

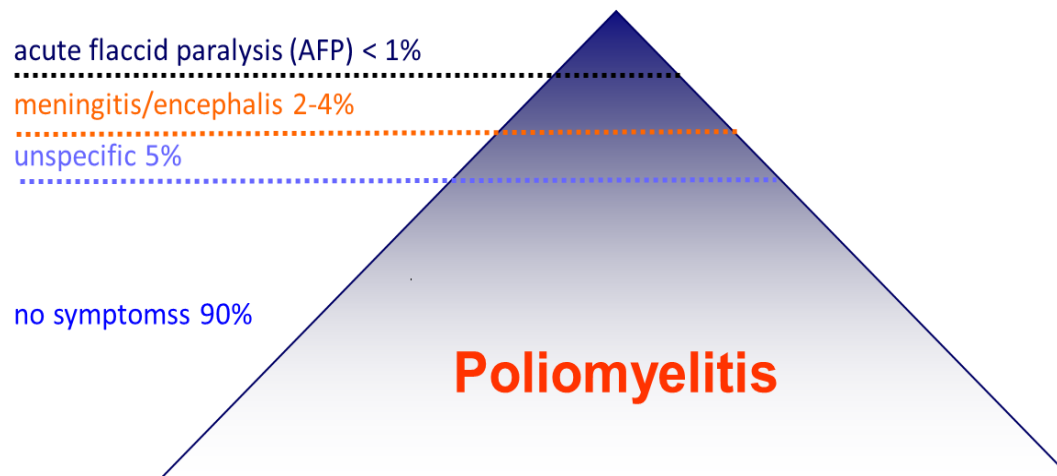
## Path to WHO certification of polio-free status and its implications for risk assessment and management

Kathrin Keeren  
Office of the National Commission for Polio  
Eradication in Germany

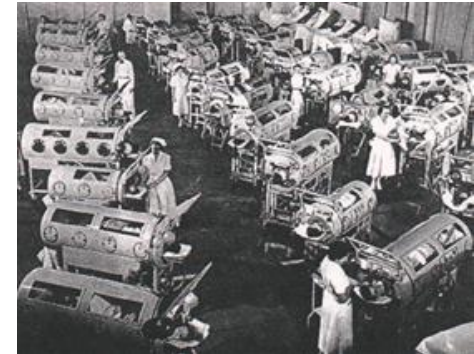


# Poliomyelitis

- Highly contagious, vaccine preventable disease
- Pathogen: poliovirus (PV) 1, 2 or 3 is shedded



- Europe certified polio free in 2002
- 2014 Public Health emergency of international concern (PHEIC) declared due to risk of re- introduction of polio into polio free regions (migration, immunization gaps)
- WPV2 (2015) and WPV3 (2019) declared eradicated





# Poliomyelitis Vaccines

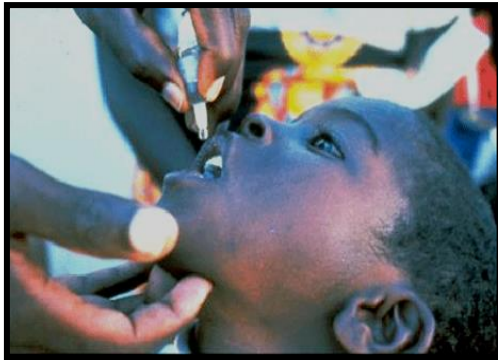
	OPV: oral polio vaccine contains live attenuated virus (Sabin)	IPV: inactivated wildtype virus
advantages	is shedded & thereby vaccinates e.g. social environment	no VAPP or VDPV
	leads to mucosal immunity to polio	
	easy (no strict cold chain, no injection)	
disadvantages	very rare cases of VAPP (Vaccine associated paralytic polio)	No mucosal immunity to polio (prevents disease in case of infection with WPV but not shedding)
	can lead to VDPVs (Vaccine derived polio virus) with regained pathogenicity in countries with low vaccination coverage	Injection needed: hygiene and cold chain matters

- OPV2 responsible for 95% of all cVDPV - and 40% of VAPP cases  
 → deployment of nOPV2 (novel OPV2) a new PV2 vaccine that is less prone to reversion to neurovirulence)

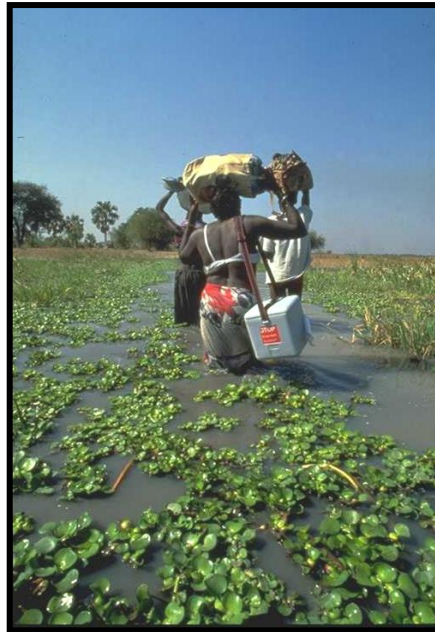


# WHO-Strategies for global Eradication of Polio

- Vaccination
- Surveillance
- Containment



Routine Vaccination



Surveillance



National Immunisation days



Mop-ups (high risk areas)



