office of Consumer Protection and Food Safety which collects, analyses and publishes representative data on the occurrence of zoonotic agents and antibiotic resistance in food, feed and live animals [4]. The main legal basis for this zoonoses monitoring system is the 2017 General Administrative Regulation on Zoonoses in the Food

Production Chain [5].

[1] Federal Ministry of Food and Agriculture. “Animal Health Act (Tiergesundheitsgesetz - TierGesG)”. Law adopted 1 May 2014. Last amended 20 November 2019. [https://www.gesetze-im-internet.de/tiergesg/BJNR132400013.html]. Accessed 20 January 2021.
[2] Federal Ministry of Food and Agriculture. 2021. “Notifiable Animal Diseases/Epidemics (Anzeigepflichtige Tierseuchen). [https://www.bmel.de/DE/themen/tiere/tiergesundheit/tierseuchen/meldepflichtige-tierkrankheiten.html]. Accessed 20 January 2021.
[3] Federal Ministry of Food and Agriculture. 2021. "Notifiable Animal Diseases/Illnesses (Meldepflichtige Tierkrankheiten)" [www.bmel.de/DE/Tier/Tiergesundheit/Tierseuchen/_texte/MeldepflichtigeTierseuchen.html]. Accessed 20 January 2021.
[4] Federal Office of Consumer Protection and Food Safety. “Zoonoses monitoring”. [https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/02_OfficialFoodControl/06_ZoonosesMonitoring/ZoonosesMonitoring_node.html;jsessionid=F707D412297EDB999B927B1064E07058.2_cid369#doc11007428bodyText3]. Accessed 20 January 2021.
[5] German Federal Government. "General Administration Regulation for Zoonoses in the Food Production Chain. (Allgemeine Verwaltungsvorschrift Zoonosen Lebensmittelkette)". Adopted 10 February 2012. Last amended 18 November 2020. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_10022012_3289026230009.htm]. Accessed 20 January 2021.

## *1.2.2b*

**Is there legislation and/or regulations that safeguard the confidentiality of information generated through surveillance activities for animals (for owners)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has regulations in place that safeguard the confidentiality of information generated through surveillance activities for animals. The General Administrative Regulation for Zoonoses in the Food Production Chain (adopted 2012, last amended 2020) includes a titled Data Transmission and Creation of a Database (§9 Datenübermittlung und Erstellung einer Datenbasis) [1]. This section stipulates that data pertaining to zoonotic surveillance must be handled in accordance with the administrative order AVV Data Exchange - AVV Data (AVV Datenaustausch 2010) [1]. Section 7 of this General Administrative Regulation on the Exchange of Data in the Field of Food Safety and Consumer Protection states that when exchanging and dealing with the data, the basic guidance of the Federal Office for Information Security and the regulations for the protection of personal data must be observed [2].

[1] German Federal Government. "General Administration Regulation for Zoonoses in the Food Production Chain. (Allgemeine Verwaltungsvorschrift Zoonosen Lebensmittelkette)". Adopted 10 February 2012. Last amended 18 November 2020. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_10022012_3289026230009.htm]. Accessed 20 January 2021.
[2] German Federal Government. “General Administrative Regulation on the Exchange of Data in the Field of Food Safety and Consumer Protection (Allgemeine Verwaltungsvorschrift über den Austausch von Daten im Bereich der Lebensmittelsicherheit und des Verbraucherschutzes, AVV Datenaustausch - AVV Data)”. Adopted 15 December 2010. [https://www.verwaltungsvorschriften-im-internet.de/bsvwvbund_15122010_321221010032.htm]. Accessed 20 January 2021.

### *1.2.2c*

**Does the country conduct surveillance of zoonotic disease in wildlife (e.g., wild animals, insects, other disease vectors)?**
Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence that Germany conducts some surveillance of zoonotic disease in wildlife. The German Federal Institute for Risk Assessment, a scientific public body under the portfolio of the Federal Ministry of Food, Agriculture and Consumer Protection, draws up a plan every year in tandem with the Federal Office of Consumer Protection and Food Safety on what zoonoses are to be included in Germany's annual zoonotic surveillance [1,2]. This Zoonoses Sampling Plan (Zoonosen Stichprobenplan) is defined by the General Administrative Regulation for Zoonoses in the Food Production Chain (adopted 2012, last amended 2020) [2]. According to the Federal Office of Consumer Protection and Food Safety, the annual plan "contains specific standards about the zoonotic agents to be tested for, the animal populations to be monitored, the stages of the food chain to be monitored, the number of samples to be tested, the sampling methods and the analysis procedures to be used" [1]. The plan investigates a representative sample of all animal populations and therefore includes wild animals [3,4]. The 2017 and 2019 Zoonoses Sampling Plans included research into wild animals, with the former including data on wild boars and the latter data on wild birds such as geese and ducks [3,4].

[1] Federal Office of Consumer Protection and Food Safety. “Zoonoses monitoring”. [https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/02_OfficialFoodControl/06_ZoonosesMonitoring/ZoonosesMonitoring_node.html;jsessionid=F707D412297EDB999B927B1064E07058.2_cid369#doc11007428bodyText3]. Accessed 20 January 2021.
[2] German Federal Government. "General Administration Regulation for Zoonoses in the Food Production Chain. (Allgemeine Verwaltungsvorschrift Zoonosen Lebensmittelkette)". Adopted 10 February 2012. Last amended 18 November 2020. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_10022012_3289026230009.htm]. Accessed 20 January 2021.
[3] Federal Office of Consumer Protection and Food Safety. "BVL-Report 12.2: Report on Food Safety Zoonoses Monitoring 2016 (Berichte zur Lebensmittelsicherheit Zoonosen-Monitoring 2016)". 2016. [www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/04_Zoonosen_Monitoring/Zoonosen_Monitoring_Bericht_2016.pdf?__blob=publicationFile&v=4]. Accessed 20 January 2021.
[4] Federal Office of Consumer Protection and Food Safety. "BVL-Report 15.2: Report on Food Safety Zoonoses Monitoring 2019 (Berichte zur Lebensmittelsicherheit Zoonosen-Monitoring 2019)". 2019. [https://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/04_Zoonosen_Monitoring/Zoonosen_Monitoring_Bericht_2019.pdf?__blob=publicationFile&v=5]. Accessed 20 January 2021.

## 1.2.3 International reporting of animal disease outbreaks

### *1.2.3a*

**Has the country submitted a report to OIE on the incidence of human cases of zoonotic disease for the last calendar year?**
Yes = 1 , No = 0

**Current Year Score: 1**

2019

OIE WAHIS database

## 1.2.4 Animal health workforce

### *1.2.4a*

**Number of veterinarians per 100,000 people**

Input number

**Current Year Score: 39.2**

2019

OIE WAHIS database

### *1.2.4b*

**Number of veterinary para-professionals per 100,000 people**

Input number

**Current Year Score: -**

No data available

OIE WAHIS database

## 1.2.5 Private sector and zoonotic

### *1.2.5a*

**Does the national plan on zoonotic disease or other legislation, regulations, or plans include mechanisms for working with the private sector in controlling or responding to zoonoses?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is insufficient evidence that Germany has any plan, legislation or regulation for working with the private sector in controlling or responding to zoonoses. While Germany's national plan highlights working with a variety of stakeholders in controlling or responding to zoonoses, there are few specifics on how the private sector is involved. The country's German Antimicrobial Resistance Strategy (DART 2020), which seeks to reduce antimicrobial resistance and applies to human medicine, veterinary medicine and agriculture, notes that in the pursuit of its goals regarding zoonoses monitoring it is committed to work with a wide array of stakeholders, including "the National Zoonoses Platform, the Higher Federal Authorities, the WHO, the OIE, the European Commission, the GHSA and G7 states, universities, academies, scientific institutions, the German Centre for Infection Research, the pharmaceutical industry and relevant institutions in the G7 partner states" [1]. While some of these institutions belong to the private sector, there is insufficient evidence of legislation or regulations setting out how the state works with the private sector in controlling or responding to zoonoses [2, 3]. The websites of the Federal Ministry of Food and Agriculture, Federal Office of Consumer Protection and Food Safety, the Federal Institute for Risk Assessment, all of which play a role in zoonoses monitoring in Germany, do not make reference to legislation, regulation or a plan for public authorities working with the private sector in controlling or responding to zoonoses [4, 5, 6].

[1] German Federal government. 2015. "DART 2020 Fighting antibiotic resistance for the good of both humans and animals". [www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/D/DART_2020/BMG_DART_2020_Bericht_en.pdf]

. Accessed 20 January 2021.
[2] Federal Office of Consumer Protection and Food Safety. 2019. "Zoonoses monitoring". [https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/02_OfficialFoodControl/06_ZoonosesMonitoring/ZoonosesMonitoring_node.html;jsessionid=F707D412297EDB999B927B1064E07058.2_cid369#doc11007428bodyText3]. Accessed 20 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/en.html]. Accessed 20 January 2021.
[4] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 20 January 2021.
[5] Federal Office of Consumer Protection and Food Safety. 2021. Website. [https://www.bvl.bund.de/DE/Home/home_node.html]. Accessed 20 January 2021.
[6] Federal Institute for Risk Assessment. 2021. Website. [www.bfr.bund.de/en/home.html]. Accessed 20 January 2021.

# 1.3 BIOSECURITY

## 1.3.1 Whole-of- government biosecurity systems

### *1.3.1a*

**Does the country have in place a record, updated within the past five years, of the facilities in which especially dangerous pathogens and toxins are stored or processed, including details on inventories and inventory management systems of those facilities?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has an inventory, updated in the last five years, of facilities in which especially dangerous pathogens and toxins are stored or processed. Germany's biosafety and biosecurity laws and regulations covering secure storage are the Biological Safety Ordinance and the Technical Regulations for Biological Agents (TRBA), adopted 17 October 2013 and last amended 2 May 2018 [1, 2]. The regulations that deal with the registration of facilities are the Protection Against Infection Act (adopted 20 July 2000, last amended 21 December 2020), the Animal Pathogen Ordinance (adopted 7 December 1971, last amended 31 August 2015), the Genetic Engineering Act (adopted 24 October 1990, last amended 31 August 2015, and the Biological Agents Ordinance (adopted 15 July 2013, last amended 29 March 2017) [1, 3, 4, 5, 6]. Section 44 of the Protection Against Infection Act states that "any person who wishes to import or export pathogens to and from the territory covered by this Act, store, supply or work with them there requires an authorization to do so from the competent authority" [3]. The websites of the Federal Ministry of Health and the Federal Ministry of the Interior, Building and Community do not make mention of a record of facilities in which especially dangerous pathogens and toxins are stored or processed [6, 7]. Germany's annual reports for the years 2017-2020 submitted to the United Nations' Biological Weapons Convention's Electronic Confidence Building Measures Portal or the VERTIC database do not mention Germany having in place any record of the facilities in which especially dangerous pathogens and toxins are stored or processed [8, 9].

[1] WFCC. 2012. “Biosafety and Biosecurity Regulations in Germany". [www.wfcc.info/iccc12/presentations/pkampfer.pdf]. Accessed 21 January 2021.
[2] Federal Institute for Occupational Safety and Health. "TBRA 100: Protective measures for activities involving biological agents in laboratories (Schutzmaßnahmen für Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien)”. Adopted 17 October 2013. Last amended 2 May 2018 [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=2]. Accessed 21 January 2021.
[3] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von

Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.
[4] Federal Ministry of Food and Agriculture. "Animal Pathogen Ordinance (Verordnung über das innergemeinschaftliche Verbringen und die Einfuhr von Tierseuchenerregern)". Adopted 7 December 1971. Last amended 31 August 2015. [https://www.gesetze-im-internet.de/tierseuchereinfv/BJNR019600971.html] Accessed 21 January 2021.
[5] Federal Government. "Genetic Engineering Act (Verordnung über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen (Gentechnik-Sicherheitsverordnung - GenTSV)" Adopted 24 October 1990. Last amended 31 August 2015. [https://www.gesetze-im-internet.de/gentsv/BJNR023400990.html]. Accessed 21 January 2021.
[6] Federal Government. "Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)". Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[6] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/en/en.html]. Accessed 21 January 2021.
[7] Federal Ministry of the Interior, Building and Community. 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 21 January 2021.
[8] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[9] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

## *1.3.1b*

**Does the country have in place legislation and/or regulations related to biosecurity which address requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has in place biosecurity legislation that addresses requirements such as physical containment, operation practices, failure reporting systems of facilities in which especially dangerous pathogens and toxins are stored or processed. The relevant domestic regulations are set out in the Technical Regulations for Biological Agents (TRBA). The regulation TRBA 100 ("Protective measures for specific and unspecific work in laboratories involving biological agents") sets out technical and organizational protective measures of biosecurity in laboratories for four levels of protection such as the use of containment measures, hygiene plans, use of personal protective equipement and recommendations for using airlocks[1]. In Germany, "he major aspects of biosecurity in microbiological laboratories are covered by existing regulations in line with the CWA 15793 [2]. The European Committee for Standardization Workshop Agreement (CWA) 15793 "Laboratory Biorisk Management Standard was adopted and published in 2008; 74 participants from 24 countries developed the management system approach to biosafety and biosecurity in the laboratories; the process was funding by the European Commission. The CWA 15793, the standard that Germany complies with, covers, among others, biorisk management policy; hazard identification, risk assessment, and risk control; roles, responsibilities, and authorities; training, awareness and competence; operational control; emergency response and contingency plans; inventory monitoring and control; accident and incident investigation; inspection and audit, and containment [3, 4, 5]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal do not include any additional information on legislation related to biosecurity which address requirements such as physical containment, operation practices, failure reporting systems and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or

processed [6].

[1] VERTIC. "Germany". TRBA 100. [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=2]. Accessed 21 January 2021.
[2] Peter Kämpfer Justus-Liebig-University Giessen, German. 2012. "Biosafety and Biosecurity Regulations in Germany". [www.wfcc.info/iccc12/presentations/pkampfer.pdf]. Accessed 21 January 2021.
[3] Laboratory Biorisk Management Standard CWA 15793:2008. [https://slideplayer.com/slide/6650644/]. Accessed 21 January 2021.
[4] Laboratory Biorisk Management CWA 15793. Text. [www.scribd.com/document/266538820/Laboratory-Biorisk-Management-CWA-15793]. Accessed 21 January 2021.
[5] Centers for Disease Control and Prevention. “CWA 16393: Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008”. January 2012. [https://www.cdc.gov.tw/Uploads/files/201504/d0feebf2-a92c-46e1-914a-b9d1435bc52f.pdf]. Accessed 21 January 2021.
[6] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.

## *1.3.1c*

**Is there an established agency (or agencies) responsible for the enforcement of biosecurity legislation and regulations?**
Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence of a single central government agency responsible for the enforcement of biosecurity legislation and regulations. Legislation on biosecurity such as the Biological Agents Ordinance (adopted 15 July 2013, last amended 29 March 2017) and the Technical Regulations for Biological Agents (TRBA) does not mention a single enforcing agency but states that the competent authorities are tasked with overseeing the implementation of biosecurity measures [1, 2]. Indeed, Germany's sixteen federal states autonomously enforce biosecurity regulations, with different authorities responsible for biosafety, biosecurity and public health in some states [3]. Domestic regulations on biosecurity are set out in the TRBA. The TRBA 100, "Protective measures for specific and unspecific work in laboratories involving biological agents" (adopted September 1999, last amended 2 May 2018), sets out technical and organizational protective measures of biosecurity in laboratories [4]. In Germany, the major aspects of biosecurity in microbiological laboratories are covered by existing regulations, according to the European Committee for Standardization's Workshop Agreement 15793 (CWA 15793) [5, 6]. The annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC database do not include information on a national agency (or agencies) responsible for the enforcement of biosecurity legislation and regulations [7, 8]. The websites of the Federal Ministry of Health, Federal Ministry of Defense, Federal Ministry of Food and Agriculture as well as local and international media do not include information on any established agency responsible for the enforcement of biosecurity legislation and regulations. [9, 10, 11]

[1] Federal Government. “Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)”. Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[2] Federal Institute for Occupational Safety and Health. “Technical Regulations for Biological Agents” [https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/TRBA.html]. Accessed 10 February 2021.
[3] Committee on Biological Agents (ABAS). "Germany’s national System for prevention of risks from biological agents and the role of the committee on biological agents and its cooperation with other bodies".

[https://osha.europa.eu/sites/default/files/seminars/documents/4%20F%C3%B6rster.pdf]. Accessed 21 January 2021.
[4] Federal Institute for Occupational Safety and Health. "TRBA 100 Protective measures for activities involving biological agents in laboratories". Adopted September 1999. Last amended 2 May 2018. [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=2]. Accessed 21 January 2021.
[5] Peter Kämpfer Justus-Liebig-University Giessen, German. 2012. "Biosafety and Biosecurity Regulations in Germany". [www.wfcc.info/iccc12/presentations/pkampfer.pdf]. Accessed 21 January 2021.
[6] Laboratory Biorisk Management CWA 15793. Text. [www.scribd.com/document/266538820/Laboratory-Biorisk-Management-CWA-15793]. Accessed 21 January 2021.
[7] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[8] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.
[9] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 21 January 2021.
[10] Federal Ministry of Defence. 2021. Website. [https://www.bmvg.de/de]. Accessed 21 January 2021.
[11] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 21 January 2021.

### *1.3.1d*

**Is there public evidence that shows that the country has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities?**

Yes = 1 , No = 0

**Current Year Score: 0**

In Germany dangerous pathogens and toxins are handled by a limited number of facilities but there is insufficient evidence that the state has taken action to consolidate its inventories into a minimum number of facilities. In 1995, the Federal Ministry of Health and the Robert Koch Institute (RKI) established a public health microbiology system consisting of national reference centers (NRCs) and consultant laboratories (CLs) [1]. There are 19 NRCs and 40 CLs (appointed for three years). These laboratories are considered national centers of research excellence in laboratory science for a particular pathogen or group of pathogens. Five NRCs and 10 CLs are situated within the RKI. The remaining centers are at universities, federal or state institutes, private laboratories and research facilities in Germany. The RKI is the only top level of security (BSL-4) laboratory where scientists handle pathogens of the highest Risk Group 4, such as Ebola, Lassa and Nipah viruses [2]. The websites of the federal ministries of Health; Defence; and Food, Agriculture and Consumer Protection, and the Federal Institute for Risk Assessment do not contain information showing that Germany has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities [3, 4, 5, 6]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC databse do not include information that show Germany has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities [7, 8].

[1] Robert Koch Institute. 2021. "National Reference Centers and Consultant Laboratories". [www.rki.de/EN/Content/infections/Diagnostics/NatRefCentresConsultantLab/natRefCentresConsultantLab_node.html]. Accessed 21 January 2021.
[2] Robert Koch Institute. 2021. "The Biosafety Level-4 Laboratory at RKI". [www.rki.de/EN/Content/infections/Diagnostics/SpecialLab/BSL4Laboratory_page.html?nn=7622198#doc8392128bodyText1]. Accessed 21 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 21 January 2021.
[4] Federal Ministry of Defence. 2021. Website. [https://www.bmvg.de/de]. Accessed 21 January 2021.

[5] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 21 January 2021.
[6] Federal Institute for Risk Assessment. 2021. Website. [www.bfr.bund.de/en/home.html]. Accessed 21 January 2021.
[7] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[8] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

### *1.3.1e*

**Is there public evidence of in-country capacity to conduct Polymerase Chain Reaction (PCR)–based diagnostic testing for anthrax and/or Ebola, which would preclude culturing a live pathogen?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has in-country capacity to conduct Polymerase Chain Reaction (PCR)–based diagnostic testing for anthrax and Ebola. The Unit ZBS 1 of the Robert Koch Institute hosts the German Consulting Laboratory for Poxviruses and offers Polymerase Chain Reaction (PCR)-based diagnostic testing for Ebola. The diagnostic range of the laboratory unit includes other viruses such as Crimean Congo haemorrhagic fever virus, Chikungunya virus, Dengue virus, Yellow fever virus, Japanese encephalitis virus, Lassa virus, Marburg, virus, Rift Valley fever virus, SARS corona virus, West Nile virus, and Venezuelan equine encephalitis virus [1]. The Unit ZBS 2 investigates highly pathogenic bacteria, including anthrax through PCR diagnostic testing, culture and antibiogram and antigen or antibody detection.

[1] Robert Koch Institute. "Specialised laboratory for highly pathogenic viruses. Consulting Laboratory for highly pathogenic viruses". 2021. [https://www.rki.de/EN/Content/infections/Diagnostics/SpecialLab/specialLab_node.html]. Accessed 21 January 2021.

## 1.3.2 Biosecurity training and practices

### *1.3.2a*

**Does the country require biosecurity training, using a standardized, required approach, such as through a common curriculum or a trainthe-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence of a requirement for standardized biosecurity training in Germany. The Technical Regulations for Biological Agents (TRBA, adopted 17 October 2013 and last amended 2 May 2018) state that personnel should be adequately trained to minimise biorisks but do not specify what exactly the training should involve [1]. Section 14 of the Biological Agents Ordinance (adopted 15 July 2013, last amended 29 March 2017) describes very generally how personnel working with biological agents must be trained but the description does not amount to a standardized curriculum nor does it reference one, nor is there an explicit focus on biosecurity [2]. Similarly, the Protection of Workers Act (adopted 7 August 1996, last amended 19 June 2020) states that an employer must give workers sufficient and appropriate training regarding safety and health protection, however, there are is no clarification as to what training should involve with regards to biosecurity training [3]. There is, however, guidance from the European Committee for Standardization Workshop Agreement (CWA) 15793, which sets out requirements for biosecurity personnel training, qualifications, experience and aptitudes of personnel;

supervision of new employees; continuity and succession planning, and biorisk-related training" [4]. Additionally, the European Union funded project EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level published a checklist in 2015 for laboratory biorisk management, which allows laboratories to perform self-evaluations on their biorisk management standards [5]. There is therefore evidence of European Union biorisk training standards but there is no German in-country legislation or regulation that enforces these standards. The websites of the Federal Ministry of Health, Federal Ministry of the Interior, Building and Community, Federal Ministry of Food and Agriculture as well as local and international media do not include information on standardized biosecurity training. [7, 8, 9]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC Database do not include specific information on a requirement for standardized biosecurity training in Germany [10, 11].

[1] Federal Institute for Occupational Safety and Health. "TBRA 100: Protective measures for activities involving biological agents in laboratories (Schutzmaßnahmen für Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien)". Adopted 17 October 2013. [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=2] Last amended 2 May 2018. Accessed 21 January 2021.
[2] Federal Government. "Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)". Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[3] Federal Government. "Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)". Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[4] Federal Government. "Protection of Workers Act (Arbeitsschutzgesetz – ArbSchG)". Adopted 7 August 1996. Last amended 19 June 2020. [https://www.gesetze-im-internet.de/arbschg/BJNR124610996.html]. Accessed 21 January 2021.
[5] European Committee for Standardization Workshop Agreement (CWA). "CWA 16393: Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008" 2012. [https://www.cdc.gov.tw/Uploads/files/201504/d0feebf2-a92c-46e1-914a-b9d1435bc52f.pdf]. Accessed 21 January 2021.
[6] EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level. 2015. "Integrated European Checklist for Laboratory Biorisk Management in Handling of High Consequence Risk Group 3 and 4 Agents (ECL-Biorisk)". [www.emerge.rki.eu/Emerge/EN/Content/Topics/Rules/ECL_Biorisk.pdf?__blob=publicationFile]. Accessed 21 January 2021.
[7] Federal Ministry of the Interior, Building and Community. 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 21 January 2021.
[8] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 21 January 2021.
[9] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 21 January 2021.
[10] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[11] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

## 1.3.3 Personnel vetting: regulating access to sensitive locations

### *1.3.3a*

**Do regulations or licensing conditions specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to the following checks: drug testing, background checks, and psychological or mental fitness checks?**

Personnel are subject to all three of these checks = 3, Personnel are subject to two of these checks = 2, Personnel are subject to one of these checks = 1, Personnel are not subject to any of these checks = 0

Current Year Score: 1

In Germany, background checks are required for people who work in facilities with sensitive biological materials. The handling of sensitive biological materials is considered a security-sensitive activity and is thus subject to checks outlined in the Security Vetting Act (adopted 20 April 1994, last amended 19 June 2020) [1, 2]. Under the act, to be security vetted, a person must submit a security declaration, which includes detailed personal data, references by three reliable persons, possible criminal records and previous security and vetting checks if available. The Security Vetting Act, however, does not mention drug, psychological or mental fitness checks. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC Database do not include information on checks for people who work in facilities with especially dangerous pathogens, toxins, or biological materials with pandemic potential [3, 4]. The Technical Regulations for Biological Agents (TRBA), adopted 17 October 2013 and last amended 2 May 2018), the Protection Against Infection Act (adopted 20 July 2000, last amended 21 December 2020), the Animal Pathogen Ordinance (Adopted 7 December 1971, last amended 31 August 2015), the Genetic Engineering Act (adopted 24 October 1990, last amended 31 August 2015, and the Biological Agents Ordinance (adopted 15 July 2013, last amended 29 March 2017) do not include any information on mental fitness checks or drug tests [5, 6, 7, 8, 9].

[1] German Federal Government. “Security Vetting Act (Sicherheitsüberprüfungsgesetz - SÜG). Adopted 20 April 1994. Last amended 19 June 2020. [www.gesetze-im-internet.de/s_g/BJNR086700994.html]. Accessed 21 January 2021.
[2] The United Nations Office at Geneva. "Security vetting of personnel handling dangerous biological materials". Submitted by the Federal Republic of Germany. [www.onug.ch/80256EDD006B8954/(httpAssets)/A134CBD2DB0EE78AC12574A2004258C5/$file/Germany+Security+vetting+of+personnel+handling+dangerous+biolgical+materials+WP.pdf]. Accessed 21 January 2021.
[3] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[4] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.
[5] Federal Institute for Occupational Safety and Health. "TBRA 100: Protective measures for activities involving biological agents in laboratories (Schutzmaßnahmen für Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien)”. Adopted 17 October 2013. [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=2] Last amended 2 May 2018. Accessed 21 January 2021.
[6] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.
[7] Federal Ministry of Food and Agriculture. “Animal Pathogen Ordinance (Verordnung über das innergemeinschaftliche Verbringen und die Einfuhr von Tierseuchenerregern)”. Adopted 7 December 1971. Last amended 31 August 2015. [https://www.gesetze-im-internet.de/tierseuchereinfv/BJNR019600971.html]. Accessed 21 January 2021.
[8] Federal Government. “Genetic Engineering Act (Verordnung über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen (Gentechnik-Sicherheitsverordnung - GenTSV)” Adopted 24 October 1990. Last amended 31 August 2015. [https://www.gesetze-im-internet.de/gentsv/BJNR023400990.html]. Accessed 21 January 2021.
[9] Federal Government. “Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)”. Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.

