



Rijksinstituut voor Volksgezondheid
en Milieu

*Ministerie van Volksgezondheid,
Welzijn en Sport*

Pandemische paraatheid: internationale ontwikkelingen en de rol van het RIVM

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Wereldwijd

- › Wereldwijde respons op COVID-19 pandemie
 - Verschillende evaluaties
- › Amendementen International Health Regulations (2005)
- › Additioneel: nieuw pandemisch akkoord

IHR

Indicators		
Level	C4.2. Implementation of a laboratory biosafety ²⁴ and biosecurity ²⁵ regime	
Level 1	National laboratory biosafety and biosecurity guidelines and/or regulations are under development	<input type="checkbox"/>
Level 2	National laboratory biosafety and biosecurity guidelines and/or regulations are in place and implemented by some laboratories at the national level	<input type="checkbox"/>
Level 3	National laboratory biosafety and biosecurity guidelines and/or regulations are in place and implemented by all laboratories at the national level	<input type="checkbox"/>
Level 4	National laboratory biosafety and biosecurity guidelines and/or regulations are implemented by all laboratories at national, intermediate and local levels	<input type="checkbox"/>
Level 5	National laboratory biosafety and biosecurity guidelines and/or regulations are exercised, reviewed, evaluated and updated on a regular basis, as applicable and a system for oversight of the regulation is in place	<input type="checkbox"/>

- > Bindend voor alle lidstaten van de WHO
- > Doel is het voorkomen van, beschermen tegen en beheersen van internationale verspreiding van ziekten, zonder het handels- en personenverkeer te belemmeren
- > Huidge versie uit 2005
- > 'all hazards approach'
- > Verplicht om *core capacities* op orde te hebben
- > Jaarlijkse SPAR, periodieke JEE
- > In Nederland verankerd in de Wet Publieke Gezondheid uit 2008



IHR JEE

- > P7.1. Whole-of-government biosafety and biosecurity system is in place for human, animal and agriculture facilities
- > P7.2. Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture)

P7. BIOSAFETY AND BIOSECURITY

Target: A whole-of-government multisectoral national biosafety⁴² and biosecurity⁴³ system with high-consequence biological agents⁴⁴ identified, held, secured and monitored in a minimal number of facilities according to best practices,⁴⁵ biological risk management training and educational outreach conducted to promote a shared culture of responsibility,⁴⁶ reduce dual-use risks, mitigate biological proliferation and deliberate use threats, and ensure safe transfer of biological agents; and country-specific biosafety and biosecurity legislation, laboratory licensing and pathogen control measures in place as appropriate.

Technical questions

P7.1. Whole-of-government biosafety and biosecurity system in place for all sectors (including human, animal and agriculture facilities)

1. Is there active monitoring and development of an updated record and inventory of high-consequence biological agents within facilities that store or process high-consequence biological agents?
 - a. Does the country have in place an updated record of where and in which facilities high-consequence agents are housed?
 - i. Have collections of high-consequence agents been identified?
 - ii. What guidance is to be provided to countries which do not have supporting systems and legislation already in place to enable them to require inventory records of "high-consequence agents" kept by facilities?
 - iii. Is there an agreed list of "high-consequence agents" to which this question applies?
 - iv. How often are facilities expected to update such records?



SPAR NL 2022

Main strengths

Based on the analysis of the latest annual reporting data, the top strengths are:



Main challenges

Based on the analysis of the latest annual reporting data, the top challenges are:

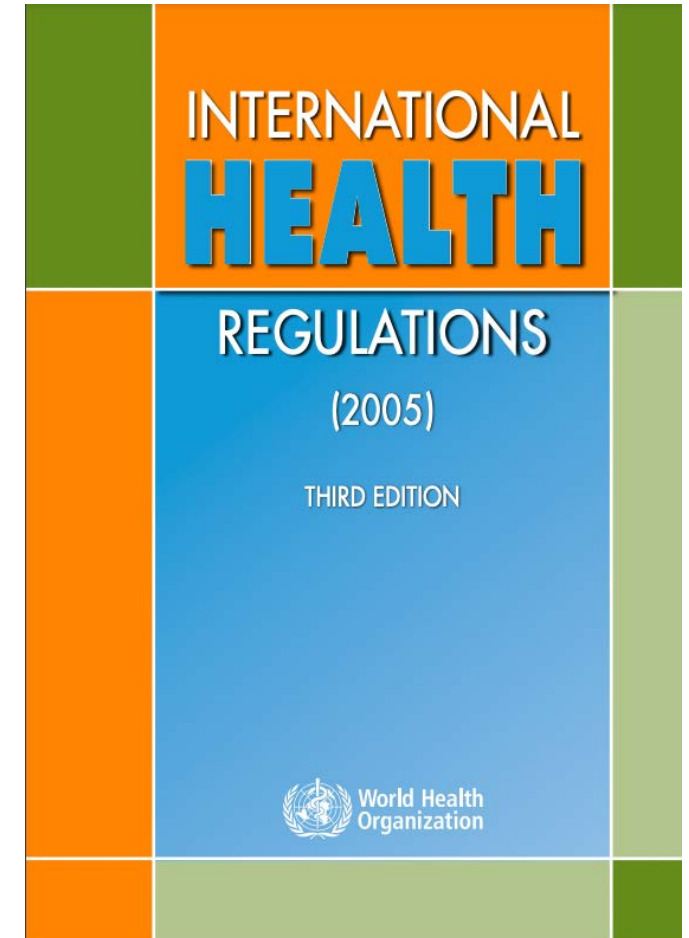


> C4 Laboratory = 84%



IHR amendementen

- › Ruim 370 amendementen ingediend, door een Review Committee van onafhankelijke experts beoordeeld
- › Onderhandelingen in WGIHR
- › EU-coördinatie