## 1.3.4 Transportation security

### *1.3.4a*

**Does the country have publicly available information on national regulations on the safe and secure transport of infectious substances (specifically including Categories A and B)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has publicly available information on national regulations on the safe and secure transport of infectious substances (Categories A and B). The legal basis for the transport of dangerous goods and infectious substances in Germany is the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). The ADR covers infectious substances and is binding for all commercial transporters through Section 3 of the Ordinance on the Domestic and International Transport of Dangerous Goods by Road, Rail and Inland Waterways (adopted 17 June 2009, last amended 11 March 2019) [1, 2]. Germany's 2020 Confidence Building Measure Report, submitted to the United Nations as part of its commitments under the Biological Weapons Convention and the VERTIC Database does not mention national regulations on the safe and secure transport of infectious substances (Categories A and B) [3, 4]. Information on transport of infectious substances (Categories A and B) can be found through the Federal Ministry of Transport and Digital Infrastructure's website [5].

[1] United Nations. Economic Commission for Europe Inland Transport Committee. Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR). 2011[https://unece.org/sites/default/files/2021-01/ADR2021_Vol1e_0.pdf]. Accessed 21 January 2021.
[2] Federal Ministry of Transport and Digital Infrastructure. “Ordinance on the Domestic and International Transport of Dangerous Goods by Road, Rail and Inland Waterways (GGVSEB)”. Adopted 17 June 2009. Last amended 11 March 2019. [https://www.bmvi.de/SharedDocs/DE/Anlage/G/Gefahrengut/ggvseb-2019-engl.pdf?__blob=publicationFile]. Accessed 21 January 2021.
[3] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[4] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.
[5] Federal Ministry of Transport and Digital Infrastructure. “Carriage of Dangerous Goods”. 2021. [https://www.bmvi.de/DE/Themen/Mobilitaet/Gueterverkehr-Logistik/Gefahrgut/gefahrgut.html]. Accessed 21 January 2021.

## 1.3.5 Cross-border transfer and end-user screening

### *1.3.5a*

**Is there legislation and/or regulations in place to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is legislation in place to oversee the cross-border transport and end-user screening of especially dangerous pathogens, toxins and pathogens with pandemic potential. For Germany end-user screening is legally required by the European Union's Regulation No 428/2009 on Setting up a Community Regime for the Control of Exports, Transfer, Brokering and Transit of Dual-Use Items. In its list of items covered by the term "dual-use", the regulation includes 91 pathogens and toxins: 32

human viruses, 17 animal viruses, 4 rickettsiae, 15 bacteria, 19 toxins, 2 fungi and 2 mycoplasmas [1]. Among others, this includes the pathogens and toxins associated with plague, cholera, encephalitis, Ebola, dengue fever, anthrax, salmonellosis, brucellosis, shigellosis, yellow fever and botulism. However, the list omits pathogens and toxins associated with some major infectious diseases, such as influenza and tuberculosis. The regulation states that export authorization is subject to identification of the end-user and intended use [1]. It further states that dual-use items may not be exported when the exporter is informed by member state authorities that they are intended for the production of weapons of mass destruction, or for military use more broadly where the destination country is subject to an arms embargo imposed by the organization for Security and Co-operation in Europe (OSCE) or United Nations Security Council [1]. Regulations issued by the European Council are legally binding legislative acts in all European Union member states [2]. Furthermore, Germany has implemented Regulation No 428/2009 through the Foreign Trade and Payments Ordinance (adopted 2 August 2013, last amended 26 October 2020), which references Regulation No 428/2009 extensively and lists dangerous pathogens, toxins and pathogens with pandemic potential, which require export licenses [3]. Germany's 2018, 2019 and 2020 Confidence Building Measure Reports, submitted to the United Nations as part of its commitments under the Biological Weapons Convention, do not mention legislation to oversee the cross-border transport and end-user screening of especially dangerous pathogens, toxins and pathogens with pandemic potential [4].

[1] European Council. Council Regulation (EC) No 428/2009 of 5 May 2009. "Setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items." [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R0428-20191231]. Accessed 21 January 2021.
[2] European Union. "Types of EU Law." [https://ec.europa.eu/info/law/law-making-process/types-eu-law_enAccessed 21 January 2021.
[3] Federal Office for Economic Affairs and Export Control. “Foreign Trade and Payments Ordinance (Außenwirtschaftsverordnung (AWV))”. Adopted 2 August 2013. Last amended 26 October 2020. [https://www.gesetze-im-internet.de/awv_2013/BJNR286500013.html]. Accessed 21 January 2021.
[4] Germany. Confidence Building Measures Reports. [https://bwc-ecbm.unog.ch/state/germany]. Accessed 21 January 2021.

# 1.4 BIOSAFETY

## 1.4.1 Whole-of-government biosafety systems

### *1.4.1a*

**Does the country have in place national biosafety legislation and/or regulations?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has in place national biosafety legislation and regulations. The Biological Agents Ordinance (adopted 15 July 2013, last amended 29 March 2017) sets out measures for the protection of the safety and health of employees with regards to all activities involving biological agents [1]. The ordinance classifies biological agents into risk groups, differentiates protection levels by risk level and sets out documentation and record-keeping obligations. The Federal Institute for Occupational Safety and Health, an institute under the Federal Ministry of Labour and Social Affairs, has published Technical Rules for Biological Agents (TBRA, adopted 17 October 2013 and last amended 2 May 2018) and Resolutions of the Committee for Biological Agents on requirements for activities with biological agents in special cases [2]. The TBRA are split into various subcategories such as: basic measures to be taken for activities involving biological agents (TBRA 500), criteria for the classification of biological agents (TBRA 450), biological agents in health care and welfare facilities (TBRA 250), protective measures for activities involving biological agents in agriculture and forestry and comparable activities (TBRA 230), occupational safety measures in acute biohazard situations (TBRA 130) and protective measures for activities involving biological agents in all

laboratories (TBRA 100). Resolution 610 of the Committee for Biological Agents, published in October 2016, deals with "Protective measures for activities outside of special isolation units involving the care of patients infected with highly pathogenic organisms or suspected of having a disease" [3]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal do not include additional relevant information on national biosafety legislation or regulations [4].

[1] Federal Government. "Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)". Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[2] Federal Institute for Occupational Safety and Health. Federal Institute for Occupational Safety and Health. "TBRA 100: Protective measures for activities involving biological agents in laboratories (Schutzmaßnahmen für Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien)". Adopted 17 October 2013. Last amended 2 May 2018 [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=2]. Accessed 21 January 2021.
[3] Federal Institute for Occupational Safety and Health. Federal Institute for Occupational Safety and Health. "Resolution 610 Protective measures for activities outside of special isolation units involving the care of patients infected with highly pathogenic organisms or suspected of having a disease." October 2016. [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/Resolution-610.pdf?__blob=publicationFile&v=2]. Accessed 21 January.
[4] Germany. Confidence Building Measures Reports. [https://bwc-ecbm.unog.ch/state/germany]. Accessed 21 January 2021.

## *1.4.1b*

**Is there an established agency responsible for the enforcement of biosafety legislation and regulations?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has an established agency responsible for the enforcement of biosafety legislation and regulations. Legislation on biosecurity such as the Biological Agents Ordinance (adopted 15 July 2013, last amended 29 March 2017) and the Technical Regulations for Biological Agents (TRBA) does not mention a single enforcing agency [1, 2]. In Germany, many biosafety regulations are enforced by the regional state authorities, who have primary responsibility for healthcare, law enforcement, and civilian emergency management [3]. A 2012 presentation by Professor Peter Kämpfer from Justus-Liebig-University Giessen, Germany, explains that the regulatory framework for biosafety in Germany is complex and disjointed and that there are "different levels and types of inspection, enforcement and sanctions" [5]. The websites of the Federal Ministry of Health, Federal Ministry of Defence, Federal Ministry of Food and Agriculture as well as local and international media do not include information on any established agency responsible for the enforcement of biosafety legislation and regulations [5, 6, 7]. Moreover, annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC Database do not make reference to a national agency responsible for the enforcement of biosafety legislation and regulations [8, 9].

[1] Federal Government. "Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)". Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[2] Federal Institute for Occupational Safety and Health. "Technical Regulations for Biological Agents" [https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/TRBA.html]. Accessed 10 February 2021.
[3] Rappert, B. and Gould C. "Biosecurity: Origins, Transformations and Practices". Palgrave Macmillan, 2009. [https://books.google.co.th/books?id=9YSDDAAAQBAJ&pg=PA220&lpg=PA220&dq=biosafety+regulations+germany+enforce

ment&source=bl&ots=-4D6piJW0A&sig=rBITKt66DiNPnnau_cIJFr2tk9M&hl=en&sa=X&ved=2ahUKEwi-2oPmnrDeAhULWX0KHQS5D0YQ6AEwCHoECAUQAQ#v=onepage&q=biosafety%20regulations%20germany%20enforcement&f=false]. Accessed 21 January 2021.
[4] Kämpfer, P. "Biosafety and Biosecurity Regulations in Germany" Presentation. Justus-Liebig-University Giessen, Germany. 2012. [www.wfcc.info/iccc12/presentations/pkampfer.pdf]. 2012. Accessed 21 January 2021.
[5] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 15 January 2019.
[6] Federal Ministry of Defence. 2021. Website. [https://www.bmvg.de/en]. Accessed 21 January 2021.
[7] Federal Ministry of Food and Agriculture. 2021. Website. [www.bmel.de/EN/Homepage/homepage_node.html]. Accessed 21 January 2021.
[8] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[9] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

## 1.4.2 Biosafety training and practices

### *1.4.2a*

**Does the country require biosafety training, using a standardized, required approach, such as through a common curriculum or a trainthe-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence of a requirement for standardized biosafety training in Germany. The Technical Regulations for Biological Agents (TRBA, adopted 17 October 2013 and last amended 2 May 2018) state that personnel should be adequately trained to minimise biorisks but it does not specify what exactly the training should involve [1]. Section 14 of the Biological Agents Ordinance (adopted 15 July 2013, last amended 29 March 2017) describes very generally how personnel working with biological agents must be trained but the description does not amount to a standardized curriculum or reference one, nor is there an explicit focus on biosafety [2]. Similarly, the Protection of Workers Act (adopted 7 August 1996, last amended 19 June 2020) states that an employer must give workers sufficient and appropriate training regarding safety and health protection, however, there are is no clarification as to what training should involve with regards to biosafety training [3]. There is, however, guidance from the European Committee for Standardization Workshop Agreement (CWA) 15793, which sets out requirements for biosafety personnel training, awareness and biorisk-related training. [4]. Additionally, the European Union funded project EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level published a checklist in 2015 for laboratory biorisk management, which allows laboratories to perform self-evaluations on their biorisk management standards [5]. There is therefore evidence of European Union biorisk training standards but there is no German in-country legislation or regulation that enforces these standards. The websites of the Federal Ministry of Health, Federal Ministry of the Interior, Building and Community Federal Ministry of Food and Agriculture as well as local and international media do not include information on standardized biosafety training. [7, 8, 9]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC Database do not include specific information on a requirement for standardized biosafety training in Germany [10, 11].

[1] Federal Institute for Occupational Safety and Health. "TBRA 100: Protective measures for activities involving biological agents in laboratories (Schutzmaßnahmen für Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien)". Adopted 17

October 2013. [https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile&v=2] Last amended 2 May 2018. Accessed 21 January 2021.
[2] Federal Government. "Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)". Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[3] Federal Government. "Biological Agents Ordinance (Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV)". Adopted 15 July 2013. Last amended 29 March 2017. [https://www.gesetze-im-internet.de/biostoffv_2013/BJNR251410013.html]. Accessed 21 January 2021.
[4] Federal Government. "Protection of Workers Act (Arbeitsschutzgesetz – ArbSchG)". Adopted 7 August 1996. Last amended 19 June 2020. [https://www.gesetze-im-internet.de/arbschg/BJNR124610996.html]. Accessed 21 January 2021.
[5] European Committee for Standardization Workshop Agreement (CWA). "CWA 16393: Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008" 2012. [https://www.cdc.gov.tw/Uploads/files/201504/d0feebf2-a92c-46e1-914a-b9d1435bc52f.pdf]. Accessed 21 January 2021.
[6] EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level. 2015. "Integrated European Checklist for Laboratory Biorisk Management in Handling of High Consequence Risk Group 3 and 4 Agents (ECL-Biorisk)". [www.emerge.rki.eu/Emerge/EN/Content/Topics/Rules/ECL_Biorisk.pdf?__blob=publicationFile]. Accessed 21 January 2021.
[7] Federal Ministry of the Interior, Building and Community. 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 21 January 2021.
[8] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 21 January 2021.
[9] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 21 January 2021.
[10] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[11] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

# 1.5 DUAL-USE RESEARCH AND CULTURE OF RESPONSIBLE SCIENCE

## 1.5.1 Oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research

### *1.5.1a*

**Is there publicly available evidence that the country has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?**
Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential or dual-use research. There is no evidence of such an assessment on the websites of the Federal Ministry of Health and associated agencies; the Federal Ministry of Defence; the Ministry of Food and Agriculture and associated agencies; the Federal Ministry of Education and Research, and the Robert Koch Institute [1, 2, 3, 4, 5]. However, the Robert Koch Institute (RKI) has published its code of conduct for risk assessment and risk mitigation that focuses on assessing dual use potential of life sciences research [6]. Moreover, as a party to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Germany participates in confidence-building measures, including the submission of reports on research that is or could be related to biological weapons [6, 7, 8]. The three most recent such reports that are

publicly available – those submitted in 2018, 2019 and 2020 – do not show evidence of a formal assessment of dual-use research but they do explain that under the RKI's Dual Use Regulations and the Bundeswehr Institute of Microbiology's dual use research of concern regulations, scientists are required to assess the potential of their research before a project is started, during the project period and before results are published [10]. The reports also contain details on the institutions in Germany (such as the Robert Koch Institute) conducting research on dangerous pathogens/toxins and biological weapons [10]. There is no evidence that Germany has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential or dual-use research on the VERTIC database [11].

[1] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 21 January 2021.
[2] Federal Ministry of Defence. 2021. Website. [www.bmvg.de/en]. Accessed 21 January 2021.
[3] Federal Ministry of Food and Agriculture. 2021. Website. [www.bmel.de/EN/Homepage/homepage_node.html]. Accessed 21 January 2021.
[4] Federal Ministry of Education and Research. 2021. Website. [www.bmbf.de/en/index.html]. Accessed 21 January 2021.
[5] Robert Koch Institute. 2021. Website. [www.rki.de/EN/Home/homepage_node.html]. Accessed 21 January 2021.
[6] Robert Koch Institute. 2013. "Dual use potential of life sciences research".
[https://www.rki.de/EN/Content/Institute/Dual_Use/code_of_conduct.html]. Accessed 21 January 2021.
[7] United Nations. 2018. "Report on universalization activities." [http://undocs.org/bwc/msp/2018/3]. Accessed 21 January 2021.
[8] United Nations. 2015. "Guide to Participating in Confidence-Building Measures of the Biological Weapons Convention."
[https://unoda-web.s3-accelerate.amazonaws.com/wp-content/uploads/assets/publications/more/cbm-guide/cbm-guide-2015.pdf]. Accessed 21 January 2021.
[9] BWC1972.org. "CBMs." [http://bwc1972.org/home/the-biological-weapons-convention/about-the-bwc/text-of-the-biological-weapons-convention-2/cbms/]. Accessed 21 January 2021.
[10] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[11] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

## *1.5.1b*

**Is there legislation and/or regulation requiring oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?**

Yes = 1 , No = 0

**Current Year Score: 0**

In Germany, there is no public evidence of a national policy or legislation requiring oversight of dual-use research, such as research with especially dangerous pathogens, toxins, and/or pathogens with pandemic potential. The German Ethics Council, an independent political advisory body, in 2014 recommended that the German government legally address â€œdual-use research of concern (DURC) in a report titled Biosecurity Freedom and Responsibility of Research [1, 2]. In response, Lars Schaade, the vice president of the Robert Koch Institute (RKI) in Berlin, said he supported some of the council's proposals, such as developing a code of conduct for German scientists but did not see the need for new legislation and a national DURC committee [1]. The Robert Koch Institute has indeed published its code of conduct for risk assessment and risk mitigation that focuses on assessing the dual use potential of life sciences research. Other German institutions can use this code of conduct for self-assessment [3]. There is no evidence that legislation requiring oversight of dual-use research has been introduced since nor is there a national policy that addresses the issue. The websites of the Federal Ministry of

Health, Federal Ministry of Education and Research, Federal Ministry of Food and Agriculture, Federal Ministry of Defence and Robert Koch Institute do not make reference to any such policy [4, 5, 6, 7, 8]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC Database do not include information showing the existence of a national policy requiring oversight of dual use research, such as research with especially dangerous pathogens, toxins, and/or pathogens with pandemic potential [9, 10].

[1] Science Magazine. 2014. "German Ethics Council: Government Should Regulate Dangerous Research". [www.sciencemag.org/news/2014/05/german-ethics-council-government-should-regulate-dangerous-research]. Accessed 21 January 2021.
[2] German Ethics Council. “Biosecurity – Freedom and Responsibility of Research (Biosicherheit – Freiheit und Verantwortung in der Wissenschaft)”. 2014. [https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-biosicherheit.pdf]. Accessed 21 January 2021.
[3] Robert Koch Institute. 2013. “Dual use potential of life sciences research”. [https://www.rki.de/EN/Content/Institute/Dual_Use/code_of_conduct.html]. Accessed 21 January 2021.
[4] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 21 January 2021.
[5] Federal Ministry of Education and Research. 2021. Website. [www.bmbf.de/en/index.html]. Accessed 21 January 2021.
[6] Federal Ministry of Food and Agriculture. 2021. Website. [www.bmel.de/EN/Homepage/homepage_node.html]. Accessed 21 January 2021.
[7] Federal Ministry of Defence. 2021. Website. [www.bmvg.de/en]. Accessed 21 January 2021.
[8] Robert Koch Institute. 2021. Website. [www.rki.de/EN/Home/homepage_node.html]. Accessed 21 January 2021.
[9] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[10] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

### *1.5.1c*

**Is there an agency responsible for oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?**

Yes = 1 , No = 0

**Current Year Score: 0**

In Germany, there is no evidence of a specific agency responsible for the oversight of research with especially dangerous pathogens, pathogens with pandemic potential, or other dual-use research. Germany's federal ministries fund approximately 40 federal research and development institutions [1]. Assessment of dual-research potential is conducted by specialized research ethics committees (RECs), but not by a single national agency [2]. The websites of the Federal Ministry of Health, the Federal Ministry of Defence, the Federal Ministry of Food and Agriculture, and the Robert Koch Institute do not make reference to an agency responsible for the oversight of research with especially dangerous pathogens, pathogens with pandemic potential, or other dual-use research [3, 4, 5, 6]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC Database do not include information showing that Germany has a specific agency responsible for the oversight of research with especially dangerous pathogens, pathogens with pandemic potential, or other dual-use research [7, 8].

[1] Federal Ministry of Education and Research. 2021. "Federal Institutions". [www.research-in-germany.org/en/research-landscape/research-organisations/federal-institutions.html]. Accessed 21 January 2021.

[2] BMC Medical Ethics. 2018. "The dual use of research ethics committees: why professional self-governance falls short in preserving biosecurity". [https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-018-0295-0]. Accessed 21 January 2021.
[3] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 21 January 2021.
[4] Federal Ministry of Defence. 2021. Website. [www.bmvg.de/en]. Accessed 21 January 2021.
[5] Federal Ministry of Food and Agriculture. 2021. Website. [www.bmel.de/EN/Homepage/homepage_node.html]. Accessed 21 January 2021.
[6] Robert Koch Institute. 2021. Website. [www.rki.de/EN/Home/homepage_node.html]. Accessed 21 January 2021.
[7] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[8] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

## 1.5.2 Screening guidance for providers of genetic material

### *1.5.2a*

**Is there legislation and/or regulation requiring the screening of synthesized DNA (deoxyribonucleic acid) against lists of known pathogens and toxins before it is sold?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence of legislation, regulations, policies or other guidelines requiring the screening of synthesized DNA before it is sold. Although Germany has national legislation regarding genetic engineering, there is no evidence that screening of synthesized DNA before it is sold is mandatory. The Genetic Engineering Act (adopted 20 June 1990, last amended 19 June 2020) covers genetically modified organisms, meaning any organism whose genetic material has been altered in a way that does not occur naturally by mating or natural recombination such as through recombinant DNA techniques using vector systems [1]. Section 16 of the Act specifies conditions for release and placing on the market. A release authorization shall be only be granted if the requirements of the act are met and it is ensured that all precautions necessary according to state-of-the-art knowledge are taken, and if it is ensured that the DNA has no detrimental effects on the life and health of human beings, animals and plants as well as the symbiotic structure of the environment at large [1]. However, the requirements do not specify that synthesized DNA codes must be screened for against lists of known pathogens and toxins. The websites of the Federal Ministry of Health, the Federal Ministry of Food and Agriculture, the Federal Ministry of Defence and the Federal Ministry of Transport and Digital Infrastructure do not mention national legislation, regulation, policy, or other guidance, requiring the mandatory screening of synthesized DNA before it is sold [2, 3, 4, 5]. Annual reports for the years 2017-2020 for Germany published on the UN's Biological Weapons Convention's Electronic Confidence Building Measures Portal and the VERTIC Databse do not include information that shows Germany has in place national legislation requiring the screening of synthesized DNA before it is sold [6, 7].

[1] Federal Government. “German Genetic Engineering Act (Gesetz zur Regelung der Gentechnik (Gentechnikgesetz - GenTG))”. Adopted 20 June 1990. Last amended 19 June 2020. [https://www.gesetze-im-internet.de/gentg/BJNR110800990.html]. Accessed 22 January 2021.
[2] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 22 January 2021.
[3] Federal Ministry of Food and Agriculture and Consumer Protection. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 22 January 2021.

[4] Federal Ministry of Defence. 2021. Website. [www.bmvg.de/en]. Accessed 22 January 2021.
[5] Federal Ministry of Transport and Digital Infrastructure. 2021. Website. [https://www.bmvi.de/DE/Home/home.html]. Accessed 22 January 2021.
[6] UNOG. "Confidence Building Measures". [https://bwc-ecbm.unog.ch/system/files/form-pdf-auto-public/10697_bwc_cbm_2020_germany-public.pdf]. Accessed 22 February 2021.
[7] VERTIC Database. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/g/]. Accessed 22 February 2021.

## 1.6 IMMUNIZATION

### 1.6.1 Vaccination rates

#### *1.6.1a*

**Immunization rate (measles/MCV2)**

Immunization rate (measles/MCV2), 95% or greater = 2, 80-94.9% = 1, Less than 80%, or no data = 0

**Current Year Score: 1**

2019

World Health Organization

#### *1.6.1b*

**Are official foot-and-mouth disease (FMD) vaccination figures for livestock publicly available through the OIE database?**

Yes = 1 , No = 0

**Current Year Score: 1**

2020

OIE WAHIS database

# Category 2: Early detection and reporting for epidemics of potential international concern

## 2.1 LABORATORY SYSTEMS STRENGTH AND QUALITY

### 2.1.1 Laboratory testing for detection of priority diseases

#### *2.1.1a*

**Does the national laboratory system have the capacity to conduct diagnostic tests for at least 5 of the 10 WHO-defined core tests?**

Evidence they can conduct 5 of the 10 core tests and these tests are named = 2, Evidence they can conduct 5 of the 10 core tests and the tests are not named = 1, No evidence they can conduct 5 of the 10 core tests = 0

Current Year Score: 2

The national laboratory system has the capacity to conduct diagnostic tests for at least 6 of the 10 WHO-defined core tests. The national network of reference centres (NRZ) and consulting laboratories (KL) can conduct polymerase chain reaction (PCR) testing for Influenza virus, virus culture for poliovirus, serology for HIV, microscopy for mycobacterium tuberculosis, diagnostic testing for plasmodium spp., and bacterial culture for Salmonella enteritidis serotype Typhi [1]. The RKI has published a comprehensive list which details the type of tests its laboratories can carry out, however, there is no evidence that Germany has defined or conducts the four country tests [2, 3, 4, 5, 6].

[1] Robert Koch Institute. 2021. "National Reference Centres and Consulting Laboratories (Nationale Referenzzentren und Konsiliarlabore)". [https://www.rki.de/DE/Content/Infekt/NRZ/nrz_liste.pdf?__blob=publicationFile]. Accessed 22 January 2021.
[2] Robert Koch Institute. 2021. "Department 1: Infectious Diseases". [www.rki.de/EN/Content/Institute/DepartmentsUnits/InfectDiseases/Div11/Div11_node.html]. Accessed 22 January 2021.
[3] Robert Koch Institute. 2021. "Unit 11: Enteropathogenic Bacteria and Legionella". [www.rki.de/EN/Content/Institute/DepartmentsUnits/InfectDiseases/Div11/Div11_node.html]. Accessed 22 January 2021.
[4] Robert Koch Institute. 2021. "Unit 17: Influenza and Other Respiratory Viruses". [www.rki.de/EN/Content/Institute/DepartmentsUnits/InfectDiseases/Div17/Div17_node.html]. Accessed 22 January 2021.
[5] Robert Koch Institute. 2021. "Unit 18: HIV and Other Retroviruses". https://www.rki.de/EN/Content/Institute/DepartmentsUnits/InfectDiseases/Div18/Div18_node.html]. Accessed 22 January 2021.
[6] Robert Koch Institute. 2021. "FG 15 Virale Gastroenteritis- und Hepatitiserreger und Enteroviren". [https://www.rki.de/DE/Content/Institut/OrgEinheiten/Abt1/FG15/fg15_node.html]. Accessed 22 January 2021.

## *2.1.1b*

**Is there a national plan, strategy or similar document for conducting testing during a public health emergency, which includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing?**

Yes, there is evidence of a plan, and it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 2, Yes, there is evidence of a plan, but there is insufficient evidence that it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 1, No evidence of a plan = 0

Current Year Score: 1

Germany has a national plan for conducting testing during a public health emergency, which includes scaling capacity and defining goals for testing but does not include considerations for testing for novel pathogens. The National Pandemic Plan: Part I Structures and Measures, published by the Robert Koch Institute (RKI) in 2017, lays out a four-tiered plan for the deployment of diagnostic facilities during a pandemic [1]. The plan involves a network of influenza laboratories, which can be successively used for testing and diagnosis as the public health situation deteriorates. In tier 1, when the first suspected cases of infection arise, test samples are sent for diagnosis exclusively to the National Reference Centre (NRZ) for Influenza, and as the situation worsens, laboratories in the influenza laboratory network carry out initial testing, with the NRZ for influenza confirming results. In the worst-case scenario, further laboratory facilities across the country capable of influenza diagnosis are mobilized. The goals for testing follow the development of the pandemic, the focus can be on “containment” or “mitigation/damage control”. Decisions regarding testing operations and the coordination thereof are to be made centrally by the NRZ for influenza, in conjunction with a network of specialized laboratories. There is no mention in this four-tiered plan of testing specifically for novel pathogens [1]. The RKI is tasked with the bulk of detection and surveillance of novel

pathogens, however, these tasks do not appear to be coordinated with a plan for diagnostic operations ensuing from a public health emergency [2].

[1] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 22 January 2021.
[2] Robert Koch Institute. Website. [https://www.rki.de/DE/Content/Institut/institut_node.html;jsessionid=4B01451B7F10FE5BD2DA94A30E2FB55D.internet091]. Accessed 22 January 2021.

## 2.1.2 Laboratory quality systems

### *2.1.2a*

**Is there a national laboratory that serves as a reference facility which is accredited (e.g., International Organization for Standardization [ISO] 15189:2003, U.S. Clinical Laboratory Improvement Amendments [CLIA])?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has 5 accredited national laboratories that serves as reference facilities. The accredited National Reference Centres (NRZ) include those for Salmonella and other Enteritis pathogens; Measles, Mumps and Rubella; Influenza; Poliomyelitis and Enteroviruses; and Staphylococci and Enterococci [1]. For example, the National Reference Centre for Salmonella and other Enteritis pathogens has been accredited with the ISO 15189 (medical laboratories) and ISO 17025 (testing laboratories) standards since 2011 [2]. The German Accreditation Body (DAkkS) is responsible for the accreditation of laboratories and the enforcement of international standards [3]. DAkkS lists all the bodies it has accredited on its website, including National Reference Centres (NRZ) [4]. DAkkS is a non-profit organization and the sole provider of accreditations in Germany, with a mandate from the federal government. [2].

[1] Robert Koch Institute. Website. 2021. [https://www.rki.de/DE/Content/Institut/OrgEinheiten/QM/QM_node.html]. Accessed 22 January 2021.
[2] Robert Koch Institute. Website. 2021. [https://www.rki.de/DE/Content/Infekt/NRZ/Salmonellen/salmo_inhalt.html]. Accessed 22 January 2021.
[3] German Accreditation Body (DAkkS). Website. 2021. [https://www.dakks.de/en/content/profile]. Accessed 22 January 2021.
[4] German Accreditation Body (DAkkS). Website. 2021. [https://www.dakks.de/en/content/accredited-bodies-dakks]. Accessed 22 January 2021.

### *2.1.2b*

**Is there a national laboratory that serves as a reference facility which is subject to external quality assurance review?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence that some national laboratories that serve as reference facilities are subject to external quality assurance reviews. Germany has 5 accredited national laboratories that serves as reference facilities. The accredited national reference centers include those for salmonella and other enteritis pathogens; measles, mumps and rubella; influenza; poliomyelitis and enteroviruses; and staphylococci and enterococci [1]. These laboratories adhere to national standards that are based on ISO

15189, which requires accredited laboratories to be subjected to external quality assurance reviews [2]. Moreover, the national reference center for salmonella and other enteritis pathogens was officially accredited with the ISO 15189 in 2011, meaning that it must be subjected to external quality assurance reviews [3]. The German Accreditation Body (DAkkS) is responsible for the accreditation of laboratories and the enforcement of international standards [4, 5]. DAkkS is a non-profit organization and the sole provider of accreditations in Germany, with a mandate from the federal government [3].

[1] Robert Koch Institute. Website. 2021. [https://www.rki.de/DE/Content/Institut/OrgEinheiten/QM/QM_node.html]. Accessed 22 January 2021.
[2] World Health Organization. "Overview of External Quality Assessment (EQA)". [https://www.who.int/ihr/training/laboratory_quality/10_b_eqa_contents.pdf]. Accessed 22 February 2021
[3] Robert Koch Institute. Website. 2021. [https://www.rki.de/DE/Content/Infekt/NRZ/Salmonellen/salmo_inhalt.html]. Accessed 22 January 2021.
[4] German Accreditation Body (DAkkS). Website. 2021. [https://www.dakks.de/en/content/profile]. Accessed 22 January 2021.
[5] German Accreditation Body (DAkkS). Website. 2021. [https://www.dakks.de/en/content/accredited-bodies-dakks]. Accessed 22 January 2021.

# 2.2 LABORATORY SUPPLY CHAINS

## 2.2.1 Specimen referral and transport system

### *2.2.1a*

**Is there a nationwide specimen transport system?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence of a nationwide specimen transport system. In Germany specimens can be transported by qualified private courier companies that move biological material to and from laboratories [1]. The Professional Association for Health and Care Workers recommends using a qualified courier for the transport of dangerous goods when sending specimens that may contain Category A infectious substances. Samples potentially containing Category B infectious substances can be sent in the post using specially approved packaging [1]. Transport of specimens must abide by the standards of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) [2]. According to the Robert Koch Institute, there are three courier companies qualified for the transport of Category A infectious substances: World Courier, Trans O Flex and CMK-Logistik [3]. All of these companies offer nationwide coverage for the transport of these infectious substances [4, 5, 6].

[1] Professional Association for Health and Care Workers (BGW). 2017. "Sending Patient Samples Properly (Patientenproben richtig versenden)". [www.bgw-online.de/SharedDocs/Downloads/DE/Medientypen/BGW%20Broschueren/BGW09-19-011-Patientenproben_Download.pdf?__blob=publicationFile]. Accessed 22 January 2021.
[2] United Nations. Economic Commission for Europe Inland Transport Committee. Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR). 2011[https://unece.org/sites/default/files/2021-01/ADR2021_Vol1e_0.pdf]. Accessed 22 January 2021.
[3] Robert Koch Institute. "Sample Transport according to the ADR". [https://www.rki.de/DE/Content/Infekt/Biosicherheit/Probentransport/Probentransport_node.html]. Accessed 25 February 2021.
[4] World Courier. "Our global courier network." [https://www.worldcourier.com/expertise-our-global-network]. Accessed 25 February 2021.

[5] Trans O Flex. "Services." ("Leistungen.") [https://www.trans-o-flex.com/produkte/expressversand-national/#leistungen]. Accessed 25 February 2021.
[6] CMK-Logistik. [https://cmk-logistik.de/]. Accessed 25 February 2021.

## 2.2.2 Laboratory cooperation and coordination

### *2.2.2a*

**Is there a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak?**

Yes = 2 , Yes, but there is evidence of gaps in implementation = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has a general national plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during a disease outbreak. There is no such evidence on the websites of the Federal Ministry of Health, the Federal Ministry of Food and Agriculture, or the Robert Koch Institute. [1, 2, 3] However, the National Pandemic Plan: Part I Structures and Measures, published by the Robert Koch Institute (RKI) in 2017, lays out a four-tiered plan for the deployment of diagnostic facilities during an influenza pandemic. The plan involves a previously established network of influenza laboratories, which can be successively used for testing and diagnosis as the public health situation deteriorates. In tier 1, when the first suspected cases of infection arise, test samples are sent exclusively to the National Reference Centre (NRZ) for influenza for diagnosis. The NRZ for influenza draws up a standard operating procedure (SOP) at this stage to ensure that diagnostic operations are uniform. As the situation worsens, laboratories in the influenza laboratory network carry out initial testing, with the NRZ for influenza confirming results. In the worst-case scenario, further laboratory facilities across the country capable of influenza diagnosis are mobilized in line with the SOP. These laboratories are assisted by the NRZ for influenza and as well as the network of influenza laboratories [1]. The plan does not mention licensing requirements, but section 13 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2021) authorizes testing centres to send test samples to national reference centres, the RKI, consulting laboratories and professionally independent laboratories for special diagnosis [2].

[1] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 22 January 2021.
[2] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 22 January 2021.
[3] Robert Koch Institute. Website. 2021. [https://www.rki.de/DE/Content/Institut/OrgEinheiten/QM/QM_node.html]. Accessed 22 January 2021.
[4] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 22 January 2021.
[5] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2021. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.

# 2.3 REAL-TIME SURVEILLANCE AND REPORTING

## 2.3.1 Indicator and event-based surveillance and reporting systems

### *2.3.1a*

**Is there evidence that the country is conducting ongoing event-based surveillance and analysis for infectious disease?**

Yes, there is evidence of ongoing event-based surveillance and evidence that the data is being analyzed on a daily basis = 2, Yes, there is evidence of ongoing event-based surveillance, but no evidence that the data are being analyzed on a daily basis = 1, No = 0

**Current Year Score: 0**

There is insufficient evidence to confirm that there is ongoing event-based surveillance and analysis for infectious disease in Germany [1]. The Joint Information and Situation Centre of the Federal Government and the Federal States (GMLZ), under the portfolio of the Federal Office of Civil Protection and Disaster Assistance (BBK), is tasked with the preparation of comprehensive situation reports on topics relating to civil protection in Germany, including threats posed by infectious diseases [2, 3]. Focusing not on the observation of the situation, but on the assessment and analysis of developments [1]. However, the BBK's website does not specify whether event-based surveillance plays a role in producing these situation reports [2]. The websites of the Federal Ministry of Health, the Federal Office of Civil Protection and Disaster Assistance, the Federal Ministry of the Interior, Building and Community, and local news outlets make no reference to ongoing event-based surveillance and analysis for infectious disease [4, 2, 5].

[1] Federal Office of Civil Protection and Disaster Assistance. "Joint Information and Situation Centre of the Federal Government and the Federal States (GMLZ)". [www.bbk.bund.de/EN/Topics/Crisis_management/GMLZ/GMLZ_node.html]. Accessed 22 January 2021.
[2] Federal Office of Civil Protection and Disaster Assistance. Website. 2021. [https://www.bbk.bund.de/DE/Home/home_node.html]. Accessed 22 January 2021.
[3] German Parliament. 12 April 2019. “Report on Civil Protection Risk Analysis 2017”. [http://dipbt.bundestag.de/doc/btd/19/095/1909520.pdf]. Accessed 31 January 2021.
[4] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 22 January 2021.
[5] Federal Ministry of the Interior, Building and Community. 2021. Website. [www.bmi.bund.de/EN/home/home_node.html]. Accessed 22 January 2021.

### *2.3.1b*

**Is there publicly available evidence that the country reported a potential public health emergency of international concern (PHEIC) to the WHO within the last two years?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence that Germany has reported a potential public health emergency of international concern (PHEIC) to the World Health Organization (WHO) in the last two years. In 2017, Germany was among several countries who reported to the WHO an unusual increase in hepatitis A cases, particularly among men who have sex with men [1]. Germany did report cases of COVID-19 as a potential PHEIC to the WHO prior to the WHO's own declaration of COVID-19 as a PHEIC on 30 January 2020 [2].

[1] World Health Organisation. 7 Jun 2017. “Hepatitis A outbreaks mostly affecting men who have sex with men – European Region and the Americas”. [https://www.who.int/news/item/07-06-2017-hepatitis-a-outbreaks-mostly-affecting-men-who-have-sex-with-men-european-region-and-the-americas]. Accessed 22 January 2021.
[2] World Health Organization. "Novel Coronavirus (2019-nCoV) Situation Report - 10" 30 January 2020. [https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200130-sitrep-10-ncov.pdf?sfvrsn=d0b2e480_2]

## 2.3.2 Interoperable, interconnected, electronic real-time reporting systems

### *2.3.2a*

**Does the government operate an electronic reporting surveillance system at both the national and the sub-national level?**
Yes = 1 , No = 0

**Current Year Score: 1**

Germany has an electronic real-time surveillance and reporting system at both the national and the sub-national level in place. In 2001, the Robert Koch Institute (RKI) implemented SurvNet@RKI, a new electronic reporting system for surveillance of notifiable infectious diseases [1]. The SurvNet software was made available to all health authorities and regional state officials to ensure that all persons (doctors, and laboratories for example) legally required to report on infectious diseases in line with the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) could do so [2, 3]. The system centralizes reported data so that it can be analyzed on both a regional state level by state health departments and on a federal level by the RKI [1]. SurvNet is used in all 431 local health departments (LHD), the 16 state health departments and the RKI. In 2006 the RKI received approximately 300, 000 case reports and 6240 outbreak reports per year through this system [4].

[1] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 22 January 2021.
[2] Robert Koch Institute. Website. 2021. [https://www.rki.de/DE/Content/Infekt/IfSG/Software/software_inhalt.html]. Accessed 22 January 2021.
[3] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2021. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 22 January 2021.
[4] Faensen, D., Claus, H., Benzler, J., Ammon. A., Pfoch, T., Breuer, T., Krause, G. “SurvNet@RKI - A multistate electronic reporting system for communicable diseases”. Eurosurveillance Vol.11 Issues 4-6 Apr-Jun 2006. [https://edoc.rki.de/bitstream/handle/176904/677/25Ti4x2Kin0rE.pdf?sequence=1&isAllowed=y]. Accessed 22 January 2021.

### *2.3.2b*

**Does the electronic reporting surveillance system collect ongoing or real-time laboratory data?**
Yes = 1 , No = 0

**Current Year Score: 1**

Germany's electronic reporting surveillance system collects real-time laboratory data. The SurvNet reporting system collects data on infectious diseases daily in line with the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) [1, 2]. Information pertaining to suspected cases of infectious disease is submitted manually by a clinician or

laboratory to the local health department (LDH), where it is entered into the SurvNet system. If, the case information is consistent with case definitions outlined by the Robert Koch Institute (RKI), the case information is anonymized and passed on to the state health department and the RKI [1]. This process is carried out by an integrated algorithm in the SurvNet software [3]. According to a paper published in 2017, 58% of cases of infectious diseases were reported within one working day from the local public health agency to the state public health agency, with no cases taking longer than 4 days, from the point of notification, to reach the state public health agency [1].

[1] Schumacher, J., Diercke, M. Salmon, M., Czogiel, I., Schumacher, D., Claus, H., et al. 2017. "Timeliness in the German surveillance system for infectious diseases: Amendment of the infection protection act in 2013 decreased local reporting time to 1 day". Plos One. [https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0187037]. Accessed 21 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.
[3] Faensen, D., Claus, H., Benzler, J., Ammon. A., Pfoch, T., Breuer, T., Krause, G. "SurvNet@RKI - A multistate electronic reporting system for communicable diseases". Eurosurveillance Vol.11 Issues 4-6 Apr-Jun 2006. [https://edoc.rki.de/bitstream/handle/176904/677/25Ti4x2Kin0rE.pdf?sequence=1&isAllowed=y]. Accessed 22 January 2021.

# 2.4 SURVEILLANCE DATA ACCESSIBILITY AND TRANSPARENCY

## 2.4.1 Coverage and use of electronic health records

### *2.4.1a*

**Are electronic health records commonly in use?**

Electronic health records are commonly in use = 2, Electronic health records are not commonly in use, but there is evidence they are used = 1, No evidence electronic health records are in use = 0

**Current Year Score: 1**

Electronic health records are in use in Germany, but they are not the norm. Efforts to digitize physical health records have been largely unsuccessful to date. The main obstacles to achieving eHealth are Germany's stringent laws on data protection and a lack of financial and human resources [1, 2]. Plans for the comprehensive digitization of health records were embodied in the E-Health Act (adopted 21 December 2015) which aimed to set up a system of electronic health cards (eGK) [3]. Since 1 January 2015, only the eGK can been used as proof of eligibility for statutory health insurance services and starting 1 January 2021, all patients must be provided with an electronic medical file by their health insurance provider [4]. However, only administrative data must be stored on the card and digital file, the storage of sensitive medical data is managed exclusively by the patient and this information is encrypted. The patient has the option to toggle viewing permissions for their practitioner and can delete documents from their medical file. Electronic health records can only be accessed and decrypted by approved viewers (such as medical practitioners) with the patient's consent. Files can only be unlocked once the patient and medical practitioner present their eGK or health professional card and enter their respective PINs [4]. There is no information on the current state of the digitisation of Germany's medical records, however, according to a 2020 report on German eHealth by McKinsey and Company, the health records of 69% of German inpatients and 44% German outpatients could be accessed digitally [2]. Furthermore, in 2019, 93% of doctors communicated with hospitals on paper, while only 44% of all healthcare facilities used electronic health records [2]. This suggests that although electronic health records exist in Germany, they are not commonly in use.

[1] TaylorWessing. "E-Health Law in Germany". March 2016. [https://www.taylorwessing.com/synapse/ti-ehealth-law-germany.html]. Accessed 22 January 2021.
[2] McKinsey and Company. November 2020. “eHealth Monitor 2020 Deutschlands Weg in die digitale Gesundheitsversorgung – Status quo und Perspektiven”. [https://www.mckinsey.com/~/media/mckinsey/locations/europe%20and%20middle%20east/deutschland/news/presse/2020/2020-11-12%20ehealth%20monitor/ehealth%20monitor%202020.pdf]. Accessed 22 January 2020.
[3] Federal Government. “E-Health Act (Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen sowie zur Änderung weiterer Gesetze)”. Adopted 21 December 2015. [https://www.bgbl.de/xaver/bgbl/text.xav?SID=&tf=xaver.component.Text_0&tocf=&qmf=&hlf=xaver.component.Hitlist_0&bk=bgbl&start=%2F%2F*%5B%40node_id%3D%27635488%27%5D&skin=pdf&tlevel=-2&nohist=1]. Accessed 22 January 2020.
[4] Federal Ministry of Health. Website. 2021. “The electronic health card”. [https://www.bundesgesundheitsministerium.de/themen/krankenversicherung/egk.html#c1063]. Accessed 24 January 2021.

## *2.4.1b*

**Does the national public health system have access to electronic health records of individuals in their country?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence to suggest that the German public health system has access to the electronic health records of German citizens, however these health records are encrypted. Germany has a universal multi-payer health care system [1]. German patients are increasingly using electronic health records in conjunction with electronic health cards (eGK) through a telematics infrastructure [2]. However, only administrative data must be stored on the eGK and digital file, the storage of sensitive medical data is managed exclusively by the patient, and this information is encrypted. The patient has the option to toggle viewing permissions for their practitioner and can delete documents from their medical file. Electronic health records can only be accessed and decrypted by approved viewers (such as medical practitioners) with the patient's consent. Files can only be unlocked once the patient and medical practitioner present their eGK or health professional card and enter their respective PINs [2]. As such, the German public health system does not have permission to view the electronic health records of German citizens, it only as access to them in encrypted format. Viewing permission is reserved to the health professionals responsible for a patient's treatment and cannot be granted without the use of specialized cards [2]. The only form of patient information which can be viewed without permission is emergency medical data such as allergies and underlying medical conditions. Such data can be used by emergency services during emergencies; however, the patient decides whether to use this function and what information is to be included [2, 3]. There is no evidence of the national public health system having viewing permissions for electronic health records of German citizens on the website of the Federal Ministry of Health [4].

[1] Federal Ministry of Health. Website. 2021. “The Health Care System". [https://www.bundesgesundheitsministerium.de/themen/gesundheitswesen.html]. Accessed 24 January 2021.
[2] Federal Ministry of Health. Website. 2021. “The electronic health card”. [https://www.bundesgesundheitsministerium.de/themen/krankenversicherung/egk.html#c1063]. Accessed 24 January 2021.
[3] Busse, R., Blümel, M. “Germany: Health System Review”. Health Systems in Transition. 2014. [www.euro.who.int/__data/assets/pdf_file/0008/255932/HiT-Germany.pdf?ua=1]. Accessed 22 January 2020.
[4] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 22 January 2021.

### *2.4.1c*

**Are there data standards to ensure data is comparable (e.g., ISO standards)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany uses data standards to ensure that electronic health data is comparable. According to section 291 of the E-Health Act (adopted 21 December 2015), the Company for Telematic Applications of the Electronic Health Card (Gematik) is tasked with drawing up standards and guides in the form of an "interoperability directory" for the electronic health record informatics system to ensure its "interoperability" [1]. Section 291 stipulates that Gematik, with the agreement of the Ministry of Health, will select experts in informatics, healthcare and standardization to advise in this task. These experts can come from a variety of fields including national and international organizations for standardization [1]. The telematics infrastructure set up by Gematik is a uniform cross-sector platform for electronic communication in the healthcare sector, that allows the exchange of information between all health professionals [2]. Gematik's website stresses the importance of adhering to common technical standards for data communication, but it does not mention recognised international standard explicitly [3]. There is evidence that Gematik conducts interoperability tests to gauge the interoperability of its telematics system [4].

[1] Federal Government. “E-Health Act (Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen sowie zur Änderung weiterer Gesetze)”. Adopted 21 December 2015. [https://www.bgbl.de/xaver/bgbl/text.xav?SID=&tf=xaver.component.Text_0&tocf=&qmf=&hlf=xaver.component.Hitlist_0&bk=bgbl&start=%2F%2F*%5B%40node_id%3D%27728233%27%5D&skin=pdf&tlevel=-2&nohist=1]. Accessed 22 February 2021.
[2] Gematik. “Telematics infrastructure - Germany's the digital health network”. [https://www.gematik.de/telematikinfrastruktur/]. Accessed 22 February 2021.
[3] Gematik. “Overview”. [https://www.gematik.de/ueber-uns/overview/]. Accessed 22 February 2021.
[4] Gematik. “Glossary of Telematics Infranstructure”. [https://www.gematik.de/fileadmin/user_upload/fachportal/files/Spezifikationen/Methodische_Festlegungen/gemGlossar_V5.0.0.pdf]. Accessed 22 February 2021.

## 2.4.2 Data integration between human, animal, and environmental health sectors

### *2.4.2a*

**Is there evidence of established mechanisms at the relevant ministries responsible for animal, human, and wildlife surveillance to share data (e.g., through mosquito surveillance, brucellosis surveillance)?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence of established data-sharing mechanisms at the relevant ministries responsible for animal, human, and wildlife surveillance. The Robert Koch Institute’s (RKI) SurvNet reporting system collects data on infectious human diseases daily in line with the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) [1, 2]. This data can be publicly accessed in a dedicated database called SurvStat [3]. The Friedrich Loeffler Institute, the Federal Institute for Animal Health has a similar reporting system called the Animal Disease Information System (TSIS). The TSIS website has a publicly available database and monthly reports on dangerous animal diseases [4]. The Federal Office of Consumer Protection and Food Safety’s (BVL) monitoring of zoonoses includes surveillance of some wild animals and its findings are published annually [5]. However, a reporting system akin to SurvNet or TSIS is not used, instead, health authorities from the

Länder submit their data directly to the BVL and there is no publicly available database [5].

[1] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 22 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2020.
[3] Robert Koch Institute. 2021. "SurvStat@RKI 2.0". [https://survstat.rki.de/Default.aspx]. Accessed 24 January 2021.
[4] Friedrich Loeffler Institute. 2021. "Animal Disease Information System". [https://tsis.fli.de/Default.aspx]. Accessed 24 January 2021.
[5] Federal Ministry of Food and Agriculture and Consumer Protection. 2021. "Zoonoses Monitoring" [https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/02_AmtlicheLebensmittelueberwachung/06_ZoonosenMonitoring/lm_zoonosen_monitoring_node.html]. Accessed 24 January 2021.

## 2.4.3 Transparency of surveillance data

### *2.4.3a*

**Does the country make de-identified health surveillance data on infectious diseases publicly available via reports (or other format) on government websites (such as the Ministry of Health, Ministry of Agriculture, or similar)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany maintains a database of de-identified health surveillance data on disease outbreaks. The Robert Koch Institute's (RKI) SurvStat database is updated weekly and allows information on diseases outbreaks to be accessed in the form of custom queries, graphs and charts [1, 2]. The lag time for publishing data is less than one month [2]. In addition, the RKI publishes an epidemiological yearbook on notifiable diseases [3]. These yearbooks contain a summary of key developments in Germany's epidemiological situation, as well as statistical information on monitored diseases such as case numbers, case demography and geographical distribution [4]. No information about weekly reports on disease outbreaks was found on the website of the Federal Ministry of Health [5].

[1] Robert Koch Institute. "SurvStat@RKI 2.0". [https://survstat.rki.de/Default.aspx]. Accessed 24 January 2021.
[2] Robert Koch Institute. "SurvStat@RKI 2.0". [https://survstat.rki.de/Content/Instruction/Content.aspx]. Accessed 10 February 2021.
[3] Robert Koch Institute. Website. [https://www.rki.de/DE/Content/Infekt/Jahrbuch/jahrbuch_node.html;jsessionid=C88B051E4546B0A7C75294CC2D018DFB.internet061]. Accessed 22 January 2021.
[4] Robert Koch Institute. 1 March 2020. "Epidemiological Yearbook for Notifiable Diseases 2019 (Infektionsepidemiologisches Jahrbuch meldepflichtiger Krankheiten für 2019)". [https://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2019.pdf?__blob=publicationFile]. Accessed 24 January 2021.
[5] Federal Ministry of Health. Website. 2021. [https://www.bundesgesundheitsministerium.de/]. Accessed 24 January 2021.

### *2.4.3b*

**Does the country make de-identified COVID-19 surveillance data (including details such as daily case count, mortality rate, etc) available via daily reports (or other formats) on government websites (such as the Ministry of Health, or similar)?**

Yes = 1 , No = 0

Current Year Score: 1

Germany makes de-identified COVID-19 surveillance data publicly available via reports on its government websites. The Robert Koch Institute (RKI), the central federal institution responsible for disease prevention and control in Germany, publishes daily situation reports on the COVID-19 on its website. These daily situation reports are available in German and English, they include information on case numbers, death tolls, intensive care unit capacities, demographic information on cases and an estimation of the current R-value of the virus [1]. A Covid-19-Dashboard with Coronavirus Disease 2019 key metrics is also available and updated at least daily [2].

[1] Robert Koch Institute. Daily Situation Reports (Aktueller Lage-/Situationsbericht des RKI zu COVID-19). [https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Gesamt.html]. Accessed 22 January 2021.
[2] Robert Koch Institute. "Covid -19-Dashboard". 2021 [https://experience.arcgis.com/experience/478220a4c454480e823b17327b2bf1d4/page/page_1/]. Accessed 22 January 2021.

## 2.4.4 Ethical considerations during surveillance

### *2.4.4a*

**Is there legislation and/or regulations that safeguard the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities?**

Yes = 1 , No = 0

Current Year Score: 1

In Germany there is legislation that safeguards the confidentiality of identifiable health information for individuals, particularly that generated through health surveillance activities. Section 14 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) stipulates that cases of notifiable diseases being reported via an electronic system must be pseudonymized [1]. Furthermore, all notifiable disease case data that is sent to local health departments (LHD) is anonymized before it is passed on electronically via the SurvNet system to state health departments and to the Robert Koch Institute [2]. In addition, the confidentiality of identifiable health information for individuals is safeguarded by the 2016 European Union General Data Protection Regulation. [3]

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.
[2] Faensen, D., Claus, H., Benzler, J., Ammon. A., Pfoch, T., Breuer, T., Krause, G. "SurvNet@RKI - A multistate electronic reporting system for communicable diseases". Eurosurveillance Vol.11 Issues 4-6 Apr-Jun 2006. [https://edoc.rki.de/bitstream/handle/176904/677/25Ti4x2Kin0rE.pdf?sequence=1&isAllowed=y]. Accessed 22 January 2021.
[3] Official Journal of the European Union. 27 April 2016. "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)". [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN]. Accessed 8 August 2020.