WHO pandemic agreement

- Nederland is voorstander van een proactieve inzet
 - › Onderhandelingen in INB sessies, EU-coördinatie
 - › Van conceptual zero draft naar first draft (16 oktober)
 - › Article 4; pandemic prevention and public health surveillance
 - › Article 6; preparedness, readiness and resilience



EU ontwikkelingen

- › EU Health Union: aanpassing wet- en regelgeving nav COVID-19
 - Versterkte mandaten ECDC en EMA
 - Besluit 1082/2013 wordt verordening (verplichtender)
 - HERA (leveringszekerheid van medische tegenmaatregelen)



SCBTH

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 - Art. 8 Assessment of national PPR planning
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 - Art. 10 Coordination of PPR in the HSC
 - Art. 11 Training of Healthcare Staff
 - Art. 12 Joint procurement of medical countermeasures
 - Art. 13 Epidemiological Surveillance
 - Art. 14 Digital Platform for Surveillance (“IT-platform”)
 - Art. 15 EU Reference laboratories
 - Art. 16 Network for substances of human origin
 - Art. 17 Ad-hoc monitoring
 - Art. 18 Early Warning and Response



Belangrijke nieuwe elementen:

- Versterken coördinatiestructuren op EU-niveau
- Ontwikkeling van EU-plan en nationale plannen
- Medische tegenmaatregelen
- Rapportage en assessments



SCBTH

› Ernstige Gezondheidsbedreigingen

- (a) threats of **biological origin**, consisting of:
 - (i) communicable diseases, including those of zoonotic origin;
 - (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases ('related special health issues');
 - (iii) biotoxins or other harmful biological agents not related to communicable diseases;
- (b) threats of **chemical origin**;
- (c) threats of **environmental origin**, including those due to the climate;
- (d) threats of **unknown origin**; and
- (e) events which may constitute **public health emergencies of international concern** under the International Health Regulations (IHR) ('public health emergencies of international concern'), provided that they fall under one of the categories of threats set out in points (a) to (d).



SCBTH

- › **Digital platform for surveillance** [that shall] enable the automated collection of surveillance and laboratory data
- › The designation of **EU reference laboratories** to provide support to national reference laboratories, coordinating the network of NRLs
 - (a) reference diagnostics, including test protocols;
 - (b) reference material resources;
 - (c) external quality assessments;
 - (d) scientific advice and technical assistance;
 - (e) collaboration and research;
 - (f) monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and
 - (g) training.

HERA



What does HERA do?

Preparedness phase

- ▶ Threat assessments and intelligence gathering
- ▶ Advanced R&D for medical countermeasures
- ▶ Boosting industrial capacity
- ▶ Procuring and distributing medical countermeasures
- ▶ Increasing stockpiling capacity
- ▶ Strengthening knowledge and skills

Outbreak of health emergency

Activation by the Council upon proposal of the Commission

HERA FUNCTIONS

Emergency phase

- ▶ Ensuring the availability, supply and deployment of medical countermeasures
- ▶ Acting as a central purchasing body
- ▶ Monitoring medical countermeasures
- ▶ Activating emergency measures for research, EU FAB manufacturing surge capacity and emergency funding

End of health emergency



HERA

- › Top 3 prioriteit dreigingen:
 - Pathogenen met pandemische dreiging
 - AMR
 - Chemical, biological, radiological and nuclear (CBRN) threats originating from accidental or deliberate release:
- › List of critical medical countermeasures
- › Strategische voorraden CBRN (via resEU):
 - responsmiddelen — zoals persoonlijke beschermingsmiddelen en detectie-, identificatie- en monitoringapparatuur — en geneesmiddelen, vaccins en andere therapeutische middelen
 - personeel en uitrusting voor het ontsmetten van mensen, infrastructuur, gebouwen, voertuigen en kritieke uitrusting die aan CBRN-stoffen zijn blootgesteld



Pandemische paraatheid

Beleidsopgaven

De aanpak Pandemische Paraatheid bestaat uit drie hoofdogaves:



Versterkte publieke gezondheidszorg en infectieziektebestrijding



Zorg: goed voorbereid, flexibel en opschaalbaar



Versterkte leveringszekerheid en toegang tot medische producten

Aanpak Pandemische Paraatheid

Binnen die drie beleidsopgaven zijn er vier thema's die bijzondere aandacht vragen:



Sturing en regie



Internationale strategie en samenwerking



Kennis, innovatie en ontwikkeling



ICT, data en informatievoorziening

Doelen



Pandemie voorkomen



Ziekte- en sterftelast beperken



Economische gevolgen beperken



Gevolgen voor het welzijn beperken



Plannen RIVM

- › Versterking surveillancelandschap
- › Versterking zoönosenbeleid
- › Versterking lablandschap (volgende slide)
- › Versterking regionale en landelijke IZB
- › Landelijke functionaliteit opschaling infectieziekten (LFI)
- › Sociale- en gedragswetenschappen



Toekomstbestendige microbiële diagnostiek voor publieke gezondheid en pandemische paraatheid

- › Toekomstige ontwikkelingen in de microbiologische diagnostiek die van invloed zijn op de gegevens t.b.v. publieke gezondheid. Beleidsopties voor de toekomst.
- › Inventarisatie van de huidige microbiologische diagnostiek t.b.v. publieke gezondheid en pandemische paraatheid. Invulling hiaten.
- › Formaliseren opschalingstructuur die tijdens de COVID-19-pandemie operationeel was, in samenspraak met LFI
- › Ontwikkeling en implementatie van een platform voor uitwisseling van gegevens ([Improving laboratory-based surveillance of infectious diseases in the Netherlands | RIVM](#))