### *2.4.4b*

**Is there legislation and/or regulations safeguarding the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities, include mention of protections from cyber attacks (e.g., ransomware)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has legislation safeguarding the confidentiality of identifiable health information for individuals from cyberattacks. Although the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) makes no explicit mention of cyber attacks, section 14 does make clear the importance of adequate cybersecurity for the electronic reporting system used to report cases of identifiable diseases [1]. State-of-the-art methods of encryption and authentication must be used by law to guarantee data protection and data security [1]. For example, data pertaining to cases is transmitted in encrypted form over the internet and is only accessible to authorities with special permissions [2]. Moreover, all case data is anonymized before being entered into the SurvNet reporting system, thereby ensuring confidentiality even in the case of a cyber attack [2]. In addition, as a member of the European Union, Germany is subject to the 2016 General Data Protection Regulation (GDPR), effective since 2018. [3] This extensive regulation includes specific provisions to protect data against cyber attacks, including a requirement that data held by state authorities must be overseen by a dedicated data protection officer who is proficient in dealing with cyber attacks, and a requirement to inform all individuals affected by a data breach within 72 hours. [3]

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.
[2] Faensen, D., Claus, H., Benzler, J., Ammon. A., Pfoch, T., Breuer, T., Krause, G. “SurvNet@RKI - A multistate electronic reporting system for communicable diseases”. Eurosurveillance Vol.11 Issues 4-6 Apr-Jun 2006. [https://edoc.rki.de/bitstream/handle/176904/677/25Ti4x2Kin0rE.pdf?sequence=1&isAllowed=y]. Accessed 22 January 2021.
[3] Official Journal of the European Union. 27 April 2016. "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)". [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN]. Accessed 8 August 2020.

## 2.4.5 International data sharing

### *2.4.5a*

**Has the government made a commitment via public statements, legislation and/or a cooperative agreement to share surveillance data during a public health emergency with other countries in the region?**

Yes, commitments have been made to share data for more than one disease = 2, Yes, commitments have been made to share data only for one disease = 1, No = 0

**Current Year Score: 2**

There is evidence that Germany has made a public commitment via statements or otherwise to share surveillance data for multiple diseases during a public health emergency with other countries. As a member of the European Union (EU), Germany shares surveillance data during public health emergencies with other countries in the region. All EU countries are part of the European Centre for Disease Prevention and Control’s Early Warning and Response System (EWRS). The EWRS is a platform allowing for the exchange of information on risk assessment and risk management for more timely, efficient and coordinated

public health action. The EWRS is used for notifications on disease outbreaks, exchanging information and decisions about the coordination of measures among member states. Over the years, it has played an important role in supporting various health crises such as severe acute respiratory syndrome (SARS), Ebola virus disease and avian influenza in humans [1]. Article 9 of Chapter IV of the European Union Decision on Serious Cross-Border Threats to Health (made 22 October 2013) stipulates that the European Commission shall make available to the national competent authorities through the EWRS any information that may be useful for coordinating the response including information relating to serious cross border threats to public health [2]. Additionally, Germany shares public health data in normal times through the German surveillance system of notifiable diseases, managed by the Robert Koch Institute (RKI), Germany's federal government agency and research institute responsible for disease control and prevention, which is updated weekly and available online through the SurvStat@RKI database [3]. The RKI is also the coordinator of EMERGE (Efficient response to highly dangerous and emerging pathogens at EU level), an EU-wide initiative in which 33 Associated Partners and 4 Collaborating Partners from 25 European countries collaborate to organize an efficient response to highly dangerous and emerging pathogens at EU level [4]. Data and information sharing is EMERGE's central project aim [4]. For example, one of the tasks of the RKI's Centre for Biological Threats and Special Pathogens 2 (ZBS), which deals with highly pathogenic microorganisms, is to share reference materials for diagnostics of relevant microbial pathogens within the framework of cooperative projects such as EMERGE [5]. However, the type of surveillance data Germany shares through EMERGE is not elaborated on in a desription of the project on the RKI website [6].

[1] European Centre for Disease Prevention and Control. 2021. "Early Warning and Response System (EWRS)". [https://ecdc.europa.eu/en/early-warning-and-response-system-ewrs]. Accessed 24 January 2021.
[2] European Parliament. "Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on Serious Cross-Border Threats to Health and Repealing Decision No 2119/98/EC." Official Journal of the European Union. [https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf]. Accessed 24 January 2021
[3] Robert Koch Institute. 2019. "SurvStat@RKI". [https://survstat.rki.de/Default.aspx]. Accessed 24 January 2021
[4] Robert Koch Institute. "EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level". [www.emerge.rki.eu/Emerge/EN/Home/Homepage_node.html]. Accessed 24 January 2021.
[5] Robert Koch Institute. "ZBS 2: Highly Pathogenic Microorganisms". [https://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs2/zbs2_node.html]. Accessed 10 February 2021.
[6] Robert Koch Institute. "Aims and objectives of the project". [https://www.emerge.rki.eu/Emerge/EN/Content/AboutUs/Aims/Aims_node.html]. Accessed 10 February 2021.

# 2.5 CASE-BASED INVESTIGATION

## 2.5.1 Case investigation and contact tracing

### *2.5.1a*

**Is there a national system in place to provide support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing in the event of a public health emergency?**

Yes, there is evidence that the national government supports sub-national systems to prepare for future public health emergencies = 2, Yes, there is evidence that the national government supports sub-national systems, but only in response to active public health emergencies = 1, No = 0

**Current Year Score: 1**

In Germany, there is evidence of a national system in place to provide support at the sub-national level to conduct contact tracing in the event of an active public health emergency, but not for future emergencies. Starting in the spring of 2020, approximately 500 Containment Scouts were hired by the Federal Office of Administration, on behalf of the Robert Koch Institute (RKI), Germany's leading research institute for the control and prevention of infectious diseases. The Containment Scouts consist mainly of students of medicine or medical science, and they provide on-site support to health departments at state level through faster and more effective contact tracing. To ensure that these Scouts are well prepared for their jobs, the RKI provides online-training materials, which covered infectious disease epidemiology, outbreak investigations, contact tracing and the use of the "Corona-Warn-App". The Containment Scout initiative was extended until the start of 2021, after a successful trial period in the Summer of 2020 [1]. No evidence of a pre-emptive plan to rapidly conduct contact tracing in the event of future public health emergencies was found in the RKI's 2017 National Pandemic Plan, the Protection Against Infection Act (adopted 20 July 2000, last amended 21 December 2020), or on the websites of the RKI and the Ministry of Health [2, 3, 4, 5].

[1] Robert Koch Institute. 2021. "What is a Containment Scout?" [https://www.rki.de/SharedDocs/FAQ/NCOV2019/FAQ_Scout.html;jsessionid=5792E356F6A1572FE919C993E7C4167B.internet062?nn=2370796]. Accessed 27 January 2021.
[2] Robert Koch Institute. 2021. Website. [https://www.rki.de/DE/Home/homepage_node.html;jsessionid=DAEFD036FAD771AF541FCA45E56AB25C.internet052]. Accessed 27 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 27 January 2021.
[4] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 22 January 2021.
[5] German Federal Government. ""Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))"". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021."

## *2.5.1b*

**Does the country provide wraparound services to enable infected people and their contacts to self-isolate or quarantine as recommended, particularly economic support (paycheck, job security) and medical attention?**

Yes, both economic support and medical attention are provided = 2, Yes, but only economic support or medical attention is provided = 1, No = 0

**Current Year Score: 1**

Germany provides economic support to enable infected people and their contacts to self-isolate or quarantine as recommended, but there is no evidence of medical wraparound services. Section 30 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) empowers the authorities to order patients and suspected patients of contagious diseases to isolate, either in a hospital or in another pre-approved manner [1]. Article 56 of the Act stipulates that persons who have not been able to work because of an epidemic, as they have been required to care for children or isolate, and whose earnings have suffered as a consequence, are entitled to financial compensation. Persons are entitled to the full amount of their earnings for the first six weeks that they are unable to work because of an epidemic [1]. There is no explicit reference to specific provisions for medical treatment during isolation in the act, though according to Section 30, only the patient's doctor may visit the patient during isolation, suggesting that these patients are able to receive medical treatment [1]. Furthermore, on 21 April 2020, the Ministry of Health issued an ordinance that aimed to facilitate the access to medication for chronically ill and self-isolating patients, however, the ordinance does not mention doctor's visits or further medical services [2]. No further evidence of specific provisions for medical treatment for persons in isolation during a

pandemic was found on the website of the Ministry of Health [3].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 26 January 2021.
[2] Federal Ministry of Health. 21 April 2020. "SARS-CoV-2 Supply of Medication Ordinance". [https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/guv-19-lp/sars-cov-2-arzneimittelversorgungs-vo.html]. Accessed 26 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 26 January 2021.

### *2.5.1c*

**Does the country make de-identified data on contact tracing efforts for COVID-19 (including the percentage of new cases from identified contacts) available via daily reports (or other format) on government websites (such as the Ministry of Health, or similar)?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany makes de-identified data on contact tracing efforts for COVID-19 available on government websites. On its website, the Robert Koch Institute (RKI), Germany's foremost research institute for disease prevention and control, provides detailed data on the ongoing coronavirus pandemic, in the form of daily reports and a live dashboard [1, 2]. The data includes regularly updated figures for confirmed cases, deaths, hospitalizations, recoveries and tests [1, 2]. However, these statistics do not refer to contact tracing [1, 2]. There is no evidence of figures related to contact tracing on the website of Ministry of Health or the website of the Federal Ministry of the Interior, Building and Community [3, 4].

[1] Robert Koch Institute. Website. 2021. [https://www.rki.de/DE/Home/homepage_node.html;jsessionid=4EA9E380AFA582BDF7DCC5CCCE039AC0.internet082]. Accessed 26 January 2021.
[2] Robert Koch Institute. "Covid -19-Dashboard". 2021 [https://experience.arcgis.com/experience/478220a4c454480e823b17327b2bf1d4/page/page_1/]. Accessed 26 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 26 January 2021.
[4] Federal Ministry of the Interior, Building and Community. 2021. Website. [https://www.bmi.bund.de/DE/startseite/startseite-node.html]. Accessed 26 January 2021.

## 2.5.2 Point of entry management

### *2.5.2a*

**Is there a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of a public health emergency?**

Yes, plan(s)/agreement(s) are in place to prepare for future public health emergencies = 2, Yes, but plan(s)/agreement(s) are in place only in response to active public health emergencies = 1, No = 0

**Current Year Score: 2**

In Germany, border control authorities are required by law to assist the health authorities with contact tracing and infectious disease surveillance for both active and future public health emergencies. Section 36 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) stipulates that the border control authorities must inform the relevant health authorities, such as local, state or federal health departments, immediately upon discovery of persons with notifiable diseases listed in section 6 and 7 of the Act. For this purpose, personal data, such as name, address and further contact details, may be collected and passed on to the relevant health authorities. Border control officials may also compare this personal data with the person's corresponding travel documents [1].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.

# 2.6 EPIDEMIOLOGY WORKFORCE

## 2.6.1 Applied epidemiology training program, such as the field epidemiology training program, for public health professionals and veterinarians (e.g., Field Epidemiology Training Program [FETP] and Field Epidemiology Training Program for Veterinarians [FETPV])

### *2.6.1a*

**Does the country meet one of the following criteria?**
**- Applied epidemiology training program (such as FETP) is available in country**
**- Resources are provided by the government to send citizens to another country to participate in applied epidemiology training programs (such as FETP)**
Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

**Current Year Score: 1**

Applied epidemiology training programs are available in Germany. The Field Epidemiology Program (FETP) has been available in Germany since 1996 and is part of the German government's effort to improve research capacity for the epidemiology of infectious diseases. The Robert Koch Institute (RKI), the federal government agency and research institute responsible for disease control and prevention, has been running the German Field Epidemiology Training Program since its inception [1, 2]. Germany is part of the European Centre for Disease Prevention and Control (ECDC) and as such eligible to participate in the European Program for Intervention Epidemiology Training (EPIET) program to send citizens to other countries for FETP training [3, 4].

[1] Ammon, A., Hamouda, O., Breuer, T., Petersen, L. 2001. "The Field Epidemiology Training Program (FETP) in Germany". Euro Surveillance: Bulletin Européen sur les maladies transmissibles (European communicable disease bulletin). 6. [https://www.researchgate.net/publication/11669729_The_Field_Epidemiology_Training_Program_FETP_in_Germany]. Accessed 24 January 2021.
[2] Robert Koch Institute. "Postgraduate Training for Applied Epidemiology (PAE) at the RKI: German Field Epidemiology Training Programme, FETP". [www.rki.de/EN/Content/Institute/DepartmentsUnits/InfDiseaseEpidem/Epidemiology_Training_Programme.html]. Accessed 24 January 2021.
[3] TEPHINET. "European Programme for Intervention Epidemiology Training (EPIET) and the European Programme for Public Health Microbiology Training (EUPHEM)". [https://www.tephinet.org/training-programs/european-programme-for-intervention-epidemiology-training-epiet-and-the-european]. Accessed 24 January 2021.

[4] European Centre for Disease Prevention and Control (ECDC). "Fellowship programme: EPIET/EUPHEM". [https://ecdc.europa.eu/en/epiet-euphem]. Accessed 24 January 2021.

### *2.6.1b*

**Are the available field epidemiology training programs explicitly inclusive of animal health professionals or is there a specific animal health field epidemiology training program offered (such as FETPV)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has field epidemiology training programs explicitly inclusive of animal health professionals. Germany's Robert Koch Institute (RKI), the federal government agency and research institute responsible for disease control and prevention, has been running the German Field Epidemiology Training Program (FETP) since 1996. The Postgraduate Training for Applied Epidemiology is explicitly inclusive of animal health professionals. Five applicants are accepted every year into the two-year programme which starts in mid-September. A prerequisite for admission is a university degree in human or veterinary medicine [1]. Germany is also part of the European Centre for Disease Prevention and Control (ECDC) and as such eligible to participate in the European Program for Intervention Epidemiology Training (EPIET) program to send citizens to other countries for FETP training [2, 3].

[1] Robert Koch Institute. "Postgraduate Training for Applied Epidemiology (PAE) at the RKI: German Field Epidemiology Training Programme, FETP". [www.rki.de/EN/Content/Institute/DepartmentsUnits/InfDiseaseEpidem/Epidemiology_Training_Programme.html]. Accessed 24 January 2021.
[2] TEPHINET. "European Programme for Intervention Epidemiology Training (EPIET) and the European Programme for Public Health Microbiology Training (EUPHEM)". [https://www.tephinet.org/training-programs/european-programme-for-intervention-epidemiology-training-epiet-and-the-european]. Accessed 24 January 2021.
[3] European Centre for Disease Prevention and Control (ECDC). "Fellowship programme: EPIET/EUPHEM". [https://ecdc.europa.eu/en/epiet-euphem]. Accessed 24 January 2021.

## 2.6.2 Epidemiology workforce capacity

### *2.6.2a*

**Is there public evidence that the country has at least 1 trained field epidemiologist per 200,000 people?**

Yes = 1 , No = 0

**Current Year Score: 0**

2020

Completed JEE assessments; Economist Impact analyst qualitative assessment based on official national sources, which vary by country

# Category 3: Rapid response to and mitigation of the spread of an epidemic

## 3.1 EMERGENCY PREPAREDNESS AND RESPONSE PLANNING

### 3.1.1 National public health emergency preparedness and response plan

#### *3.1.1a*

**Does the country have an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential?**

Evidence that there is a plan in place, and the plan is publicly available = 2, Evidence that the plan is in place, but the plan is not publicly available OR, Disease-specific plans are in place, but there is no evidence of an overarching plan = 1, No evidence that such a plan or plans are in place = 0

**Current Year Score: 2**

Germany has an overarching national public health emergency response plan addressing multiple communicable diseases with epidemic or pandemic potential, which is publicly available. The Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) outlines instructions related to a number of diseases, including the reporting obligations for notifiable diseases, screening measures, and pandemic protocols [1]. The act's broad scope limits the precision and specificity of its plans, it describes more general protocols and strategies such as the granting of special powers to the health authorities to allow a faster and more efficient response to a pandemic, the cooperation between border control and health authorities, financial support for those whose earnings have been affected by the health emergency and rules surrounding quarantine. However, section 28a of the act, adopted 18 November 2020, lists protective measures specifically against COVID-19, such as the compulsory wearing of masks, social distancing, limits on travel and the closure of non-essential businesses [1, 2]. In addition, the Robert Koch Institute, a German federal government agency and the foremost research institute responsible for disease control and prevention, published a National Pandemic Plan (NPP) in March 2017 [3]. The NPP specifically deals with the response to an outbreak of influenza but not other diseases, and there is no evidence that the RKI has published plans against other diseases [4]. Part I of the NPP sets out detailed emergency response measures, such as the scaling up of testing facilities through a pre-established laboratory network, while Part II outlines the scientific data that justifies these measures. In addition, Germany's regional states have their own publicly available influenza pandemic plans [5]. Germany's Federal Office of Civil Protection and Disaster Assistance (BBK), the agency that responds in the case of catastrophes and emergencies, has also made a handbook available that offers guidance on how businesses can prepare for a pandemic [6].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG)) Section 28a". Adopted 20 July 2000. Last amended 21 December 2020. [https://www.buzer.de/28a_IfSG.htm]. Accessed 10 February 2021.
[3] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 27 January 2021.
[4] Robert Koch Institute. Website. [https://www.rki.de/DE/Home/homepage_node.html]. Accessed 10 February 2021.
[5] Robert Koch Institute. "Pandemic Plans of the Federal States". [www.rki.de/DE/Content/InfAZ/I/Influenza/Pandemieplanung/Pandemieplaene_Bundeslaender.html?nn=2370466].

Accessed 27 January 2021.
[6] Federal Office of Civil Protection and Disaster Assistance. 16 March 2020. “Pandemic Plans for Businesses: A Handbook”. [https://www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Downloads/GesBevS/Handbuch-Betriebl_Pandemieplanung_2_Auflage.pdf?__blob=publicationFile]. Accessed 27 January 2021.

## *3.1.1b*

**If an overarching plan is in place, has it been updated in the last 3 years?**

Yes = 1 , No /no plan in place= 0

**Current Year Score: 1**

Germany's overarching national public health emergency response plan has been updated in the last 3 years. The Protection against Infection Act outlines instructions related to a number of diseases, as well as reporting obligations, quarantine measures and the restrictions to which infected persons are subject [1]. The law was first adopted 20 July 2000 and was last amended 21 December 2020 [1]. It was amended 18 November 2020 to include measures against COVID-19 [2]. However, the Robert Koch Institute’s National Pandemic Plan against influenzas, published in 2017, has not been updated since [3].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG)) Section 28a". Adopted 20 July 2000. Last amended 21 December 2020. [https://www.buzer.de/28a_IfSG.htm]. Accessed 10 February 2021.
[3] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 27 January 2021.

## *3.1.1c*

**If an overarching plan is in place, does it include considerations for pediatric and/or other vulnerable populations?**

Yes = 1 , No /no plan in place= 0

**Current Year Score: 1**

Germany’s overarching national public health emergency response plan includes considerations for pediatric and other vulnerable populations. The Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) outlines instructions related to a number of diseases, as well as reporting obligations, quarantine measures and the restrictions to which infected persons are subject [1]. Section 28 states that in the case of an outbreak of notifiable diseases the authorities can order the closure of schools, pre-schools and similar establishments [1]. Section 20 stipulates that the Federal Ministry of Health is authorized, with the consent of the Federal Council (Bundesrat), to order vulnerable segments of the population to participate in protective vaccinations or other measures of specific prophylaxis in the case of an epidemic - but there is no definition of which segments of the population are classed as vulnerable [1]. Additionally, section 36 states that homeless shelters and facilities accommodating asylum seekers and refugees must draw up internal hygiene measures to protect against infection and are subject to hygiene checks by the health authorities [1].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December

2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.

### *3.1.1d*

**Does the country have a publicly available plan in place specifically for pandemic influenza preparedness that has been updated since 2009?**

Yes = 1 , No = 0

**Current Year Score: 1**

2020

WHO Strategic Partnership for IHR and Health Security (SPH)

## 3.1.2 Private sector involvement in response planning

### *3.1.2a*

**Does the country have a specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has specific mechanisms in place for engaging with the private sector to assist with outbreak emergency preparedness and response. There is no evidence of an overarching plan that spells out how the private sector will help public health officials prepare for and respond to an outbreak. There is no mention of the involvement of the private sector in the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) [1]. The 2017 National Pandemic Plan (NPP) includes a section on pandemic planning in companies, the bureaucracy and other non-medical institutions. However, this section focuses primarily on the impact an outbreak can have on businesses and internal business processes, rather than how businesses can support response or planning [2]. Furthermore, the NPP only deals with influenza outbreaks. It does not cover multiple diseases with pandemic potential. A focus of the NPP is to maintain the functioning of critical infrastructures in the area of energy, water, telecommunication, transport, nutrition, as well as the financial and insurance sectors [2]. The websites of the Federal Ministry of Health and the Federal Office of Civil Protection and Disaster Assistance do not mention specific mechanisms for engaging with the private sector to assist with outbreak emergency preparedness and response [3, 4].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.
[2] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 27 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 26 January 2021.
[4] Federal Office of Civil Protection and Disaster Assistance. 2021. Website. [https://www.bbk.bund.de/DE/Home/home_node.html]. Accessed 27 January 2021.

## 3.1.3 Non-pharmaceutical interventions planning

### *3.1.3a*

**Does the country have a policy, plan and/or guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic?**

Yes, a policy, plan and/or guidelines are in place for more than one disease= 2, Yes, but the policy, plan and/or guidelines exist only for one disease = 1, No = 0

**Current Year Score: 2**

Germany has a plan in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic caused by influenza or COVID-19. The plan, however, does not extend to other diseases. The National Pandemic Plan (NPP), published in 2017 by the Robert Koch Institute, a German federal government agency and the foremost research institute responsible for disease control and prevention, outlines non-pharmaceutical measures that can be used to tackle the spread of an influenza virus; it does not explicitly state that these measures can be used against novel non-influenza diseases [1]. These measures include contact reducing measures, behavioural measures (such as handwashing and safe ways of sneezing and coughing), disinfection measures and the use of personal protective equipment [1]. The criteria for these NPIs are to be implemented are not very precise, dividing protective measures loosely into the following categories: detection and containment, protection, mitigation and recovery. However, many NPIs straddle multiple categories, for example contact reducing measures are classified as both containment and protection. The NPP does explain precisely what each measure is supposed to achieve, be it limiting the spread of a disease or the shielding of a vulnerable group [1]. The NPP also explains that the use of strategies like NPIs must closely follow the development of the pandemic, they must be adapted in real time as the public health situation evolves [1]. Section 28 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) gives competent authorities the powers to implement NPIs to limit the spread of an infectious disease. Sections 28 and 34 also allow the authorities to ban people suspected of various infectious diseases, such as measles, cholera and rubella, from performing teaching, educational, nursing or supervisory activities in community facilities. Finally, section 28a describes in great detail necessary NPIs to limit the spread of COVID-19, these include social distancing, wearing masks and limits on or closures of businesses [2]. No evidence of a plan addressing the implementation of NPIs for a novel disease, or applicable to other diseases, was found on the websites of the Federal Ministry of Health and the Federal Office of Civil Protection and Disaster Assistance, or that of the Robert Koch Institute [3, 4, 5].

[1] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 27 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.
[3] Federal Ministry of Health. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 26 January 2021.
[4] Federal Office of Civil Protection and Disaster Assistance. Website. [https://www.bbk.bund.de/DE/Home/home_node.html]. Accessed 27 January 2021.
[5] Robert Koch Institute. Website. [https://www.rki.de/EN/Home/homepage_node.html]. Accessed 12 February 2021.

# 3.2 EXERCISING RESPONSE PLANS

## 3.2.1 Activating response plans

### *3.2.1a*

**Does the country meet one of the following criteria?**
**- Is there evidence that the country has activated their national emergency response plan for an infectious disease outbreak in the past year?**
**- Is there evidence that the country has completed a national-level biological threat-focused exercise (either with WHO or separately) in the past year?**
Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

**Current Year Score: 0**

There is insufficient evidence that Germany activated its national emergency response plan for an infectious disease outbreak. On 25 March 2020, the Federal Government declared the outbreak of COVID-19 a national public health emergency by adopting the Draft Law for the Protection of the Population from a National Public Health Emergency. The law explicitly activated section 5 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020), thereby triggering the act's emergency response plan [1, 2]. This meant that the Ministry of Health was granted special powers to enact public health measures without consulting regional state level authorities and without needing the Federal Council's consent . However, there is no evidence of a national emergency response that was activated. [1, 2]. According to the World Health Organization's website, Germany completed a national-level biological threat-focused exercise in the form of a simulation exercise (SimEx) in November 2018. However, there is no publicly available report on the SimEx's results, nor is the type of SimEx specified [3].

[1] German Federal Parliament (Bundestag). 25 March 2020. "Draft Law for the Protection of the Population from a National Public Health Emergency (Entwurf eines Gesetzes zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite)." [https://dip21.bundestag.de/dip21/btd/19/181/1918156.pdf]. Accessed 27 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.
[3] World Health Organization. 2021. "Simulation Exercise Dashboard". [https://extranet.who.int/sph/simulation-exercise#]. Accessed 27 January 2021.

### *3.2.1b*

**Is there evidence that the country in the past year has identified a list of gaps and best practices in response (either through an infectious disease response or a biological-threat focused exercise) and developed a plan to improve response capabilities?**
Yes, the country has developed and published a plan to improve response capacity = 2 , Yes, the country has developed a plan to improve response capacity, but has not published the plan = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has undergone an exercise to identify a list of gaps and best practices in response and developed a plan to improve response capabilities in the past year. According to the World Health Organization's website, Germany completed a national-level biological threat-focused exercise in the form of a simulation exercise (SimEx) in

November 2018. However, there is no publicly available report on the SimEx's results, nor is the type of SimEx specified [1]. Additionally, the Federal Office of Civil Protection and Disaster Assistance (BKK), coordinates cross-state crisis management exercises (LÜKEX) every two years [2]. The crisis scenario, which is changed for each cycle, can be a biological threat-focused exercise, but since the first exercise in 2004, biological threats have only been selected twice [3]. LÜKEX 13, the 2013 exercise, involved responding to the intentional spreading of a biological pathogen at a major event, while LÜKEX 07, the 2007 exercise, involved simulating a global flu pandemic [3]. According to the BKK, LÜKEX 13 shed light on ways federal-state cooperation could be improved, however, the improvements are not elaborated on, nor does a publicly available report on the exercise exist [3]. An evaluation report for LÜKEX 07 is publicly available on the BKK's website, it includes the identification of gaps and best practices in emergency response [4]. There is no evidence that Germany has undergone an exercise to identify a list of gaps and best practices in response and developed a plan to improve response capabilities in the past year on the website of the Ministry of Health [5]. Germany has not particpated in an After Action Review (AAR) organized by the World Health Organization [6].

[1] World Health Organization. 2021. "Simulation Exercise Dashboard". [https://extranet.who.int/sph/simulation-exercise#]. Accessed 27 January 2021.
[2] Federal Office of Civil Protection and Disaster Assistance. 2021. "Crisis Simulation for the Protection of the German Population (LÜKEX – Krisensimulation für den Bevölkerungsschutz in Deutschland)". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/Luekex/Luekex_node.html]. Accessed 27 January 2021.
[3] Federal Office of Civil Protection and Disaster Assistance. 2021. "LÜKEX History". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/Luekex/Vergangene_Uebungen/vergangene_uebungen_node.html#doc5496466bodyText3]. Accessed 27 January 2021.
[4] Federal Office of Civil Protection and Disaster Assistance. 2007. "Evaluation Report: LÜKEX 2007". [https://www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Downloads/Luekex/LUEKEX07_Auswertungsbericht_lang.pdf?__blob=publicationFile]. Accessed 27 January 2021.
[5] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 26 January 2021.
[6] World Health Organization. "After Action Review". [https://extranet.who.int/sph/after-action-review]. Accessed 22 February 2021

## 3.2.2 Private sector engagement in exercises

### *3.2.2a*

**Is there evidence that the country in the past year has undergone a national-level biological threat-focused exercise that has included private sector representatives?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has undergone a national-level biological threat-focused exercise that has included private sector representatives in the past year. According to the World Health Organization's website, Germany completed a national-level biological threat-focused exercise in the form of a simulation exercise (SimEx) in November 2018 [1]. However, there is no publicly available report on the SimEx's results, nor is the type of SimEx specified, so it is unknown if the private sector was involved [1]. Additionally, the Federal Office of Civil Protection and Disaster Assistance (BKK), coordinates cross-state crisis management exercises (LÜKEX) every two years [2]. The crisis scenario, which is changed for each cycle, can be a biological threat-focused exercise, but since the first exercise in 2004, biological threats have only been selected twice [3]. LÜKEX 13, the 2013 exercise, involved responding to the intentional spreading of a biological pathogen at a major event, while LÜKEX 07, the 2007 exercise, involved simulating a global flu pandemic [3]. Both LÜKEX 13 and LÜKEX 07 involved the

participation of the private sector [3]. LÜKEX 07 was thoroughly planned and prepared for 18 months; its participants included almost 50 companies and economic organisations [4]. No information is given on exactly how participants from the private sector were selected apart from them having some relevance to crisis management [4]. There is no evidence that Germany has undergone a national-level biological threat-focused exercise that has included private sector representatives in the past year on the website of the Ministry of Health [5].

[1] World Health Organization. 2021. "Simulation Exercise Dashboard". [https://extranet.who.int/sph/simulation-exercise#]. Accessed 27 January 2021.
[2] Federal Office of Civil Protection and Disaster Assistance. 2021. "Crisis Simulation for the Protection of the German Population (LÜKEX – Krisensimulation für den Bevölkerungsschutz in Deutschland)". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/Luekex/Luekex_node.html]. Accessed 27 January 2021.
[3] Federal Office of Civil Protection and Disaster Assistance. 2021. "LÜKEX History". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/Luekex/Vergangene_Uebungen/vergangene_uebungen_node.html#doc5496466bodyText3]. Accessed 27 January 2021.
[4] Federal Office of Civil Protection and Disaster Assistance. 2007. "Evaluation Report: LÜKEX 2007". [https://www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Downloads/Luekex/LUEKEX07_Auswertungsbericht_lang.pdf?__blob=publicationFile]. Accessed 27 January 2021.
[5] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 26 January 2021.

# 3.3 EMERGENCY RESPONSE OPERATION

## 3.3.1 Emergency response operation

### *3.3.1a*

**Does the country have in place an Emergency Operations Center (EOC)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has an Emergency Operations Center in place. The Joint Information and Situation Centre (GMLZ) under the Federal Office of Civil Protection and Disaster Assistance is the national contact point in emergencies that threaten the German population on a national level [1]. The GMLZ is tasked with closely monitoring an emergency as well as proactively assessing and analysing its developments. Emergencies covered by the GMLZ include mass casualty incidents involving injured or sick people [1]. Established in 2002, the GMLZ operates around the clock. Individual regional states are primarily responsible for disaster management, they deal with crisis situations that are caused by natural disasters, climate change, large-scale emergencies, and pandemics or epidemics, however the GMLZ can provide expertise and assistance [2, 3].

[1] Federal Office of Civil Protection and Disaster Assistance. 2021. " Joint Information and Situation Centre (Gemeinsame Melde- und Lagezentrum (GMLZ))". [www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/GMLZ/GMLZ_node.html]. Accessed 26 January 2021.
[2] Ministry of Interior. 2015. "The Crisis Management System in Germany". December 2015. [www.bmi.bund.de/SharedDocs/downloads/EN/publikationen/2012/system_krisenmanagement_en.pdf?__blob=publicationFile&v=1]. Accessed 26 January 2021.
[3] European Civil Protection and Humanitarian Aid Operations. 2019. "Germany: Overview of the National Disaster Management System". [https://ec.europa.eu/echo/what/civil-protection/disaster-management/germany_en]. Accessed 26

January 2021.

### *3.3.1b*

**Is the Emergency Operations Center (EOC) required to conduct a drill for a public health emergency scenario at least once per year or is there evidence that they conduct a drill at least once per year?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence to suggest that Germany's Emergency Operations Centre conducts or is required to conduct a drill for a public health emergency scenario at least once per year. The Federal Office of Civil Protection and Disaster Assistance (BKK), under which Germany's Emergency Operations Centre, the Joint Information and Situation Centre (GMLZ) operates, conducts cross-state crisis management exercises (LÜKEX) every two years [1]. The crisis scenario, which is changed for each cycle, can be a biological threat-focused exercise, but since the first exercise in 2004, biological threats have only been selected twice [3]. LÜKEX 13, the 2013 exercise, involved responding to the intentional spreading of a biological pathogen at a major event, while LÜKEX 07, the 2007 exercise, involved simulating a global flu pandemic [1]. The websites of the Federal Ministry of Health, the Federal Office for Civil Protection and Disaster Assistance and international and local media do not indicate that Germany's Emergency Operations Centre is required to conduct a drill at least once per year [2, 3].

[1] Federal Office of Civil Protection and Disaster Assistance. 2021. "Crisis Simulation for the Protection of the German Population (LÜKEX – Krisensimulation für den Bevölkerungsschutz in Deutschland)". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/Luekex/Luekex_node.html]. Accessed 27 January 2021.
[2] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/en/en.html]. Accessed 27 January 2021.
[3] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 27 January 2021.

### *3.3.1c*

**Is there public evidence to show that the Emergency Operations Center (EOC) has conducted within the last year a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency/scenario?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany's Emergency Operations Centre within the Federal Office of Civil Protection and Disaster Assistance (BBK) has carried out a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency in the last year. Germany's Emergency Operations Centre, the Joint Information and Situation Centre (GMLZ) conducts cross-state crisis management exercises (LÜKEX) every two years, however these exercises are not focussed purely on dealing with public health emergencies [1]. The last LÜKEX exercise to focus on a public health emergency was LÜKEX 13, in 2013, which involved responding to the intentional spreading of a biological pathogen at a major event [1]. Additionally, Germany completed a national-level biological threat-focused exercise in the form of a simulation exercise (SimEx) with the World Health Organization in November 2018. However, there is no publicly available report on the SimEx's results, nor is the type of SimEx specified [2]. The Federal Government's declaration of the COVID-19 outbreak as a national public health emergency on 25 March 2020 did not involve triggering an emergency response from the BBK or GMLZ. Instead it activated clauses in the Protection against Infection Act (adopted 20 July 2000,

last amended 21 December 2020), granting the Ministry of Health special powers to enact public health measures without interference from regional state level authorities and without needing the Federal Council's consent [3]. There is no evidence that Germany's Emergency Operations Centre has carried out a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency in the last year on the websites of the Ministry of Health and the Federal Office of Civil Protection and Disaster Assistance (BBK) [4, 5].

[1] Federal Office of Civil Protection and Disaster Assistance. "Crisis Simulation for the Protection of the German Population (LÜKEX – Krisensimulation für den Bevölkerungsschutz in Deutschland)". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/Luekex/Luekex_node.html]. Accessed 28 January 2021.
[2] World Health Organization. "Simulation Exercise Dashboard". [https://extranet.who.int/sph/simulation-exercise#]. Accessed 28 January 2021.
[3] German Federal Parliament (Bundestag). 25 March 2020. "Draft Law for the Protection of the Population from a National Public Health Emergency (Entwurf eines Gesetzes zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite)." [https://dip21.bundestag.de/dip21/btd/19/181/1918156.pdf]. Accessed 28 January 2021.
[4] Federal Ministry of Health. Website. [https://www.bundesgesundheitsministerium.de/en/en.html]. Accessed 28 January 2021.
[5] The Federal Office for Civil Protection and Disaster Assistance (BBK). Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 28 January 2021.

# 3.4 LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

## 3.4.1 Public health and security authorities are linked for rapid response during a biological event

### *3.4.1a*

**Does the country meet one of the following criteria?**
**- Is there public evidence that public health and national security authorities have carried out an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack)?**
**- Are there publicly available standard operating procedures, guidelines, memorandums of understanding (MOUs), or other agreements between the public health and security authorities to respond to a potential deliberate biological event (i.e., bioterrorism attack)?**
Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

**Current Year Score: 1**

German public health and national security authorities carried out an exercise to respond to a potential deliberate biological event in 2013. There is evidence that guidelines for the cooperation of public health and security authorities exist, however these are not publicly available. The 2013 cross-state crisis management exercise (LÜKEX) was coordinated by the Federal Office of Civil Protection and Disaster Assistance (BBK) and involved the participation of the Federal Ministry of Health, the Federal Ministry of Defense, the Federal Ministry of the Interior, the Federal Ministry of Food and Agriculture, the Foreign Office, state and federal officials, private firms and scientific representatives [1]. The exercise consisted of responding to an intentional act of food poisoning and the deliberate spreading of a biological pathogen at a major event [1]. Although the report on this exercise (LÜKEX 13) is not available on the BBK's website it can be accessed online, the report describes various recommendations such as how to improve communication between the various ministries and actors in a similar scenario [2]. Additionally, the Federal Information Center for Biological Threats and Special Pathogens (IBBS) is responsible for strengthening national public health preparedness and response capabilities to biological threats caused by highly pathogenic

or bioterrorism-related agents. Its tasks include the development of national preparedness and response guidelines, as well as collaboration with national and international public health and security authorities [3]. There is no evidence that these response guidelines are required to address collaboration between public health and security bodies. Furthermore, there is no evidence that these guidelines, in the form of a single, comprehensive document, are in place as their existence is not elaborated upon [3]. No evidence of publicly available standard operating procedures, guidelines, memoranda of understanding (MOUs), or other agreements between the public health and security authorities to respond to a potential deliberate biological event were found on the websites of the Federal Ministry of Health or the Federal Office of Civil Protection and Disaster Assistance [4, 5].

[1] Federal Office of Civil Protection and Disaster Assistance. “Crisis Simulation for the Protection of the German Population (LÜKEX – Krisensimulation für den Bevölkerungsschutz in Deutschland)”. [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Krisenmanagement/Luekex/Luekex_node.html]. Accessed 28 January 2021.
[2] Federal Office of Civil Protection and Disaster Assistance. June 2014. “Evaluation Report LÜKEX 13: Exception Biological Threat Situations (Auswertungsbericht LÜKEX 13. Außergewöhnliche biologische Bedrohungslagen)”. [https://docplayer.org/35202115-Auswertungsbericht-luekex-13-aussergewoehnliche-biologische-bedrohungslagen.html]. Accessed 28 January 2021.
[3] Robert Koch Institute. "Federal Information Centre for Biological Threats and Special Pathogens (IBBS)". [www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/ibbs/ibbs_node.html]. Accessed 28 January 2021.
[4] Federal Ministry of Health. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 24 February 2021.
[5] Federal Office of Civil Protection and Disaster Assistance. Website. [https://www.bbk.bund.de/DE/Home/home_node.html]. Accessed 24 February 2021.

# 3.5 RISK COMMUNICATIONS

## 3.5.1 Public communication

### *3.5.1b*

**Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) outline how messages will reach populations and sectors with different communications needs (eg different languages, location within the country, media reach)?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has in place a national-level risk communication plan for a flu pandemic which outlines how messages will reach populations and sectors with different communications needs. The National Pandemic Plan (NPP), published in 2017 by the Robert Koch Institute (RKI), a German federal government agency and the foremost research institute responsible for disease control and prevention, includes a chapter dedicated to communication, it presents a plan for the communication of pandemic-related information to the public, the media and the professional public [1]. For example, on a federal level, the public are to be informed of developments in the outbreak of a given disease as well as necessary protective measures to be taken via the Federal Centre for Health Education, which compiles and makes accessible scientific and epidemiological information from the RKI, the Federal Office for Drugs and Services and the Paul-Ehrlich Institute for Vaccines and Biomedicines. The plan emphasizes that complex scientific information must be presented in a way that the public will be able to understand so as to ensure protective measures are implemented [1]. The NPP also highlights the importance of information being shared and updated very regularly as well as being distributed in other languages [1]. The General Administrative Regulations for the Coordination of Infection Control in Epidemically Significant Cases, issued 12 December

2013, also describes the division of labour, between federal and state authorities, with regards to risk and crisis communication [2]. Section 11 states that it is the responsibility of the federal government to make available information on scientific questions, the development of the health emergency situation on a federal level and information on international relations [2]. State level authorities are then supposed to supplement this information with geographically specific information before sharing it with the public [2]. To safeguard the credibility of official information, subnational officials are required to have their dispatches evaluated by the RKI, if the information they intend to publicize deviates significantly from the federal line or contains new information [2].

[1] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 28 January 2021.
[2] German Federal Government. 12 December 2013. " General Administrative Regulations for the Coordination of Infection Control in Epidemically Significant Cases (Allgemeine Verwaltungsvorschrift ber die Koordinierung des Infektionsschutzes in epidemisch bedeutsamen Fällen. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_12122013_31945300302.htm]. Accessed 28 January 2021.

## 3.5.1 Risk communication planning

### *3.5.1a*

**Does the country have in place, either in the national public health emergency response plan or in other legislation, regulation, or strategy documents, a section detailing a risk communication plan that is specifically intended for use during a public health emergency?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has in place a national-level risk communication plan for a flu pandemic. The National Pandemic Plan (NPP), published in 2017 by the Robert Koch Institute (RKI), a German federal government agency and the foremost research institute responsible for disease control and prevention, includes a chapter dedicated to communication, which presents a plan for the communication of pandemic related information to the public, the media and the professional public [1]. For example, on a federal level, the public are to be informed of developments in the outbreak of a given disease as well as necessary protective measures to be taken via the Federal Centre for Health Education, which compiles and makes accessible scientific and epidemiological information from the RKI, the Federal Office for Drugs and Services and the Paul-Ehrlich Institute for Vaccines and Biomedicines [1]. The plan emphasizes that complex scientific information must be presented in a way that the public will be able to understand so as to ensure protective measures are properly implemented and respected [1]. The NPP also highlights the importance of information being shared and updated very regularly as well as being distributed in other languages [1]. The General Administrative Regulations for the Coordination of Infection Control in Epidemically Significant Cases, issued 12 December 2013, also describe the division of labour, between federal and state authorities, with regards to risk and crisis communication [2]. Section 11 states that it is the responsibility of the federal government to make available information on scientific questions, the development of the health emergency situation on a federal level and information on international relations [2]. State-level authorities are then supposed to supplement this information with geographically specific information before sharing it with the public. To safeguard the credibility of official information, subnational officials are required to have their dispatches evaluated by the RKI, if the information they intend to publicize deviates significantly from the federal line or contains new information [2]. The Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) does not include information on a risk or crisis communication plan [3].

[1] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 28 January 2021.
[2] German Federal Government. 12 December 2013. " General Administrative Regulations for the Coordination of Infection Control in Epidemically Significant Cases (Allgemeine Verwaltungsvorschrift ber die Koordinierung des Infektionsschutzes in epidemisch bedeutsamen Fällen. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_12122013_31945300302.htm]. Accessed 28 January 2021.
[3] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 27 January 2021.

### *3.5.1c*

**Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) designate a specific position within the government to serve as the primary spokesperson to the public during a public health emergency?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence of a plan, strategy, regulation or law that designates a specific position within the government to serve as the primary spokesperson to the public during a public health emergency. There is no such provision in the 2017 National Pandemic Plan (NPP) or the General Administrative Regulations for the Coordination of Infection Control in Epidemically Significant Cases, issued 12 December 2013 [1, 2]. There is no evidence of such a designation on the websites the Ministry of the Interior, Building and Community, the Ministry of Health and the Federal Ministry of Food and Agriculture [3, 4, 5]. Information is instead shared with the public by federal and state officials primarily through official websites as opposed to personal accounts, this is in line with the requirements of the NPP and sections 10 to 13 of the General Administrative Regulations [1, 2] It may be noted that at the time of research, quotes and soundbites from the Minister of Health featured heavily on the social media outlets of the Minister of Health [6, 7, 8, 9].

[1] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 28 January 2021.
[2] German Federal Government. 12 December 2013. " General Administrative Regulations for the Coordination of Infection Control in Epidemically Significant Cases (Allgemeine Verwaltungsvorschrift ber die Koordinierung des Infektionsschutzes in epidemisch bedeutsamen Fällen. [www.verwaltungsvorschriften-im-internet.de/bsvwvbund_12122013_31945300302.htm]. Accessed 28 January 2021.
[3] Federal Ministry of the Interior, Building and Community 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 28 January 2021.
[4] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 28 January 2021.
[5] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 28 January 2021.
[6] Federal Ministry of Health. 2021. Website. “Federal Ministry of Health YouTube Account”. [https://www.youtube.com/user/BMGesundheit/featured]. Accessed 28 January 2021.
[7] Federal Ministry of Health. 2021. Website. “Federal Ministry of Health Facebook Account”. [https://www.facebook.com/bmg.bund]. Accessed 28 January 2021.
[8] Federal Ministry of Health. 2021. Website. “Federal Ministry of Health Instagram Account”. [https://www.instagram.com/bundesgesundheitsministerium/]. Accessed 28 January 2021.

[9] Federal Ministry of Health. 2021. Website. "Federal Ministry of Health Twitter Account". [https://twitter.com/BMG_Bund]. Accessed 28 January 2021.

## 3.5.2 Public communication

### *3.5.2a*

**In the past year, is there evidence that the public health system has actively shared messages via online media platforms (e.g. social media, website) to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation?**

Public health system regularly shares information on health concerns = 2, Public health system shares information only during active emergencies, but does not regularly utilize online media platforms = 1, Public health system does not regularly utilize online media platforms, either during emergencies or otherwise = 0

**Current Year Score: 2**

There is evidence that in the past year the German public health system has actively shared messages via online media platforms to inform the public about ongoing public health concerns and to dispel rumors, and misinformation. The Federal Ministry of Health shares information regularly via its accounts on YouTube, Facebook, Instagram and Twitter [1, 2, 3, 4]. A wide array of information on ongoing public health concerns and public health generally is shared via these platforms, including: explanation videos, answers to common questions, reliable resources for further reading, myth-busting content, updates to the public health situation, the introduction of new protective measures, vaccination plans and timelines, as well as regular soundbites and quotes from Jens Spahn, the Minister of Health [1, 2, 3, 4]. For example, on 24 February 2021, the Federal Ministry of Health's Instagram account posted a video explaining how to interpret vaccination against COVID-19 statistics [5]. On 13 February 2021, an illustration was posted that dispelled the myth that people with allergies have a high risk of entering into anaphylactic shock after being vaccinated [6]. In 2019, when no public health emergency had been officially declared, the Ministry of Health posted extensively on Facebook about the dangers of measles and the need to vaccinate against it. The posts stress the importance of vaccination and aim to dispel corresponding doubts and concerns [2].

[1] Federal Ministry of Health. "Federal Ministry of Health YouTube Account". [https://www.youtube.com/user/BMGesundheit/featured]. Accessed 28 January 2021.
[2] Federal Ministry of Health. "Federal Ministry of Health Facebook Account". [https://www.facebook.com/bmg.bund]. Accessed 28 January 2021.
[3] Federal Ministry of Health. "Federal Ministry of Health Instagram Account". [https://www.instagram.com/bundesgesundheitsministerium/]. Accessed 28 January 2021.
[4] Federal Ministry of Health. "Federal Ministry of Health Twitter Account". [https://twitter.com/BMG_Bund]. Accessed 28 January 2021.
[5] Federal Ministry of Health. "Federal Ministry of Health Instagram Account: Correctly understanding and interpreting vaccination statistics". [https://www.instagram.com/p/CLrQRk0qs4h/]. Accessed 28 January 2021.
[6] Federal Ministry of Health. "Federal Ministry of Health Instagram Account: Anaphylactic Shock from the vaccination against COVID-19 is very rare". [https://www.instagram.com/p/CLOjeXdqv-R/]. Accessed 28 January 2021.

### *3.5.2b*

**Is there evidence that senior leaders (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years?**

No = 1, Yes = 0

Current Year Score: 1

There is no evidence that German senior leaders have shared misinformation or disinformation on infectious diseases in the past two years. However, in May 2020, a civil servant in the Ministry of the Interior was dismissed for circulating an online report that described coronavirus as a “false alarm” and contained other false information about COVID-19 [1, 2]. Additionally, in March of 2020, the Ministry of Health and its minister, Jens Spahn, drew criticism for describing reports that massive restrictions on public life were soon to be announced as "fake news" days before the Ministry of Health announced restrictions on public life. Critics said this move hurt the credibility of official outlets and harmed efforts to fight false information [3].

[1] The Times. 13 May 2020. “German adviser sacked for report on ‘lockdown peril”. [https://www.thetimes.co.uk/article/german-adviser-sacked-for-report-on-lockdown-peril-jjzvpvrq9]. Accessed 28 January 2021.
[2] N-TV. 10 May 2020 “Corona Rebel angers the Ministry of the Interior”. [https://www.n-tv.de/politik/Corona-Rebell-veraergert-Innenministerium-article21771218.html]. Accessed 28 January 2021.
[3] ZDF. 17 March 2020. “Failed Coronavirus Tweet: The Minister and Fake News”. [https://www.zdf.de/nachrichten/politik/corona-gesundheitsministerium-fake-twitter-100.html]. Accessed 28 January 2021.

# 3.6 ACCESS TO COMMUNICATIONS INFRASTRUCTURE

## 3.6.1 Internet users

### *3.6.1a*

Percentage of households with Internet

Input number

Current Year Score: 88.13

2019

International Telecommunication Union (ITU)

## 3.6.2 Mobile subscribers

### *3.6.2a*

Mobile-cellular telephone subscriptions per 100 inhabitants

Input number

Current Year Score: 128.36

2019

International Telecommunication Union (ITU)

## 3.6.3 Female access to a mobile phone

### *3.6.3a*

**Percentage point gap between males and females whose home has access to a mobile phone**

Input number

**Current Year Score: 3.0**

2019

Gallup; Economist Impact calculation

## 3.6.4 Female access to the Internet

### *3.6.4a*

**Percentage point gap between males and females whose home has access to the Internet**

Input number

**Current Year Score: 0**

2019

Gallup; Economist Impact calculation

# 3.7 TRADE AND TRAVEL RESTRICTIONS

## 3.7.1 Trade restrictions

### *3.7.1a*

**In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of medical goods (e.g. medicines, oxygen, medical supplies, PPE) due to an infectious disease outbreak?**

Yes = 0 , No = 1

**Current Year Score: 0**

Germany has issued a restriction, without international or bilateral support, on the export of medical goods in the past year. On 4 March 2020, the Federal Ministry for Economic Affairs and Energy issued a decree banning the export of personal protective equipment (PPE), such as masks, visors, goggles, gloves and protective suits [1, 2]. However, on 12 March 2020, the decree was revised so that authorization could be requested for the export of PPE. Finally, on 19 March 2020, the order was repealed in line with European Commission's Implementing Regulation (EU) 2020/402 issued 14 March 2020, which restricted the export of medical PPE outside the European Union [3, 4].

[1] Noerr. 6 October 2020. "Restrictions on the export and movement of medical protective clothing due to coronavirus – with exceptions and prior approval requirements". [https://www.noerr.com/en/newsroom/news/restrictionsontheexportandmovementofmedicalprotectiveclothingduetocoronaviruswithexceptionsandpriora]. Accessed 28 January 2021.
[2] Federal Ministry for Economic Affairs and Energy. 14 March 2020. "Information from the Federal Ministry of Economics on the amendment of the general decree for protective equipment". [https://www.bmwi.de/Redaktion/DE/Pressemitteilungen/2020/20200317-informationen-des-

bundeswirtschaftsministeriums-zur-anpassung-der-allgemeinverf%C3%BCgung-fuer-schutzausruestung.html]. Accessed 28 January 2021.
[3] Federal Ministry for Economic Affairs and Energy. 19 March 2020. "Information from the Federal Ministry of Economics on the repeal of the general decree for protective equipment".
[https://www.bmwi.de/Redaktion/DE/Pressemitteilungen/2020/20200319-informationen-zur-aufhebung-der-allgemeinverfuegung-fuer-schutzausruestung.html]. Accessed 28 January 2021.
[4] European Commission. 14 March 2020. "COMMISSION IMPLEMENTING REGULATION (EU) 2020/402 of 14 March 2020 making the exportation of certain products subject to the production of an export authorisation". [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0402]. Accessed 28 January 2021.

### *3.7.1b*

**In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of non-medical goods (e.g. food, textiles, etc) due to an infectious disease outbreak?**

Yes = 0 , No = 1

**Current Year Score: 1**

There is no evidence that Germany has in the past year issued a restriction on the export or import of non-medical goods without international or bilateral support. There is no evidence of such restrictions on the websites of the Federal Ministry of Food and Agriculture, the Federal Ministry for Economic Affairs and Energy, the Federal Ministry of the Interior, Building and Community and the Federal Ministry of Health [1, 2, 3, 4].

[1] Federal Ministry of Food and Agriculture. 2021. Website. [https://www.bmel.de/DE/Home/home_node.html]. Accessed 28 January 2021.
[2] Federal Ministry for Economic Affairs and Energy. 2021. Website.
[https://www.bmwi.de/Navigation/DE/Home/home.html]. Accessed 28 January 2021.
[3] Federal Ministry of the Interior, Building and Community 2021. Website.
[https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 28 January 2021.
[4] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 28 January 2021.

## 3.7.2 Travel restrictions

### *3.7.2a*

**In the past year, has the country implemented a ban, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak?**

Yes = 0 , No = 1

**Current Year Score: 0**

In the past year, Germany has implemented bans without bilateral support on travelers arriving from specific countries due to an infectious disease outbreak. On 16 March 2020, Germany unilaterally banned travelers from Switzerland, Austria, France, Luxemburg and Denmark in an effort to slow the spread of COVID-19 [1]. Only goods, German nationals, residents and people commuting for work could cross these five borders into Germany, all other travellers would be denied entry [2, 3, 4, 5]. This decision lacked the support of the European Union [6].

[1] Bayerischer Rundfunk 24. 15 March 2020. "Coronavirus: Deutschland schließt Grenzen zu fünf Nachbarländern".
[https://www.br.de/nachrichten/deutschland-welt/deutschland-macht-grenzen-wegen-corona-krise-zum-teil-dicht,RtJd8Xp].

Accessed 28 January 2021.
[2] Der Spiegel. 15 March 2020. “Deutschland schließt Grenzen zu Frankreich, Österreich und der Schweiz”. [https://www.spiegel.de/politik/deutschland/coronavirus-deutschland-schliesst-grenzen-zu-frankreich-oesterreich-und-der-schweiz-a-9910fb81-f635-4be5-8138-bcbcbfd491d4]. Accessed 28 January 2021.
[3] Deutsche Welle. 15 March 2020. “Corona-Live-Ticker vom 15. März: Deutschland schließt Grenzen wegen Corona-Pandemie.” [https://www.dw.com/de/corona-live-ticker-vom-15-m%C3%A4rz-deutschland-schlie%C3%9Ft-grenzen-wegen-corona-pandemie/a-52778180-0]. Accessed 28 January 2021.
[4] BBC. 16 March 2020. “Coronavirus: Germany latest country to close borders”. [https://www.bbc.co.uk/news/world-europe-51905129]. Accessed 28 January 2021.
[5] Deutsche Welle. 6 April 2020. “Germany's coronavirus travel restrictions: What you need to know” [https://www.dw.com/en/germanys-coronavirus-travel-restrictions-what-you-need-to-know/a-53029830]. Accessed 28 January 2021.
[6] European Commission. 17 March 2020. “Statement by President von der Leyen at the joint press conference with President Michel, following the EU Leaders' videoconference on COVID-19”. [https://ec.europa.eu/commission/presscorner/detail/en/statement_20_483]. Accessed 28 January 2021.

# Category 4: Sufficient and robust health sector to treat the sick and protect health workers

## 4.1 HEALTH CAPACITY IN CLINICS, HOSPITALS, AND COMMUNITY CARE CENTERS

### 4.1.1 Available human resources for the broader healthcare system

#### *4.1.1a*

Doctors per 100,000 people
Input number
Current Year Score: 424.88

2017

WHO; national sources

#### *4.1.1b*

Nurses and midwives per 100,000 people
Input number
Current Year Score: 1323.52

2017

WHO; national sources

### *4.1.1c*

**Does the country have a health workforce strategy in place (which has been updated in the past five years) to identify fields where there is an insufficient workforce and strategies to address these shortcomings?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has a public workforce strategy in place to identify fields where there is an insufficient workforce and strategies to address these shortcomings. The Federal Cabinet approved the Federal Ministry of Labor and Social Affairs' Skilled Labor Strategy on 19 December 2018 [1]. The strategy aims to address the workforce shortages in health work, care work, artisan crafts and other specific technical fields [1, 2]. The strategy draws on the research of the Federal Employment Agency, in the form of Bottleneck Analysis of the labor market [2, 3]. In 2018, for example, the analysis showed that there is no overarching shortage of skilled workers in Germany but that in certain fields and regions (such as health work), and for certain skills, there are clear shortages [2]. The Federal Ministry of Labor and Social Affairs' strategy outlines a number of ways to tackle these shortages such as making skilled work in the relevant fields more attractive, improving the school-based vocational training system and targeted recruitment strategies to bring in non-German skilled workers in lacking fields [2].

[1] Federal Ministry of Labor and Social Affairs. "Skilled Labor Strategy approved by the Cabinet". 19 December 2018. [https://www.bmas.de/DE/Presse/Pressemitteilungen/2018/fachkraefteeinwanderungsgesetz.html]. Accessed 29 January 2021.
[2] Federal Government. 19 December 2018. "Skilled Labor Strategy". [http://www.bmas.de/SharedDocs/Downloads/DE/PDF-Pressemitteilungen/2018/fachkraeftestrategie-der-bundesregierung.pdf;jsessionid=3E8F2990CD12DE06B1D35C7DD1F646DC?__blob=publicationFile&v=1]. Accessed 29 January 2021.
[3] Federal Employment Agency. "Bottleneck Analysis: Methodical Further Development". [https://statistik.arbeitsagentur.de/DE/Statischer-Content/Grundlagen/Methodik-Qualitaet/Methodenberichte/Uebergreifend/Generische-Publikationen/Methodenbericht-Engpassanalyse-Methodische-Weiterentwicklung.pdf?__blob=publicationFile&v=7]. Accessed 29 January 2021.

## 4.1.2 Facilities capacity

### *4.1.2a*

**Hospital beds per 100,000 people**

Input number

**Current Year Score: 800**

2017

WHO/World Bank; national sources

### *4.1.2b*

**Does the country have the capacity to isolate patients with highly communicable diseases in a biocontainment patient care unit and/or patient isolation room/unit located within the country?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has the capacity to isolate patients with highly communicable diseases in a biocontainment patient care unit in hospitals located within the country. This is a legal requirement of section 30 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) [1]. In line with section 23 of the Act, the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) issues recommendations which serve as a binding basis and standard for infection prevention measures [1, 2]. The recommendations include guidance on the use of isolation units for patients with highly communicable diseases [3]. Additionally, the Permanent Working Group of Competence and Treatment Centres for high consequence infectious diseases (STAKOB) maintains a network of specialized treatment centres for high consequence infectious diseases. These centres are equipped with biocontainment units and meet the highest standards in terms of clinical isolation, staff and laboratory diagnostic capabilities [4]. There are treatment centres in Berlin, Düsseldorf, Frankfurt, Hamburg, Leipzig, Munich and Stuttgart [5].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 29 January 2021.
[2] Robert Koch Institute. 2021. “Commission for Hospital Hygiene and Infection Prevention (KRINKO)”. “[https://www.rki.de/DE/Content/Kommissionen/KRINKO/krinko_node.html;jsessionid=7A24B24C4C920D3A8EFC7E193B8DB12B.internet061]. Accessed 29 January 2021.
[3] Robert Koch Institute. 28 September 2015. “Infection Prevention in the Context of the Care and Treatment of Patients with Communicable Diseases: Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute”. [https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Infektionspraev_Pflege_Diagnostik_Therapie.pdf?__blob=publicationFile]. Accessed 29 January 2021.
[4] Robert Koch Institute. 2021. “Tasks of the Treatment Centres in Germany”. [https://www.rki.de/DE/Content/Kommissionen/Stakob/Behandlungszentren/Aufgaben.html;jsessionid=FC06355F962F64E6CD9B3C3BC40F268E.internet092?nn=5062942]. Accessed 29 January 2021.
[5] Robert Koch Institute. 2021. “Treatment Centres in Germany”. [https://www.rki.de/DE/Content/Kommissionen/Stakob/Behandlungszentren/Behandlungszentren_node.html]. Accessed 29 January 2021.

## *4.1.2c*

**Does the country meet one of the following criteria?**
**- Is there evidence that the country has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years?**
**- Is there evidence that the country has developed, updated or tested a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years?**

Yes = 1, No = 0

**Current Year Score: 1**

There is evidence that Germany has demonstrated capacity to expand isolation capacity in response to the COVID-19 pandemic, but there is no evidence that it has developed, updated or tested a plan to expand isolation capacity. According to section 30 of the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020), it is the responsibility of Germany’s sixteen constituent states to ensure that adequate isolation facilities are provided [1]. In January 2021, the states of Saxony, Baden-Württemberg, Brandenburg and Schleswig-Holstein created isolation detention centres for

those persons who refuse to self-isolate [2]. However, people who test positive for COVID-19 or who are suspected be infected are first encouraged to self-isolate at home [2, 3]. As such, there is no national plan to expand isolation capacity. Germany has the capacity to isolate patients with highly communicable diseases in biocontainment patient care units through a network of specialized treatment centers maintained by the Permanent Working Group of Competence and Treatment Centers for high consequence infectious diseases (STAKOB) [4, 5]. However, there is no evidence of plans or actions to expand this network in the past two years [4, 5, 6].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 29 April 2021.
[2] The Telegraph. 17 January 2021. “Germans who keep refusing to quarantine could be put in detention centres under new Covid rules”. [https://www.telegraph.co.uk/news/2021/01/17/germans-keep-refusing-quarantine-could-put-detention-centres/]. Accessed 29 April 2021.
[3] Robert Koch Institute. “Home Isolation for those who have tested positive for COVID-19”. [https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Flyer_Patienten.pdf?__blob=publicationFile] Accessed 29 April 2021.
[4] Robert Koch Institute. 2021. “Tasks of the Treatment Centres in Germany”. [https://www.rki.de/DE/Content/Kommissionen/Stakob/Behandlungszentren/Aufgaben.html;jsessionid=FC06355F962F64E6CD9B3C3BC40F268E.internet092?nn=5062942]. Accessed 29 April 2021.
[5] Robert Koch Institute. 2021. “Treatment Centres in Germany”. [https://www.rki.de/DE/Content/Kommissionen/Stakob/Behandlungszentren/Behandlungszentren_node.html]. Accessed 29 April 2021.
[6] Robert Koch Institute. Website. [https://www.rki.de/DE/Home/homepage_node.html;jsessionid=C0DE9AC82E0216C517ED465D18A5E7A0.internet111]. Accessed 29 April 2021

# 4.2 SUPPLY CHAIN FOR HEALTH SYSTEM AND HEALTHCARE WORKERS

## 4.2.1 Routine health care and laboratory system supply

### *4.2.1a*

**Is there a national procurement protocol in place which can be utilized by the Ministries of Health and Agriculture for the acquisition of laboratory supplies (e.g. equipment, reagents and media) and medical supplies (e.g. equipment, PPE) for routine needs?**

Yes for both laboratory and medical supply needs = 2, Yes, but only for one = 1, No = 0

**Current Year Score: 2**

There is a national procurement protocol in place that can be utilized by the health and agriculture ministries to acquire laboratory supplies and medical supplies for routine needs. The Ordinance on the Award of Public Contracts, (issued 12 April 2016, last amended 12 November 2020) establishes on a federal level procurement protocols that apply to all acquisitions by ministries, including the Federal Ministry of Health and the Federal Ministry of Food and Agriculture [1]. The Ordinance applies to all public contracts, except those relating to defence and security [1]. The Federal Procurement Office of the Ministry of Interior has a website for public procurement purposes, with a dedicated category called “Procurement of optics, medical and analysis technology, special equipment, aviation security control technology” which currently lists medical

products and medical laboratories [2].

[1] Federal Ministry of Economics and Technology. "Ordinance on the Award of Public Contracts (Procurement Ordinance (Vergabeverordnung – VgV))". Issued 12 April 2016. Last amended 12 November 2020. [https://www.gesetze-im-internet.de/vgv_2016/BJNR062410016.html]. Accessed 29 January 2021.
[2] The Federal Procurement Office of the Ministry of Interior. 2021. "The Federal Procurement Office: Referat B 19". [http://www.bescha.bund.de/SharedDocs/Organisationseinheiten/ReferateB/b19.html?nn=4067320]. Accessed 29 January 2021.

## 4.2.2 Stockpiling for emergencies

### *4.2.2a*

**Does the country have a stockpile of medical supplies (e.g. MCMs, medicines, vaccines, medical equipment, PPE) for national use during a public health emergency?**

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

**Current Year Score: 2**

Germany maintains stockpiles of medical supplies (e.g. MCMs, medicines, vaccines, medical equipment, PPE) for national use during a public health emergency at a number of administrative levels. Detailed information on the contents of these stockpiles is publicly available. In line with sections 15 and 30 of the Ordinance on the Operation of Pharmacies (ApBetrO, adopted 9 February 1987, last amended 9 December 2020), pharmacies are required in normal times to stock enough medicine and medical devices to meet the average demand for a week; larger pharmacies must stock two weeks' worth of medicinal products [1]. Additionally, pharmacies must stock medications that are especially required in emergencies [2]. These measures aim to ensure that the German population's demands for medicine and medical devices are met for a period of 1 to 2 weeks. Medical devices are not defined in the ApBetrO, so it is unclear as to whether the stockpiled medicinal products include PPE [1, 2]. The individual federal states are responsible for the provision of emergency medical supplies in the case of major casualties caused by a disaster, but they can request supplies from federal stockpiles if needed, in line with section 23 of the Civil Protection and Disaster Relief Law (ZSKG, adopted 25 March 1997, last amended 19 June 2020 [3, 4]. These federal stockpiles were first implemented as part of the 2004 project "Cooperative resource utilization and emergency stockpiling by federal and state governments", which sought to provide German cities hosting 2006 FIFA World Cup matches with emergency medical supplies in the form of "basic packages" for the treatment of traumatological injuries. After the World Cup the project was adopted as common practice and the contents of the packets were updated with disaster relief in mind [3]. These medical supplies packets are held in federal stockpiles, according to inventory reports, their contents can be split into 4 broad categories: fluid replacement, pain relief, initial surgical treatment, infection prevention and care of lightly injured [3, 5]. PPE is included in the initial surgical treatment category in the form of surgical gowns, sterilized gloves and masks [5]. However, these stockpiles of medical supplies proved insufficient in the response to the COVID-19 pandemic, as the Ministries of the Interior, Defense and Finance were forced to procure protective equipment in response to the COVID-19 outbreak. Additionally, the Ministry of Health issued public contracts for the production of masks through an "Open-House" process [6]. Any company that could meet the requirements of a minimum volume of shipments and a maximum price per unit, to be shipped in a particular time frame, had the right to be awarded a contract [6]. The Ministry of Health is to receive 233 million FFP2 (filtering face piece) and 63 million surgical masks through the participation of 361 companies in this open-house process [6]. Furthermore, in 2009 the Ministry of Health set up a federal reserve of anti-viral drugs, which included 7.5 million doses of Oseltamivir powder (Tamiflu). This reserve was set up to supplement the individual stockpiles of federal states in the event of an influenza pandemic [7, 8]. According to the document, "On the use and storage of the drug Tamiflu®", published by the German Parliament, 23 April 2013, by 2009 individual state stockpiles could provide 20% of the

German population with Tamiflu [8].

[1] Federal Government. “Ordinance on the Operation of Pharmacies (ApBetrO)”. Adopted 9 February 1987. Last amended 9 December 2020. [https://www.gesetze-im-internet.de/apobetro_1987/BJNR005470987.html]. Accessed 30 January 2021.
[2] Ministry of the Interior, Building and Community. 2015. " Civilian Defense Concept (Konzeption Zivile Verteidigung (KZV))". [www.bmi.bund.de/SharedDocs/downloads/DE/veroeffentlichungen/themen/bevoelkerungsschutz/konzeption-zivile-verteidigung.pdf?__blob=publicationFile&v=1]. Accessed 30 January 2021.
[3] Federal Office of Civil Protection and Disaster Assistance. 2021. "Medical Supplies Stockpiling". [bbk.bund.de/DE/AufgabenundAusstattung/Schutz_der_Gesundheit/Sanitaetsmaterialbevorratung/sanitaetsmaterialbevorratung_node.html]. Accessed 30 January 2021.
[4] Federal Government. “Civil Protection and Disaster Relief Law (ZSKG)”. Adopted 25 March 1997. Last amended 19 June 2020. [https://www.gesetze-im-internet.de/zsg/BJNR072610997.html]. Accessed 30 January 2021.
[5] Federal Government. February 2019. “Federal Medical Supplies Stockpiles: Contents of Basic Package A”. [https://www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Downloads/GesBevS/Inhaltsliste_Sanitaetsmaterialbevorratung_Stand_2019.pdf?__blob=publicationFile]. Accessed 30 January 2021.
[6] Federal Ministry of Health. 31 July 2020. “Questions and answers on procurement and quality assurance of protective equipment during the COVID-19 pandemic”. [https://www.bundesgesundheitsministerium.de/coronavirus/faq-schutzmasken.html]. Accessed 31 January 2021.
[7] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 30 January 2021.
[8] German Parliament. “On the use and storage of the drug Tamiflu®”. 23 April 2013. [https://dip21.bundestag.de/dip21/btd/17/132/1713202.pdf]. Accessed 30 January 2021.

## *4.2.2b*

**Does the country have a stockpile of laboratory supplies (e.g. reagents, media) for national use during a public health emergency?**

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

**Current Year Score: 0**

There is no evidence that Germany has a stockpile of laboratory supplies for national use during a public health emergency. Although federal stockpiles for both medical supplies and medical countermeasures exist, either in a federal reserve or as basic medical supplies packages, there is no evidence of laboratory reagents or media being stockpiled centrally [1, 2]. The Ordinance on the Operation of Pharmacies (ApBetrO, adopted 9 February 1987, last amended 9 December 2020), the Civil Protection and Disaster Relief Law (ZSKG, adopted 25 March 1997, last amended 19 June 2020) and the Ministry of the Interior, Building and Community’s 2017 Civilian Defense Concept do not refer to laboratory supplies [3, 4, 5]. No evidence of a central stockpile of laboratory supplies for national use during a public health emergency was found on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [6, 7, 8].

[1] Federal Office of Civil Protection and Disaster Assistance. 2021. "Medical Supplies Stockpiling". [bbk.bund.de/DE/AufgabenundAusstattung/Schutz_der_Gesundheit/Sanitaetsmaterialbevorratung/sanitaetsmaterialbevorratung_node.html]. Accessed 30 January 2021.
[2] German Parliament. “On the use and storage of the drug Tamiflu®”. 23 April 2013. [https://dip21.bundestag.de/dip21/btd/17/132/1713202.pdf]. Accessed 30 January 2021.
[3] Federal Government. “Ordinance on the Operation of Pharmacies (ApBetrO)”. Adopted 9 February 1987. Last amended 9 December 2020. [https://www.gesetze-im-internet.de/apobetro_1987/BJNR005470987.html]. Accessed 30 January 2021.

[4] Federal Government. “Civil Protection and Disaster Relief Law (ZSKG)”. Adopted 25 March 1997. Last amended 19 June 2020. [https://www.gesetze-im-internet.de/zsg/BJNR072610997.html]. Accessed 30 January 2021.
[5] Ministry of the Interior, Building and Community. 2015. " Civilian Defense Concept (Konzeption Zivile Verteidigung (KZV))". [www.bmi.bund.de/SharedDocs/downloads/DE/veroeffentlichungen/themen/bevoelkerungsschutz/konzeption-zivile-verteidigung.pdf?__blob=publicationFile&v=1]. Accessed 30 January 2021.
[6] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 21 January 2021.
[7] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 21 January 2021.
[8] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 28 January 2021.

### *4.2.2c*

**Is there evidence that the country conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency?**

Yes = 1, No = 0

**Current Year Score: 0**

There is no evidence that Germany conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency. There is publicly available evidence the inventories for certain federal stockpiles are updated regularly. For example, there are recent publicly available inventory reports for medical supplies packet stockpiles, that were first set up as part of the 2004 project “Cooperative resource utilization and emergency stockpiling by federal and state governments” [1, 2]. However, there is no indication that these inventory reports consider whether supply is sufficient for a public health emergency, nor do these reports span the entire national stockpile. In fact, Germany’s stockpiles of medical supplies proved insufficient in the response to the COVID-19 pandemic, as the Ministries of the Interior, Defense and Finance were forced to procure protective equipment in response to the COVID-19 outbreak. Additionally, the Ministry of Health issued public contracts for the production of masks through an “Open-House” process, through which it will receive 233 million FFP2 (filtering face piece) and 63 million surgical masks through the participation of 361 companies [3]. Additionally, in 2009 the Ministry of Health set up a federal reserve of anti-viral drugs, which included 7.5 million doses of Oseltamivir powder (Tamiflu). This reserve was set up to supplement the individual stockpiles of federal states in the event of an influenza pandemic [4, 5]. However, there is no evidence that this review was conducted in subsequent years, nor that the review aimed to comprehensively determine whether Germany’s national stockpile was sufficient for a public health emergency. No evidence of that Germany conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency was found on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [6, 7, 8].

[1] Federal Office of Civil Protection and Disaster Assistance. 2021. "Medical Supplies Stockpiling". [bbk.bund.de/DE/AufgabenundAusstattung/Schutz_der_Gesundheit/Sanitaetsmaterialbevorratung/sanitaetsmaterialbevorratung_node.html]. Accessed 30 April 2021.
[2] Federal Government. February 2019. “Federal Medical Supplies Stockpiles: Contents of Basic Package A”. [https://www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Downloads/GesBevS/Inhaltsliste_Sanitaetsmaterialbevorratung_Stand_2019.pdf?__blob=publicationFile]. Accessed 30 April 2021.
[3] Federal Ministry of Health. 31 July 2020. “Questions and answers on procurement and quality assurance of protective equipment during the COVID-19 pandemic”. [https://www.bundesgesundheitsministerium.de/coronavirus/faq-schutzmasken.html]. Accessed 30 April 2021.
[4] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 30 April 2021.

[5] German Parliament. "On the use and storage of the drug Tamiflu®". 23 April 2013. [https://dip21.bundestag.de/dip21/btd/17/132/1713202.pdf]. Accessed 30 April 2021.
[6] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 30 April 2021.
[7] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 30 April 2021.
[8] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 30 April 2021.

## 4.2.3 Manufacturing and procurement for emergencies

### *4.2.3a*

**Does the country meet one of the following criteria?**
**- Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?**
**- Is there evidence of a plan/mechanism to procure medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?**
Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

**Current Year Score: 1**

There is no evidence that Germany has a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency. However, there is evidence that Germany has a plan/mechanism to procure medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency.

There is no evidence of relevant plans or agreements in the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) or the Robert Koch Institute's 2017 National Pandemic Plan or on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [1, 2, 3, 4, 5]. However, in February 2020, the Ministries of the Interior, Defense and Finance procured protective equipment in response to the COVID-19 outbreak. Additionally, the Ministry of Health issued public contracts for the production of masks through an "Open-House" process [6]. Any company, who could meet the requirements of a minimum volume of shipments and a maximum price per unit, to be shipped in a particular time frame, had the right to be awarded a contract [6]. The Ministry of Health is to receive 233 million FFP2 (filtering face piece) and 63 million surgical masks through the participation of 361 companies in this open-house process [6]. The Ministry of Health states that in future it will rely heavily on the domestic production of protective masks [6]. Starting in June 2020 and until the end of 2021, a total of up to 3.2 billion masks and up to 14 million protective gowns will be available via the tender process for mask production in Germany [6]. Furthermore, reports on Germany's COVID-19 vaccination strategy and procurement of vaccination doses do not reference any plan or agreement [7, 8]. On 6 January 2021, Germany's Chancellor, Angela Merkel, met with various senior officials, including the Minister of Health Jens Spahn, the Head of the Chancellery, Helge Braun and the Minister of Finance, Olaf Scholz, to discuss whether and how the additional production of vaccines in Germany can be supported in a coordinated manner [7, 8].

Germany has been part of the European Union (EU) Joint Procurement Agreement for Medical Countermeasures, which ensures that member states have access to medical countermeasures from abroad if necessary when a serious cross-border threat to health is registered. The agreement aims to "secure more equitable access to specific medical countermeasures and improved security of supply", as well as balancing prices for EU member states. It is also designed to ensure acquisition of vaccines, antivirals and medical countermeasures for serious cross-border threats to health [9].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 31 January 2021.
[2] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 31 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 31 January 2021.
[4] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 31 January 2021.
[5] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 31 January 2021.
[6] Federal Ministry of Health. 31 July 2020. "Questions and answers on procurement and quality assurance of protective equipment during the COVID-19 pandemic". [https://www.bundesgesundheitsministerium.de/coronavirus/faq-schutzmasken.html]. Accessed 31 January 2021.
[7] Tagesschau. 5 January 2021. "Spahn defends the vaccination strategy". [https://www.tagesschau.de/inland/spahn-impfstrategie-kritik-103.html]. Accessed 31 January 2021.
[8] Deutsche Welle. 5 January 2021. "Merkel seeks clarity on the procurement of vaccination doses". [https://www.dw.com/de/merkel-will-klarheit-bei-impfstoff-beschaffung/a-56133327]. Accessed 31 January 2021.
[9] European Commission. "Joint Procurement Of Medical Countermeasures". [https://ec.europa.eu/health/preparedness_response/joint_procurement_en]. Accessed 3 September 2020

## *4.2.3b*

**Does the country meet one of the following criteria?**
**- Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies (e.g. reagents, media) for national use during a public health emergency?**
**- Is there evidence of a plan/mechanism to procure laboratory supplies (e.g. reagents, media) for national use during a public health emergency?**
Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

**Current Year Score: 0**

There is no evidence that Germany has any plans or agreements to leverage domestic manufacturing capacity or procure laboratory supplies for national use during public health emergencies. There is no evidence of relevant plans or agreements in the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) or the Robert Koch Institute's 2017 National Pandemic Plan or on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [1, 2, 3, 4, 5]. In April it was reported that various laboratories tasked with testing for COVID-19 were running low on crucial chemical reagents. This led federal states to expedite processes for the procurement of the necessary laboratory supplies from suppliers worldwide [6].

[1] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 31 January 2021.
[2] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 31 January 2021.
[3] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 31 January 2021.
[4] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 31 January 2021.
[5] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website.

[www.bbk.bund.de/EN/Home/home_node.html]. Accessed 31 January 2021.
[6] Der Tagesspiegel. 3 April 2020. [https://www.tagesspiegel.de/wissen/hilferuf-eines-berliner-labors-das-material-fuer-coronavirus-tests-wird-auf-dem-weltmarkt-knapp/25710424.html]. Accessed 31 January 2021.

# 4.3 MEDICAL COUNTERMEASURES AND PERSONNEL DEPLOYMENT

## 4.3.1 System for dispensing medical countermeasures (MCM) during a public health emergency

### *4.3.1a*

**Does the country have a plan, program, or guidelines in place for dispensing medical countermeasures (MCM) for national use during a public health emergency (i.e., antibiotics, vaccines, therapeutics and diagnostics)?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence of a plan, program, or guidelines for dispensing medical countermeasures for national use during a public health emergency in Germany. In 2015, the Ministry of the Interior, Building and Community published the Civilian Defense Concept (KZV) [1]. The KZV outlines how civil defense tasks should be completed across all levels of government and how the federal government should prepare for emergencies [1]. Section 7.5.3 of the document, on medicines and medical devices, states that the stockpiling of medicine and medical devices is done primarily in a decentralized fashion and carried out via a network of pharmacies and wholesalers. Pharmacies are required by law to stock enough medicinal products to meet the average demand for a week; larger pharmacies must stock two weeks' worth of medicinal products [1]. Additionally, pharmacies must stock medications that are especially required in emergencies [1]. These obligations aim to ensure that the German population's demands for medicinal products are met for a period of 1 to 2 weeks [1]. Despite describing how pharmacies should prepare for a public health emergency, the document does not describe exactly how medical products will reach patients. Furthermore, the document does not describe how a medical countermeasure specific to fighting the outbreak of a particular disease could be dispensed from a pharmacy. It focuses more on ensuring that the day to day medicinal needs of the population can still be met during an emergency. The document's recommendation that pharmacies stock medicinal products required in emergencies does not explicitly mention particular medical countermeasures. Moreover, no publicly available document was found that describes in the form of a concrete and detailed plan, how medical countermeasures such as anti-viral medicines in the federal reserve are supposed to be dispensed to patients [2, 3, 4]. No evidence of such a plan was found on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [2, 3, 4].

[1] Ministry of the Interior, Building and Community. 2015. " Civilian Defense Concept (Konzeption Zivile Verteidigung (KZV))". [www.bmi.bund.de/SharedDocs/downloads/DE/veroeffentlichungen/themen/bevoelkerungsschutz/konzeption-zivile-verteidigung.pdf?__blob=publicationFile&v=1]. Accessed 29 January 2021.
[2] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 21 January 2021.
[3] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 21 January 2021.
[4] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 28 January 2021.

## 4.3.2 System for receiving foreign health personnel during a public health emergency

### *4.3.2a*

**Is there a public plan in place to receive health personnel from other countries to respond to a public health emergency?**
Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence of a public plan in place to receive health personnel from other countries to respond to public health emergencies. Germany has a bilateral agreement in place with Austria to provide personnel, including medical personnel, to respond to emergencies. The agreement outlines various procedures to facilitate cross-border movement of trained medical personnel, such as visa and passport free travel and facilitation of import / export procedures for equipment required to respond to emergencies. The agreement also outlines other procedures for communications and costs, among other logistical needs. [1] Beyond this agreement, there is evidence that Germany can request and provide personnel support to other countries, but no evidence of other agreements facilitating the arrival of emergency personnel. As a member of the European Union, Germany has access to the European Centre for Disease Prevention and Control, which, among other things, provides support during public health emergencies [2]. Germany also participates in the European Medical Corps through the European Union (EU) Civil Protection Mechanism [3, 4, 5]. The European Medical Corps enables quick medical assistance and public health expertise from all EU Member States and Participating States to a health emergency inside and outside the EU. Medical assistance comprises primarily of emergency medical teams, mobile biosafety laboratories and medical evacuation capacities. However, the EMC does not outline procedures for how to facilitate the movement of health personnel within Europe or elsewhere [5]. The Federal Office of Civil Protection and Disaster Assistance, whose tasks include public health protection of the population, has broad bilateral, regional and international contacts but none of them focus specifically on receiving health personnel [6]. The websites of the Federal Ministry of Health and the Federal Ministry of Interior do not mention a plan to receive health personnel from other countries to respond to a public health emergency [7, 8].

[1] National Council of Austria. 1992. “Agreement between the Republic of Austria and the Federal Republic of Germany on mutual assistance with disasters or serious accidents.” (“Abkommen zwischen der Republik Österreich und der Bundesrepublik Deutschland über die gegenseitige Hilfeleistung bei Katastrophen oder schweren Unglücksfällen.”) [https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10005818]. Accessed 8 August 2020.
[2] European Centre for Disease Prevention and Control. "ECDC activities on epidemic intelligence and outbreak response." [https://www.ecdc.europa.eu/en/about-us/what-we-do/ecdc-activities-epidemic-intelligence-and-outbreak-response]. Accessed 29 January 2021.
[3] European Commission. 2021. “EU Civil Protection Mechanism”. [http://ec.europa.eu/echo/what/civil-protection/mechanism_en]. Accessed 29 January 2021.
[4] European Commission. 2021. “European Emergency Response Capacity”. [https://ec.europa.eu/echo/what/civil-protection/european-emergency-response-capacity_en]. Accessed 29 January 2021.
[5] European Commission. 2021. “Medical Corps” [https://ec.europa.eu/echo/what-we-do/civil-protection/european-medical-corps_en]. Accessed 29 January 2021.
[6] Federal Office of Civil Protection and Disaster Assistance. 2021. "Public Health Protection of the population". [www.bbk.bund.de/EN/Topics/Publichealthprotection/publichealthprotection_node.html]. Accessed 29 January 2021.
[7] Federal Ministry of Health. 2021. Website. [www.bundesgesundheitsministerium.de/en/en.html]. Accessed 29 January 2021.
[8] Federal Ministry of the Interior. 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 29

January 2021.

# 4.4 HEALTHCARE ACCESS

## 4.4.1 Access to healthcare

### *4.4.1a*

**Does the constitution explicitly guarantee citizens' right to medical care?**

Guaranteed free = 4, Guaranteed right = 3, Aspirational or subject to progressive realization = 2, Guaranteed for some groups, not universally = 1, No specific provision = 0

**Current Year Score: 0**

2020

World Policy Analysis Center

### *4.4.1b*

**Access to skilled birth attendants (% of population)**

Input number

**Current Year Score: 98.7**

2015

WHO/World Bank/United Nations Children's Fund (UNICEF)

### *4.4.1c*

**Out-of-pocket health expenditures per capita, purchasing power parity (PPP; current international $)**

Input number

**Current Year Score: 750.57**

2017

WHO Global Health Expenditure database

## 4.4.2 Paid medical leave

### *4.4.2a*

**Are workers guaranteed paid sick leave?**

Paid sick leave = 2, Unpaid sick leave = 1, No sick leave = 0

**Current Year Score: 2**

2020

World Policy Analysis Center

### 4.4.3 Healthcare worker access to healthcare

#### *4.4.3a*

**Has the government issued legislation, a policy, or a public statement committing to provide prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no publicly available evidence of German regulation, policy or a public statement committing to provide prioritized health care services to healthcare workers who become sick as a result of responding to a public health emergency. The Civil Protection and Disaster Relief Law (ZSKG, adopted 25 March 1997, last amended 19 June 2020 does not include such a provision [1]. The websites of the Ministry of Health and Ministry of Interior do not include information on prioritized health care services to healthcare workers in emergencies [2, 3]. There is no evidence of prioritized treatment for healthcare workers infected with COVID-19 [4].

[1] Federal Government. "Civil Protection and Disaster Relief Law (ZSKG)". Adopted 25 March 1997. Last amended 19 June 2020. [https://www.gesetze-im-internet.de/zsg/BJNR072610997.html]. Accessed 30 January 2021.
[2] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 30 January 2021.
[3] Federal Ministry of the Interior. 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 30 January 2021.
[4] Ärzteblatt. "SARS-CoV-2: 33, 000 New infected health care workers in January". 2 February 2021. [aerzteblatt.de/nachrichten/120743/SARS-CoV-2-33-000-Neuinfektionen-bei-Gesundheitspersonal-im-Januar]. Accessed 10 February 2021.

## 4.5 COMMUNICATIONS WITH HEALTHCARE WORKERS DURING A PUBLIC HEALTH EMERGENCY

### 4.5.1 Communication with healthcare workers

#### *4.5.1a*

**Is there a system in place for public health officials and healthcare workers to communicate during a public health emergency?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has a system in place for two-way communication between public officials, including public health officials and healthcare workers, during a public health emergency. In 2015, the Ministry of the Interior, Building and Community published the Civilian Defense Concept (KZV) which recommends the implementation of a comprehensive communication system to allow the flow of key information between affected actors during an emergency [1]. The document does not elaborate more on what this system should look like, nor does it explicitly mention communication between public health officials and healthcare workers [1]. The Robert Koch Institute's 2017 National Pandemic Plan recommends communication of pandemic information between federal ministries and professional medical associations during a public health emergency, but it does not reference an existing communication system [2]. There is no

evidence of such a communication system in the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) or on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [3, 4, 5, 6].

[1] Ministry of the Interior, Building and Community. 2015. " Civilian Defense Concept (Konzeption Zivile Verteidigung (KZV))". [www.bmi.bund.de/SharedDocs/downloads/DE/veroeffentlichungen/themen/bevoelkerungsschutz/konzeption-zivile-verteidigung.pdf?__blob=publicationFile&v=1]. Accessed 31 January 2021.
[2] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 31 January 2021.
[3] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 31 January 2021.
[4] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 31 January 2021.
[5] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 31 January 2021.
[6] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 31 January 2021.

### *4.5.1b*

**Does the system for public health officials and healthcare workers to communicate during an emergency encompass healthcare workers in both the public and private sector?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is no evidence that Germany has a system in place for public officials, including public health officials and healthcare workers, to communicate during a public health emergency. In 2015, the Ministry of the Interior, Building and Community published the Civilian Defense Concept (KZV) which recommends the implementation of a comprehensive communication system to allow the flow of key information between affected actors during an emergency [1]. The document does not elaborate more on what this system should look like, nor does it explicitly mention communication between public health officials and healthcare workers [1]. The Robert Koch Institute's 2017 National Pandemic Plan recommends communication of pandemic information between federal ministries and professional medical associations during a public health emergency, but it does not reference an existing communication system [2]. There is no evidence of such a communication system in the Protection against Infection Act (adopted 20 July 2000, last amended 21 December 2020) or on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [3, 4, 5, 6].

[1] Ministry of the Interior, Building and Community. 2015. " Civilian Defense Concept (Konzeption Zivile Verteidigung (KZV))". [www.bmi.bund.de/SharedDocs/downloads/DE/veroeffentlichungen/themen/bevoelkerungsschutz/konzeption-zivile-verteidigung.pdf?__blob=publicationFile&v=1]. Accessed 31 January 2021.
[2] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 31 January 2021.
[3] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 31 January 2021.
[4] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 31 January 2021.
[5] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 31 January 2021.

[6] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 31 January 2021.

# 4.6 INFECTION CONTROL PRACTICES AND AVAILABILITY OF EQUIPMENT

## 4.6.1 Healthcare associated infection (HCAI) prevention and control programs

### *4.6.1a*

**Is there evidence that the national public health system is monitoring for and tracking the number of healthcare associated infections (HCAI) that take place in healthcare facilities?**

Yes = 1 , No = 0

**Current Year Score: 1**

The German public health system monitors and tracks the number of health care associated infections that take place in healthcare facilities. Monitoring is carried out through the Hospital Surveillance System (KISS), coordinated by the National Reference Centre for the Surveillance of Nosocomial Infections. KISS was first implemented in 1996 as a standardized system through which HCAI data from hospital wards and departments could be transmitted anonymously to the relevant national reference center (NRZ). Hospitals can choose to participate in one or several components of KISS, depending on their individual needs. In order to participate, hospitals must complete a course on KISS data collection methods and training diagnosis with fixed definitions [1]. The NRZ for the Surveillance of Nosocomial Infections is part of the national reference center network of the Robert Koch Institute, a government agency and Germany's foremost institute on disease prevention and control [2]. The HCAI data collected by KISS and the analysis provided by the NRZ for the Surveillance of Nosocomial Infections is used by the Commission on for Hospital Hygiene and Infection Prevention (KRINKO) to draw up recommendations for the prevention of nosocomial infections in in healthcare facilities [3].

[1] National Reference Centre for the Surveillance of Nosocomial Infections. 2021. "KISS Project Description". [https://www.nrz-hygiene.de/surveillance/kiss/]. Accessed 31 January 2021.
[2] Robert Koch Institute. 2021. Website. [https://www.rki.de/DE/Home/homepage_node.html]. Accessed 31 January 2021.
[3] Robert Koch Institute. 2020. "Surveillance of Nosocomial Infections: Recommendations of the Commission on for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute. [https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Surv_NI_Rili.pdf?__blob=publicationFile]. Accessed 31 January 2021.

# 4.7 CAPACITY TO TEST AND APPROVE NEW MEDICAL COUNTERMEASURES

## 4.7.1 Regulatory process for conducting clinical trials of unregistered interventions

### *4.7.1a*

**Is there a national requirement for ethical review (e.g., from an ethics committee or via Institutional Review Board approval) before beginning a clinical trial?**

Yes = 1 , No = 0

Current Year Score: 1

In Germany there is a national requirement for ethical review before beginning a clinical trial involving human beings. Section 40 of the Medicinal Products Act (adopted 24 August 1987, last amended 9 December 2020) stipulates that clinical trials on human beings may only begin if they have been approved by the competent ethics committee and the competent higher federal authority [1]. Germany has a total of 53 research ethics committees (REC), attached to medicine and university faculties, medical associations and federal state governments. These RECs are the only legally competent ethics committees to assess all kinds of biomedical research including drug research [2]. There is no leading REC, clinical trials on humans must either be approved by the REC of the institution where research is being conducted (in the case of a university) or by the REC of the regional medical association [2].

[1] Federal Government. "Medicinal Products Act (Arzneimittelgesetz – AMG)". Adopted 24 August 1987. Last amended 9 December 2020. [http://www.gesetze-im-internet.de/amg_1976/BJNR024480976.html]. Accessed 31 January 2021.
[2] European Network of Research Ethics Committees (EUREC). "National Information: Germany". [http://www.eurecnet.org/information/germany.html]. Accessed 31 January 2021.

## *4.7.1b*

**Is there an expedited process for approving clinical trials for unregistered medical countermeasures (MCM) to treat ongoing epidemics?**

Yes = 1 , No = 0

Current Year Score: 0

There is no public evidence of an existing expedited process for approving clinical trials for unregistered medical countermeasures to treat ongoing pandemics. There is no mention of such a process in the Medicinal Products Act (adopted 24 August 1987, last amended 9 December 2020), which regulates clinical trials, or the Protection Against Infection Act (adopted 20 July 2000, last amended 21 December 2020) [1, 2]. There is no evidence of such a process in the Robert Koch Institute's 2017 National Pandemic Plan or on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [3, 4, 5, 6]. However, there have been attempts to accelerate the approval of clinical trials for unregistered medical countermeasures in response to the COVID-19 pandemic. On 10 July 2020, the European Parliament also adopted a temporary derogation from certain rules for clinical trials so as to speed the development of COVID-19 vaccines, this derogation applied to clinical trials in all European Union member states [7, 8].

[1] Federal Government. "Medicinal Products Act (Arzneimittelgesetz – AMG)". Adopted 24 August 1987. Last amended 9 December 2020. [http://www.gesetze-im-internet.de/amg_1976/BJNR024480976.html]. Accessed 31 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.
[3] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 31 January 2021.
[4] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 31 January 2021.
[5] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 31 January 2021.
[6] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 31 January 2021.
[7] European Parliament. 10 July 2020. "Parliament to allow COVID-19 vaccines to be developed more quickly". [https://www.europarl.europa.eu/news/en/press-room/20200706IPR82731/parliament-to-allow-covid-19-vaccines-to-be-

developed-more-quickly]. Accessed 31 January 2021.
[8] European Parliament. 10 July 2020. "Position of the European Parliament".
[https://www.europarl.europa.eu/doceo/document/TC1-COD-2020-0128_EN.pdf]. Accessed 10 February 2021.

## 4.7.2 Regulatory process for approving medical countermeasures

### *4.7.2a*

**Is there a government agency responsible for approving new medical countermeasures (MCM) for humans?**

Yes = 1 , No = 0

**Current Year Score: 1**

Germany has a government agency responsible for approving new medical countermeasures (MCM) for humans. According to section 77 of the Medicinal Products Act (adopted 24 August 1987, last amended 9 December 2020), the Federal Institute for Drugs and Medical Devices is responsible for the approval of medicinal products to be used on humans [1]. However, according to 77 of the act, vaccines, advanced therapy medicinal products, xenogeneic medicinal products and blood components manufactured using genetic engineering are to be approved by the Paul Ehrlich Institute for Vaccines and Biomedicine [1, 2, 3].

[1] Federal Government. "Medicinal Products Act (Arzneimittelgesetz – AMG)". Adopted 24 August 1987. Last amended 9 December 2020. [http://www.gesetze-im-internet.de/amg_1976/BJNR024480976.html]. Accessed 31 January 2021.
[2] Federal Institute for Drugs and Medical Devices. 2021. "National Approval of Medical Products".
[https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/Zulassungsverfahren/National/_node.html]. Accessed 31 January 2021.
[3] Paul Ehrlich Institute for Vaccines and Biomedicine. 2021. "Vaccines for Humans".
[https://www.pei.de/DE/arzneimittel/impfstoffe/impfstoffe-node.html;jsessionid=BB21815A8F2A81842A97653E19AA1FA2.intranet232]. Accessed 31 January 2021.

### *4.7.2b*

**Is there an expedited process for approving medical countermeasures (MCM) for human use during public health emergencies?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is insufficient evidence for the existence of a legally or otherwise established expedited process for approving medical countermeasures for human use during public health emergencies in Germany. There is no mention of such a process in the Medicinal Products Act (adopted 24 August 1987, last amended 9 December 2020), which regulates the development and approval or medical products, or the Protection Against Infection Act (adopted 20 July 2000, last amended 21 December 2020) [1, 2]. There is no evidence of such a process in the Robert Koch Institute's 2017 National Pandemic Plan or on the websites of the Ministry of Health, the Ministry of Defense or the Federal Office for Civil Protection and Disaster Assistance [3, 4, 5, 6]. However, there have been attempts to accelerate the approval of medical countermeasures in response to the COVID-19 pandemic. On 10 July 2020, the European Parliament also adopted a temporary derogation from certain rules for clinical trials so as to speed the development of COVID-19 vaccines, this derogation applied to clinical trials in all European Union member states [7, 8].

[1] Federal Government. “Medicinal Products Act (Arzneimittelgesetz – AMG)”. Adopted 24 August 1987. Last amended 9 December 2020. [http://www.gesetze-im-internet.de/amg_1976/BJNR024480976.html]. Accessed 31 January 2021.
[2] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 21 January 2021.
[3] Robert Koch Institute. “National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)”. 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 31 January 2021.
[4] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 31 January 2021.
[5] Federal Ministry of Defense. 2021. Website. [https://www.bmvg.de/de]. Accessed 31 January 2021.
[6] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 31 January 2021.
[7] Deutsches Ärzteblatt. 25 September 2020. “COVID-19 vaccine development: faster, but safe”. [https://www.aerzteblatt.de/archiv/215884/COVID-19-Impfstoffentwicklung-Schneller-aber-sicher]. Accessed 31 January 2021.
[8] European Parliament. 10 July 2020. “Position of the European Parliament”. [https://www.europarl.europa.eu/doceo/document/TC1-COD-2020-0128_EN.pdf]. Accessed 10 February 2021.

# Category 5: Commitments to improving national capacity, financing plans to address gaps, and adhering to global norms

## 5.1 INTERNATIONAL HEALTH REGULATIONS (IHR) REPORTING COMPLIANCE AND DISASTER RISK REDUCTION

### 5.1.1 Official IHR reporting

#### *5.1.1a*

Has the country submitted IHR reports to the WHO for the previous calendar year?

Yes = 1 , No = 0

Current Year Score: 1

2020

World Health Organization

### 5.1.2 Integration of health into disaster risk reduction

#### *5.1.2a*

Are epidemics and pandemics integrated into the national risk reduction strategy or is there a standalone national disaster risk reduction strategy for epidemics and pandemics?

Yes = 1 , No = 0

**Current Year Score: 1**

Epidemics and pandemics are integrated into Germany's risk reduction strategy. The Federal Office of Civil Protection and Disaster Assistance (BBK), under the portfolio of the Ministry of the Interior, carries out the bulk of risk and crisis management research in Germany. Integral to the office's management strategy is rigorous and comprehensive analysis of risks and crisis related vulnerabilities, including those posed by pandemics and epidemics, which allows ways of reducing both risks and potential damage ensuing from crises to be found [1]. Since 2010, the Ministry of the Interior has shared risk analysis reports with the German parliament every year [2]. These reports deal with various risks including those posed by pandemics and epidemics and suggest ways to both avoid and reduce these risks [3]. For example, in 2012 a risk analysis was published that assessed the implications and dangers of a pandemic caused by a hypothetical "Modi-SARS" virus. The project was led by the Robert Koch Institute and resulted in a detailed estimation of the extent of damage caused by a pandemic (casualties as well as economic, social and psychological damage), projections of how the number of disease cases might develop over the duration of the outbreak, and recommendations for how the risks associated with pandemics can be better prevented and controlled [4]. There is no evidence of a stand-alone risk reduction strategy document per se, but the Report on Civil Protection Risk Analysis, presented to parliament in 2017, summarized and assessed previous years' risk analysis and highlighted key recommendations [3]. The report also commented on how successfully these recommendations had been implemented [3].

[1] Federal Office of Civil Protection and Disaster Assistance. 2021. "Risk Management". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Risikomanagement/risikomanagement_node.html]. Accessed 31 January 2021.
[2] Federal Office of Civil Protection and Disaster Assistance. 2021. "Risk Analysis". [https://www.bbk.bund.de/DE/AufgabenundAusstattung/Risikomanagement/RisikoanalysenBundundLaender/risikoanalysenBundundLaender_node.html]. Accessed 31 January 2021.
[3] German Parliament. 12 April 2019. "Report on Civil Protection Risk Analysis 2017". [http://dipbt.bundestag.de/doc/btd/19/095/1909520.pdf]. Accessed 31 January 2021.
[4] German Parliament. 3 January 2013. "Report on Civil Protection Risk Analysis 2012". [https://www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Downloads/Krisenmanagement/BT-Bericht_Risikoanalyse_im_BevSch_2012.pdf?__blob=publicationFile]. Accessed 24 February 2021.

# 5.2 CROSS-BORDER AGREEMENTS ON PUBLIC HEALTH AND ANIMAL HEALTH EMERGENCY RESPONSE

## 5.2.1 Cross-border agreements

### *5.2.1a*

**Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to public health emergencies?**

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

**Current Year Score: 2**

Germany has cross-border agreements on public health emergencies with neighboring countries and as part of a regional group, and there is no evidence of gaps in implementation. As a member of the European Union (EU), Germany has access to the European Center for Disease Prevention and Control, which, among other things, provides support during public health emergencies [1]. In addition, within the EU, the Health Security Committee provides a platform for the health ministries of

member states to co-ordinate national responses to cross-border public health emergencies [2, 3]. Additionally, Germany has signed bilateral agreements on mutual disaster assistance with all of its neighbouring states and the following states: Lithuania, Denmark, Belgium, France, the Netherlands, Austria, Poland, Luxembourg, Russia, the Czech Republic, Hungary, and Switzerland. These agreements do not give specific definitions of what constitutes a disaster and they only mention "mutual assistance" with no elaboration as to what that might mean [4, 5].

[1] European Centre for Disease Prevention and Control. "ECDC activities on epidemic intelligence and outbreak response." [https://www.ecdc.europa.eu/en/about-us/what-we-do/ecdc-activities-epidemic-intelligence-and-outbreak-response]. Accessed 31 January 2021.
[2] European Commission. "Health Security Committee members." [https://ec.europa.eu/health/preparedness_response/risk_management/hsc/members_en]. Accessed 31 January 2021.
[3] European Parliament and Council of the European Union. Decision No 1082/2013/EU of 22 October 2013. "On serious cross-border threats to health and repealing Decision No 2119/98/EC." [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02013D1082-20131105]. Accessed 31 January 2021.
[4] European Civil Protection and Humanitarian Aid Operations. 2019. "Germany: Overview of the National Disaster Management System". [https://ec.europa.eu/echo/what/civil-protection/disaster-management/germany_en]. Accessed 31 January 2021.
[5] Federal Government. "Bilateral Agreements on Mutual Disaster Assistance of the Federal Republic as of March 2020." [https://www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/FIS/DownloadsRechtundVorschriften/Katastrophenhilfeabkommen/Bekanntmachung%20Abkommen%20Gesamt%20Neu.pdf?__blob=publicationFile]. Accessed 31 January 2021.

### *5.2.1b*

**Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to animal health emergencies?**

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

**Current Year Score: 2**

Germany has cross-border agreements with regards to animal health emergencies as part of a regional group, and there is no evidence of gaps in implementation. As a member of the European Union (EU), Germany is entitled to request assistance from the EU's Veterinary Emergency Team. [1, 2] The members of this team are experts in "veterinary sciences, virology, wildlife, laboratory testing, risk management and other relevant areas". [1] In January 2020, there was an intervention in Germany for African Swine Fever. [3] Experts from the EU's Veterinary Emergency Team provided German authorities with scientific, technical, managerial and practical assistance on the spot and helped draw up suitable control and eradication measures for African swine fever (ASF) with a focus on preparedness, surveillance and coordination efforts [4].

[1] European Commission. "Veterinary Emergency Team". [https://ec.europa.eu/food/animals/animal-diseases/emergency-team_en]. Accessed 31 January 2021.
[2] European Commission. Decision No 2007/142/EC of 28 February 2007. "Establishing a Community Veterinary Emergency Team to assist the Commission in supporting Member States and third countries in veterinary matters relating to certain animal diseases." [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32007D0142]. Accessed 31 January 2021.
[3] European Commission. "EU Veterinary Emergency Team missions." [https://ec.europa.eu/food/sites/food/files/animals/docs/ad_emergency_cvet_experts_missions.pdf]. Accessed 31 January 2021.
[4] European Commission. 22-24 September 2020. "ASF mission of the EU Veterinary Emergency Team (EUVET) to Germany (Neuzelle area)". [https://ec.europa.eu/food/sites/food/files/animals/docs/reg-com_ahw_20201020_pres_asf_deu-

euvet.pdf]. Accessed 24 February 2021.

# 5.3 INTERNATIONAL COMMITMENTS

## 5.3.1 Participation in international agreements

### *5.3.1a*

**Does the county have signatory and ratification (or same legal effect) status to the Biological Weapons Convention?**

Signed and ratified (or action having the same legal effect) = 2, Signed = 1, Non-compliant or not a member = 0

**Current Year Score: 2**

2021

Biological Weapons Convention

### *5.3.1b*

**Has the country submitted confidence building measures for the Biological Weapons Convention in the past three years?**

Yes = 1 , No = 0

**Current Year Score: 1**

2021

Biological Weapons Convention

### *5.3.1c*

**Has the state provided the required United Nations Security Council Resolution (UNSCR) 1540 report to the Security Council Committee established pursuant to resolution 1540 (1540 Committee)?**

Yes = 1 , No = 0

**Current Year Score: 1**

2021

Biological Weapons Convention

### *5.3.1d*

**Extent of United Nations Security Council Resolution (UNSCR) 1540 implementation related to legal frameworks and enforcement for countering biological weapons:**

Very good (60+ points) = 4, Good (45–59 points) = 3, Moderate (30–44 points) = 2, Weak (15–29 points) = 1, Very weak (0–14 points) or no matrix exists/country is not party to the BWC = 0

**Current Year Score: 4**

2021

Biological Weapons Convention

### 5.3.2 Voluntary memberships

#### *5.3.2a*

Does the country meet at least 2 of the following criteria?
- Membership in Global Health Security Agenda (GHSA)
- Membership in the Alliance for Country Assessments for Global Health Security and IHR Implementation (JEE Alliance)
- Membership in the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP)
- Membership in the Australia Group (AG)
- Membership in the Proliferation Security Initiative (PSI)

Needs to meet at least two of the criteria to be scored a 1 on this measure. , Yes for five = 1 , Yes for four = 1 , Yes for three = 1 , Yes for two = 1 , Yes for one = 0 , No for all = 0

Current Year Score: 1

2021

Global Health Security Agenda; JE Alliance; Global Partnership; Australia Group; PSI

## 5.4 JOINT EXTERNAL EVALUATION (JEE) AND PERFORMANCE OF VETERINARY SERVICES PATHWAY (PVS)

### 5.4.1 Completion and publication of a Joint External Evaluation (JEE) assessment and gap analysis

#### *5.4.1a*

Has the country completed a Joint External Evaluation (JEE) or precursor external evaluation (e.g., GHSA pilot external assessment) and published a full public report in the last five years?

Yes = 1 , No = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

#### *5.4.1b*

Has the country completed and published, within the last five years, either a National Action Plan for Health Security (NAPHS) to address gaps identified through the Joint External Evaluation (JEE) assessment or a national GHSA roadmap that sets milestones for achieving each of the GHSA targets?

Yes = 1 , No = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

## 5.4.2 Completion and publication of a Performance of Veterinary Services (PVS) assessment and gap analysis

### *5.4.2a*

**Has the country completed and published a Performance of Veterinary Services (PVS) assessment in the last five years?**

Yes = 1 , No = 0

**Current Year Score: 0**

2021

OIE PVS assessments

### *5.4.2b*

**Has the country completed and published a Performance of Veterinary Services (PVS) gap analysis in the last five years?**

Yes = 1 , No = 0

**Current Year Score: 0**

2021

OIE PVS assessments

# 5.5 FINANCING

## 5.5.1 National financing for epidemic preparedness

### *5.5.1a*

**Is there evidence that the country has allocated national funds to improve capacity to address epidemic threats within the past three years?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is evidence that Germany has allocated national funds to improve capacity to address epidemic threats within the past three years. Jens Spahn, the German health minister, has claimed that hospitals were the “backbone” of Germany’s comparatively good COVID-19 response, however, he also conceded that much was to be learned from the pandemic [1]. On 18 September 2020, the Hospital Future Act (KHZG) was approved by parliament, the act highlights the importance of competent and technically advanced hospitals not only to respond to COVID-19, but also for the provision of high standards of health care [2, 3]. The act makes available EUR 3 billion (US$ 3.61 billion) for projects contributing to the improvement of hospitals. These projects include cross-sector telemedical network structures, electronic documentation of care and treatment services, patient portals, digital medication management and IT security measures [2, 3]. The act states the health care system should be optimized not only for normal service but also times of crisis [2]. There is no evidence of funds being allocated specifically to improve Germany's capacity to address epidemic threats prior to the COVID-19 pandemic

[1] Die Zeit Online. 16 September 2020. "Jens Spahn designates Hospitals as the backbone of response". [https://www.zeit.de/politik/deutschland/2020-09/corona-krise-jens-spahn-gesundheitswesen-krankenhausgipfel?utm_referrer=https%3A%2F%2Fwww.google.com%2F]. Accessed 2 February 2021.
[2] German Parliament. 8 September 2020. "Draft law for a future program for hospitals: Hospital Future Act (KHZG)". [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/K/KHZG-BT_bf.pdf]. Accessed 2 February 2021.
[3] Healthcare IT News. 22 September 2020. "German hospitals to get €3 billion funding boost for digitalization". [https://www.healthcareitnews.com/news/emea/german-hospitals-get-3-billion-funding-boost-digitalisation]. Accessed 2 February 2021.

## 5.5.2 Financing under Joint External Evaluation (JEE) and Performance of Veterinary Services (PVS) reports and gap analyses

### *5.5.2a*

**Does the Joint External Evaluation (JEE) report, National Action Plan for Health Security (NAPHS), and/or national GHSA roadmap allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?**

Yes = 1 , No/country has not conducted a JEE = 0

**Current Year Score: 0**

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

### *5.5.2b*

**Does the Performance of Veterinary Services (PVS) gap analysis and/or PVS assessment allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?**

Yes = 1 , No/country has not conducted a PVS = 0

**Current Year Score: 0**

2021

OIE PVS assessments

## 5.5.3 Financing for emergency response

### *5.5.3a*

**Is there a publicly identified special emergency public financing mechanism and funds which the country can access in the face of a public health emergency (such as through a dedicated national reserve fund, an established agreement with the World Bank pandemic financing facility/other multilateral emergency funding mechanism, or other pathway identified through a public health or state of emergency act)?**

Yes = 1 , No = 0

**Current Year Score: 0**

There is insufficient evidence to confirm that a public health emergency fund or separate financing mechanism for public health emergencies exist in Germany. There is no evidence of such a fund or mechanism on the websites of the Federal Ministry of Health, the Federal Ministry of the Interior, Building and Community, the Federal Office of Civil Protection and Disaster Assistance, nor in the Robert Koch Institute's 2017 National Pandemic Plan, the Civil Protection and Disaster Relief Law (ZSKG), the 2015 Civilian Defense Concept (KZV) or the Protection against Infection Act [1, 2, 3, 4, 5, 6, 7]. Germany's public health service is mainly financed through public budgets [8]. Section 29 of the Civil Protection and Disaster Relief Law (adopted 25 March 1997, last amended 19 June 2020) stipulates that the federal government bears the costs of civil protection and compensates the federal states and communities for costs they incur during a crisis or disaster such as a public health emergency [5]. Germany is not eligible for funding from the World Bank's Pandemic Emergency Financing Facility; as this facility only offers coverage to countries eligible for financing from the International Development Association (IDA) [9, 10]. Throughout the coronavirus pandemic, federal contributions to the liquidity reserve of the public health fund and increases to the Ministry of Health's budget have been made ad hoc, following the approval of parliament [11, 12].

[1] Federal Ministry of Health. 2021. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 2 February 2021.
[2] Federal Ministry of the Interior, Building and Community 2021. Website. [https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 2 February 2021.
[3] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website. [www.bbk.bund.de/EN/Home/home_node.html]. Accessed 2 February 2021.
[4] Robert Koch Institute. "National Pandemic Plan: Part I Structures and Measures (Nationaler Pandemieplan: Teil I Strukturen und Maßnahmen der Länder)". 2017. [https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf]. Accessed 2 February 2021.
[5] Federal Government. "Civil Protection and Disaster Relief Law (ZSKG)". Adopted 25 March 1997. Last amended 19 June 2020. [https://www.gesetze-im-internet.de/zsg/BJNR072610997.html]. Accessed 2 February 2021.
[6] Ministry of the Interior, Building and Community. 2015. " Civilian Defense Concept (Konzeption Zivile Verteidigung (KZV))". [www.bmi.bund.de/SharedDocs/downloads/DE/veroeffentlichungen/themen/bevoelkerungsschutz/konzeption-zivile-verteidigung.pdf?__blob=publicationFile&v=1]. Accessed 2 February 2021.
[7] German Federal Government. "Protection against Infection Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG))". Adopted 20 July 2000. Last amended 21 December 2020. [http://www.gesetze-im-internet.de/ifsg/BJNR104510000.html]. Accessed 2 February 2021.
[8] European Observatory on Health Systems and Policies.2018. "Organization and financing of public health services in Europe: Country reports. Germany". [https://www.ncbi.nlm.nih.gov/books/NBK507327/]. Accessed 2 February 2021.
[9] World Bank. 9 May 2017. "Pandemic Emergency Financing Facility: Frequently Asked Questions". [www.worldbank.org/en/topic/pandemics/brief/pandemic-emergency-facility-frequently-asked-questions]. Accessed 2 February 2021.
[10] International Development Association. 2021. "Borrowing Countries". [http://ida.worldbank.org/about/borrowing-countries]. Accessed 2 February 2021.
[11] Deutschland.de. 2021. "The Federal Government informs about the Corona crisis". [https://www.deutschland.de/en/news/german-federal-government-informs-about-the-corona-crisis]. Accessed 2 February 2021.
[12] Deutsche Welle. 25 March 2020. "What's in Germany's emergency coronavirus budget?". [https://www.dw.com/en/whats-in-germanys-emergency-coronavirus-budget/a-52917360]. Accessed 2 February 2021.

## 5.5.4 Accountability for commitments made at the international stage for addressing epidemic threats

### *5.5.4a*

**Is there evidence that senior leaders (president or ministers), in the past three years, have made a public commitment either to:**

**- Support other countries to improve capacity to address epidemic threats by providing financing or support?**

**- Improve the country's domestic capacity to address epidemic threats by expanding financing or requesting support to improve capacity?**

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

**Current Year Score: 1**

There is evidence that senior leaders in Germany have made public commitments in the past three years to financially support other countries in their efforts to address epidemic threats. In October 2018, the German chancellor, Angela Merkel, demanded that the international community step up collaboration to combat diseases and epidemics when presenting an action plan, submitted together with Norway and Ghana, to achieve the United Nations' (UN's) 2030 Agenda for Sustainable Development's third goal: improving global health [1]. Crucial to this goal is strengthening the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks [2]. Additionally, Germany has made numerous commitments to improving global health security [3]. Germany has pledged support to the the UN's High-Level Panel on Global Response to Health Crises and the UN Global Health Crises Task Force, the latter is tasked with assessing the implementation of the former's recommendations on protecting humanity from future health crises [4]. The task force's aims include strategic support for national health systems to prevent global health crises, integrating communities in efforts to prevent global health crises and supporting regional arrangements to prevent and respond to health crises [4]. Germany has also made financial contributions towards the Pandemic Emergency Financing Facility (PEF) and the Coalition for Epidemic Preparedness Innovations (CEPI) [3]. The PEF allows the world's poorest countries to request and receive financial aid through either insurance or cash windows so as to better respond to health crises [5]. Although the PEF does not provide countries with funds to autonomously improve their preparedness for health emergencies such as epidemics, it does provide rapid financial and technical support for countries to better respond to epidemic threats. As such, it does improve eligible countries' capacity to address epidemic threats, albeit not autonomously. The CEPI aims to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks. The program does not cater to a particular country but promises international support, its mission is centred around preparedness and thus improves global capacity to address future epidemic threats [6]. There is, however, no evidence of public commitments to obtaining funds to improve Germany's capacity to address epidemic threats on the websites of the Federal Ministry of Health, the Federal Ministry of the Interior, Building and Community, the Federal Office of Civil Protection and Disaster Assistance [7, 8, 9].

[1] Deutsche Welle. 16 October 2018. "Merkel calls for greater collaboration in the field of global health". [https://www.dw.com/de/merkel-fordert-mehr-globale-gesundheitszusammenarbeit/a-45914946]. Accessed 2 February 2021.
[2] United Nations. 25 September 2015. "Transforming our world: the 2030 Agenda for Sustainable Development". [https://sdgs.un.org/2030agenda]. Accessed 2 February 2021.
[3] The Lancet. 3 July 2017. "Germany's expanding role in global health". [https://www.thelancet.com/action/showPdf?pii=S0140-6736%2817%2931460-5]. Accessed 24 February 2021.
[4] United Nations. "Global Health Crises Task Force." [https://www.un.org/en/global-health-crises-task-force/index.html]. Accessed 24 February 2021.
[5] The World Bank. "Pandemic Emergency Financing Facility". [https://www.worldbank.org/en/topic/pandemics/brief/pandemic-emergency-financing-facility]. Accessed 24 February 2021.

[6] Coalition for Epidemic Preparedness Innovations. [https://cepi.net/about/whyweexist/]. Accessed 2 February 2021.
[7] Federal Ministry of Health. [https://www.bundesgesundheitsministerium.de/]. Accessed 2 February 2021.
[8] Federal Ministry of the Interior, Building and Community 2021. Website.
[https://www.bmi.bund.de/EN/home/home_node.html]. Accessed 2 February 2021.
[9] The Federal Office for Civil Protection and Disaster Assistance (BBK). 2021. Website.
[www.bbk.bund.de/EN/Home/home_node.html]. Accessed 2 February 2021.

### *5.5.4b*

**Is there evidence that the country has, in the past three years, either:**
**- Provided other countries with financing or technical support to improve capacity to address epidemic threats?**
**- Requested financing or technical support from donors to improve the country's domestic capacity to address epidemic threats?**
Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

**Current Year Score: 1**

Germany has provided and received financial and technical support to improve its capacity and that of other countries to address epidemic threats in the past three years. Germany is a major donor to both the Contingency Fund for Emergencies (CFE) and the Pandemic Emergency Financing Facility (PEF) [1, 2]. Although neither of these mechanisms provide countries with funds to autonomously improve their preparedness for health emergencies such as epidemics, both mechanisms do provide rapid financial and technical support for countries to better respond to epidemic threats. As such, the CFE and PEF do improve eligible countries' capacity to address epidemic threats, albeit not autonomously. Additionally, in June 2020, Health Minister Jens Spahn pledged to support the World Health Organization (WHO) during the COVID-19 pandemic. He announced that Germany would contribute an additional EUR 41.4m (US$ 49.77m) to WHO's core work and an additional EUR 200m (US$ 240.44) towards the implementation of the COVID-19 Strategic Preparedness and Response Plan [3]. This plan outlines the public health measures that the international community is prepared to provide to support all countries to prepare for and respond to COVID-19 [4]. According to the Georgetown Infectious Disease Atlas Global Health Security Tracker, in 2020, Germany disbursed US$ 249.66m to the Coalition for Epidemic Preparedness Innovations (CEPI) [5]. The CEPI aims to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks. The program does not cater to a particular country but promises international support, its mission is centred around preparedness and thus improves global capacity to address future epidemic threats [6]. According to the same source, Germany received a total of US$ 1.4m between 2015 and 2020 from a Dutch AIDS non-governmental organization [7].

[1] World Health Organization. "Contingency Fund for Emergencies (CFE)".
[https://www.who.int/emergencies/funding/contingency-fund-for-emergencies]. Accessed 2 February 2021.
[2] The World Bank. 2021. "Fact Sheet: Pandemic Emergency Financing Facility".
[https://www.worldbank.org/en/topic/pandemics/brief/fact-sheet-pandemic-emergency-financing-facility]. Accessed 2 February 2021.
[3] World Health Organization. 29 June 2020. "Partners in health: Germany and France commit to increased support to WHO affirming the Organization's crucial role in global public health". [https://www.who.int/news/item/29-06-2020-partners-in-health-germany-and-france-commit-to-increased-support-to-who-affirming-the-organization-s-crucial-role-in-global-public-health]. Accessed 2 February 2021.
[4] World Health Organization. 4 February 2020. "Strategic preparedness and response plan".
[https://www.who.int/publications/i/item/strategic-preparedness-and-response-plan-for-the-new-coronavirus]. Accessed 2 February 2021.
[5] Georgetown Infectious Disease Atlas. "Global Health Security Tracker: Germany/ Funder".

[https://tracking.ghscosting.org/details/869/funder]. Accessed 2 February 2021.
[6] Coalition for Epidemic Preparedness Innovations. [https://cepi.net/about/whyweexist/]. Accessed 2 February 2021.
[7] Georgetown Infectious Disease Atlas. "Global Health Security Tracker: Germany/ Recipient".
[https://tracking.ghscosting.org/details/869/recipient]. Accessed 2 February 2021.

### *5.5.4c*

**Is there evidence that the country has fulfilled its full contribution to the WHO within the past two years?**

Yes = 1 , No = 0

**Current Year Score: 1**

2021

Economist Impact analyst qualitative assessment based on official national sources, which vary by country

## 5.6 COMMITMENT TO SHARING OF GENETIC AND BIOLOGICAL DATA AND SPECIMENS

### 5.6.1 Commitment to sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) in both emergency and nonemergency research

### *5.6.1a*

**Is there a publicly available plan or policy for sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza?**

Yes = 1 , No = 0

**Current Year Score: 1**

There is publicly available of a policy for sharing genetic data, clinical specimens, and isolated specimens along with the associated epidemiological data with international organizations and other countries that goes beyond influenza. On 24 February 2017, the ministers of the Global Health Security Initiative (GHSI), of which Germany is a member, developed a voluntary agreement to facilitate the rapid sharing of non-influenza biological materials among GHSI members during a potential or actual public health emergency [1, 2]. This voluntary agreement goes further than the World Health Organization's Pandemic Influenza Preparedness (PIP) Framework, which addresses the sharing of influenza viruses with pandemic potential only [2].

[1] Global Health Security Initiative. "GHSI Members." [http://ghsi.ca/ghsi-members/]. Accessed 2 February 2021
[2] Global Health Security Initiative. 24 February 2017. "Ministerial Statements: Brussels, Belgium".
[http://ghsi.ca/ministerial-statements/brussels-february-2017/]. Accessed 2 February 2021

### *5.6.1b*

**Is there public evidence that the country has not shared samples in accordance with the Pandemic Influenza Preparedness (PIP) framework in the past two years?**

Yes = 0 , No = 1

Current Year Score: 1

There is no public evidence that Germany has failed to share samples in accordance with the Pandemic Influenza Preparedness (PIP) framework in the past two years. The World Health Organization has not reported any non-compliance from Germany, and there is no evidence of non-compliance in German or international media [1, 2].

[1] World Health Organization. 2021. Website. [http://www.who.int/]. Accessed 8 August 2020.
[2] World Health Organization. 2021. "Pandemic Influenza Preparedness (PIP) Framework". [www.who.int/influenza/pip/en/]. Accessed 2 February 2021

### *5.6.1c*

**Is there public evidence that the country has not shared pandemic pathogen samples during an outbreak in the past two years?**

Yes = 0 , No = 1

Current Year Score: 1

There is no evidence that Germany has not shared pandemic pathogen samples during an outbreak in the past two years. There is no publicly available evidence that Germany has shared or not shared COVID-19 samples with the World Health Organization (WHO) or other countries [1, 2]. The websites of the German Federal Ministry of Health, the WHO and local and international media outlets do not mention Germany sharing or not sharing pandemic pathogen samples during an outbreak in the past two years [1, 2]. However, in 2020, the Robert Koch Institute did share A1H1N1 virus samples with the WHO [3].

[1] World Health Organization (WHO). 2021 "Pandemic Influenza Preparedness (PIP) Framework". [www.who.int/influenza/pip/en/]. Accessed 31 January 2021.
[2] German Federal Ministry of Health. 2019. Website. [https://www.bundesgesundheitsministerium.de/]. Accessed 31 January 2021..
[3] World Health Organization. "Global Influenza Surveillance and Response System". [https://extranet.who.int/ivtm2/Home/ShipmentShippedMaterial?laboratoryId=189&materialId=4073]. Accessed 11 February 2021.

# Category 6: Overall risk environment and vulnerability to biological threats

## 6.1 POLITICAL AND SECURITY RISK

### 6.1.1 Government effectiveness

### *6.1.1a*

**Policy formation (Economist Intelligence score; 0-4, where 4=best)**

Input number

Current Year Score: 3

2020

Economist Intelligence

### *6.1.1b*

**Quality of bureaucracy (Economist Intelligence score; 0-4, where 4=best)**

Input number

**Current Year Score: 4**

2020

Economist Intelligence

### *6.1.1c*

**Excessive bureaucracy/red tape (Economist Intelligence score; 0-4, where 4=best)**

Input number

**Current Year Score: 3**

2020

Economist Intelligence

### *6.1.1d*

**Vested interests/cronyism (Economist Intelligence score; 0-4, where 4=best)**

Input number

**Current Year Score: 3**

2020

Economist Intelligence

### *6.1.1e*

**Country score on Corruption Perception Index (0-100, where 100=best)**

Input number

**Current Year Score: 80**

2020

Transparency International

### *6.1.1f*

**Accountability of public officials (Economist Intelligence score; 0-4, where 4=best)**

Input number

**Current Year Score: 3**

2020

Economist Intelligence

### *6.1.1g*

**Human rights risk (Economist Intelligence score; 0-4, where 4=best)**

Input number

**Current Year Score: 3**

2020

Economist Intelligence

## 6.1.2 Orderly transfers of power

### *6.1.2a*

**How clear, established, and accepted are constitutional mechanisms for the orderly transfer of power from one government to another?**

Very clear, established and accepted = 4, Clear, established and accepted = 3, One of the three criteria (clear, established, accepted) is missing = 2, Two of the three criteria (clear, established, accepted) are missing = 1, Not clear, not established, not accepted = 0

**Current Year Score: 4**

2021

Economist Intelligence

## 6.1.3 Risk of social unrest

### *6.1.3a*

**What is the risk of disruptive social unrest?**

Very low: Social unrest is very unlikely = 4, Low: There is some prospect of social unrest, but disruption would be very limited = 3, Moderate: There is a considerable chance of social unrest, but disruption would be limited = 2, High: Major social unrest is likely, and would cause considerable disruption = 1, Very high: Large-scale social unrest on such a level as to seriously challenge government control of the country is very likely = 0

**Current Year Score: 3**

2021

Economist Intelligence

## 6.1.4 Illicit activities by non-state actors

### *6.1.4a*

**How likely is it that domestic or foreign terrorists will attack with a frequency or severity that causes substantial disruption?**

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

**Current Year Score: 3**

2021

Economist Intelligence

### *6.1.4b*

**What is the level of illicit arms flows within the country?**

4 = Very high, 3 = High, 2 = Moderate, 1 = Low, 0 = Very low

**Current Year Score: 4**

2020

UN Office of Drugs and Crime (UNODC)

### *6.1.4c*

**How high is the risk of organized criminal activity to the government or businesses in the country?**

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

**Current Year Score: 3**

2021

Economist Intelligence

## 6.1.5 Armed conflict

### *6.1.5a*

**Is this country presently subject to an armed conflict, or is there at least a moderate risk of such conflict in the future?**

No armed conflict exists = 4, Yes; sporadic conflict = 3, Yes; incursional conflict = 2, Yes, low-level insurgency = 1, Yes; territorial conflict = 0

**Current Year Score: 4**

2021

Economist Intelligence

## 6.1.6 Government territorial control

### *6.1.6a*

**Does the government's authority extend over the full territory of the country?**

Yes = 1, No = 0

**Current Year Score: 1**

2021

Economist Intelligence

## 6.1.7 International tensions

### *6.1.7a*

**Is there a threat that international disputes/tensions could have a negative effect?**

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

**Current Year Score: 3**

2021

Economist Intelligence

# 6.2 SOCIO-ECONOMIC RESILIENCE

## 6.2.1 Literacy

### *6.2.1a*

**Adult literacy rate, population 15+ years, both sexes (%)**

Input number

**Current Year Score: 99.9**

2008-2018

United Nations Development Programme (UNDP); United Nations Educational, Scientific and Cultural Organization (UNESCO); The Economist Intelligence Unit

## 6.2.2 Gender equality

### *6.2.2a*

**United Nations Development Programme (UNDP) Gender Inequality Index score**

Input number

**Current Year Score: 0.92**

2018

United Nations Development Programme (UNDP); The Economist Intelligence Unit

## 6.2.3 Social inclusion

### *6.2.3a*

**Poverty headcount ratio at $1.90 a day (2011 PPP) (% of population)**

Input number

**Current Year Score: 0**

2016

World Bank; Economist Impact

### *6.2.3b*

**Share of employment in the informal sector**

Greater than 50% = 2, Between 25-50% = 1, Less than 25% = 0

**Current Year Score: 0**

The latest available figures indicate that less than 25% of Germany's employment is in the informal sector. A 2011 report from the World Bank stated that 11.9% of Germany's population was employed in the informal sector according to the latest available figures, from 2007 [1]. The statistical databases maintained by the World Bank and the International Labor Organization do not provide statistics on informal employment in Germany [2, 3, 4].

[1] Mihails Hazans. December 2011. "Informal Workers across Europe. Evidence from 30 European Countries." World Bank. [https://openknowledge.worldbank.org/bitstream/handle/10986/3681/WPS5912.pdf?sequence=1&isAllowed=y]. Accessed 2 February 2021
[2] World Bank. "Informal employment (% of total non-agricultural employment)." [https://data.worldbank.org/indicator/SL.ISV.IFRM.ZS?locations=DE]. Accessed 2 February 2021
[3] International Labor Organization. "Country profiles." [https://ilostat.ilo.org/data/country-profiles/]. Accessed 2 February 2021
[4] International Labor Organization. "Statistics on the informal economy." [https://ilostat.ilo.org/topics/informality/]. Accessed 2 February 2021

### *6.2.3c*

**Coverage of social insurance programs (% of population)**

Scored in quartiles (0-3, where 3=best)

**Current Year Score: 3**

2016, or latest available

World Bank; Economist Impact calculations

## 6.2.4 Public confidence in government

### *6.2.4a*

**Level of confidence in public institutions**

Input number

**Current Year Score: 2**

2021

Economist Intelligence Democracy Index

## 6.2.5 Local media and reporting

### *6.2.5a*

**Is media coverage robust? Is there open and free discussion of public issues, with a reasonable diversity of opinions?**

Input number

**Current Year Score: 2**

2021

Economist Intelligence Democracy Index

## 6.2.6 Inequality

### *6.2.6a*

**Gini coefficient**

Scored 0-1, where 0=best

**Current Year Score: 0.32**

Latest available.

World Bank; Economist Impact calculations

# 6.3 INFRASTRUCTURE ADEQUACY

## 6.3.1 Adequacy of road network

### *6.3.1a*

**What is the risk that the road network will prove inadequate to meet needs?**

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

**Current Year Score: 3**

2021

Economist Intelligence

## 6.3.2 Adequacy of airports

### *6.3.2a*

**What is the risk that air transport will prove inadequate to meet needs?**

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

**Current Year Score: 4**

2021

Economist Intelligence

## 6.3.3 Adequacy of power network

### *6.3.3a*

**What is the risk that power shortages could be disruptive?**

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

**Current Year Score: 3**

2021

Economist Intelligence

# 6.4 ENVIRONMENTAL RISKS

## 6.4.1 Urbanization

### *6.4.1a*

**Urban population (% of total population)**

Input number

**Current Year Score: 77.38**

2019

World Bank

## 6.4.2 Land use

### *6.4.2a*

**Percentage point change in forest area between 2006–2016**

Input number

**Current Year Score: -0.01**

2008-2018

World Bank; Economist Impact

### 6.4.3 Natural disaster risk

#### *6.4.3a*

What is the risk that the economy will suffer a major disruption owing to a natural disaster?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 4

2021

Economist Intelligence

## 6.5 PUBLIC HEALTH VULNERABILITIES

### 6.5.1 Access to quality healthcare

#### *6.5.1a*

Total life expectancy (years)

Input number

Current Year Score: 80.89

2018

United Nations; World Bank, UNICEF; Institute for Health Metrics and Evaluation (IHME); Central Intelligence Agency (CIA) World Factbook

#### *6.5.1b*

Age-standardized NCD mortality rate (per 100 000 population)

Input number

Current Year Score: 329.3

2019

WHO

#### *6.5.1c*

Population ages 65 and above (% of total population)

Input number

Current Year Score: 21.56

2019

World Bank

### *6.5.1d*

**Prevalence of current tobacco use (% of adults)**

Input number

**Current Year Score: 28**

2018

World Bank

### *6.5.1e*

**Prevalence of obesity among adults**

Input number

**Current Year Score: 22.3**

2016

WHO

## 6.5.2 Access to potable water and sanitation

### *6.5.2a*

**Percentage of homes with access to at least basic water infrastructure**

Input number

**Current Year Score: 99**

2017

UNICEF; Economist Impact

### *6.5.2b*

**Percentage of homes with access to at least basic sanitation facilities**

Input number

**Current Year Score: 99**

2017

UNICEF; Economist Impact

## 6.5.3 Public healthcare spending levels per capita

### *6.5.3a*

**Domestic general government health expenditure per capita, PPP (current international $)**

Input number

**Current Year Score: 4737.33**

2018

WHO Global Health Expenditure database

## 6.5.4 Trust in medical and health advice

### *6.5.4a*

**Trust medical and health advice from the government**

Share of population that trust medical and health advice from the government , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

**Current Year Score: 2**

2018

Wellcome Trust Global Monitor 2018

### *6.5.4b*

**Trust medical and health advice from medical workers**

Share of population that trust medical and health advice from health professionals , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

**Current Year Score: 2**

2018

Wellcome Trust Global Monitor 2018