# GPEI strategic plan timeline



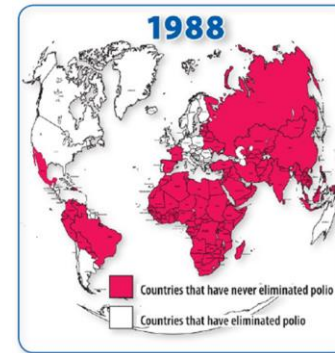
Source: WHO



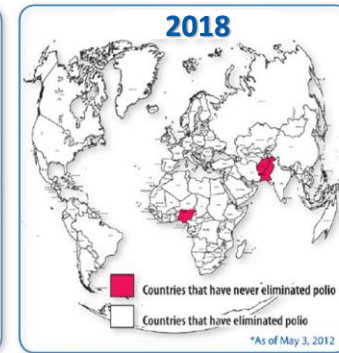
# Polio Eradication- status quo

- endemic countries left: PAK, AFG, (NIG last case 2016)
- 4 out of 6 WHO-regions polio-free:
  - American 1994
  - Western Pazific 2000
  - European 2002
  - South East Asian 2014 (India)
  - (Africa: certification expected soon)

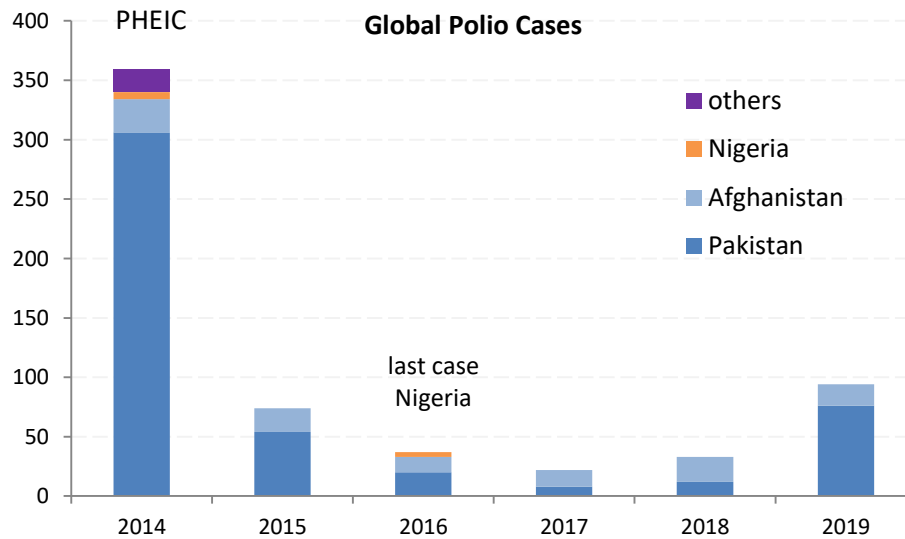
80%  
global population



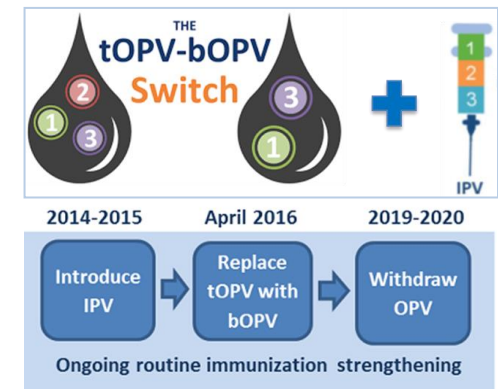
n=350.000



n=33



Vaccination scheme changed 2016  
**tOPV → bOPV + 1 x IPV**



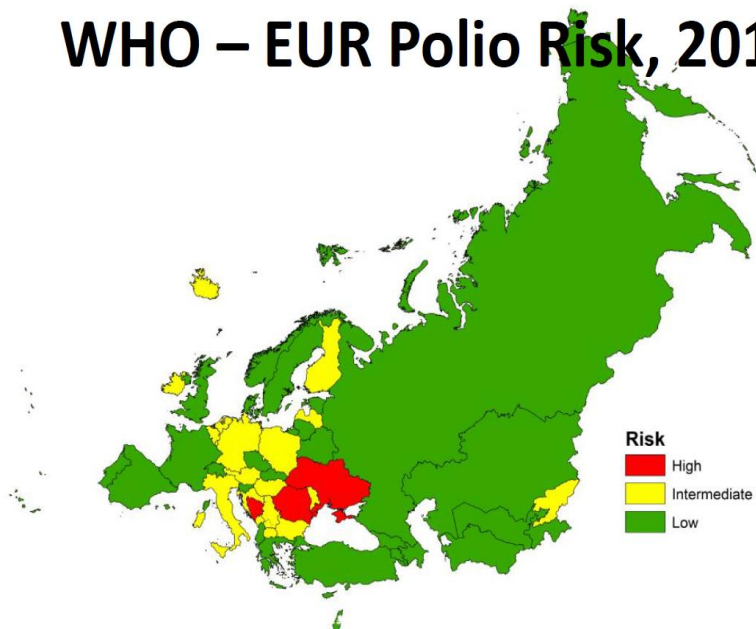


# Risk of re-introduction of Polio to Europe?

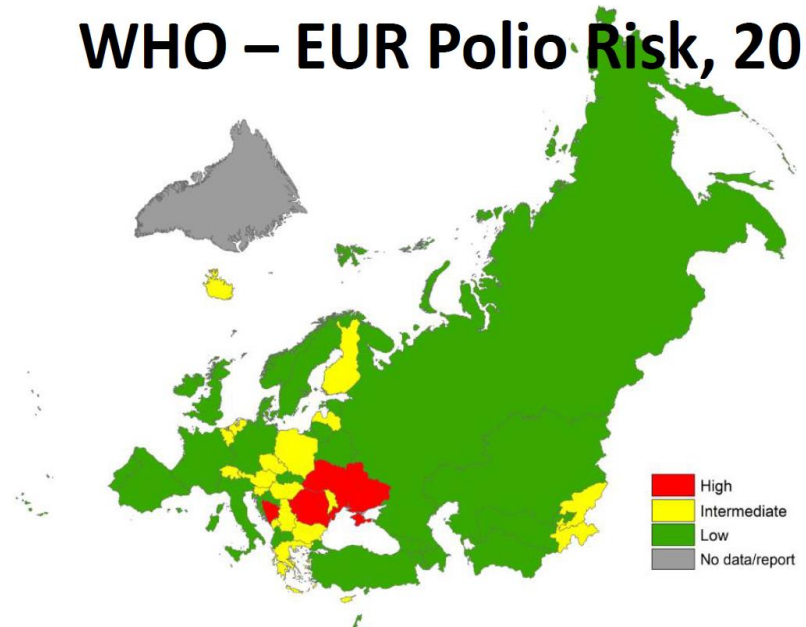
## RCC decision

RCC: European Regional Commission for the Certification of Poliomyelitis Eradication  
 Decision based on: **surveillance quality, population immunity** and other factors  
 (outbreak preparedness, containment, program sustainability) annually reported by each country

### WHO – EUR Polio Risk, 2017



### WHO – EUR Polio Risk, 2018



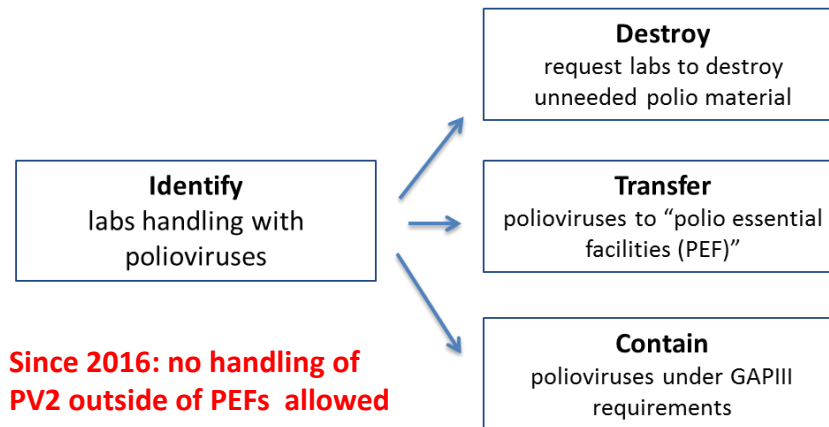
**high risk: Bosnia and Herzegovina, Romania and Ukraine**



# Background Containment

= safe use and storage of Poliovirus in labs

- eliminate risk of (un)-intended release of PV from labs (only way of infection)
- WHO demands destruction or documented safe storage of PV



- 1997: Germany: joins GPEI
- Responsibility: each country



The Leaders of the Group of Seven commit to Polio Eradication (42nd G7 Summit on 26-27 May 2016 in Ise-Shima, Japan)





# Appropriate reduction of labs, working with Polio (=Risk reduction)

## ➤ Polio Essential Facilities (PEF) Aim: globally < 20 PEFs

- Vaccination
- Diagnostic
- Eradication supporting research

## ➤ Requirements: WHO Global Action Plan III (GAPIII)

- **Structural:** access control, video control, air locks with chemical showers, decontamination of wastewater
- **Documentation:** keep an inventory and record any transfer of material
- **Workers:** Vaccination every 3 years

## ➤ High vaccination rate (>95%) of population

## ➤ High standard hygiene and wastewater treatment plant

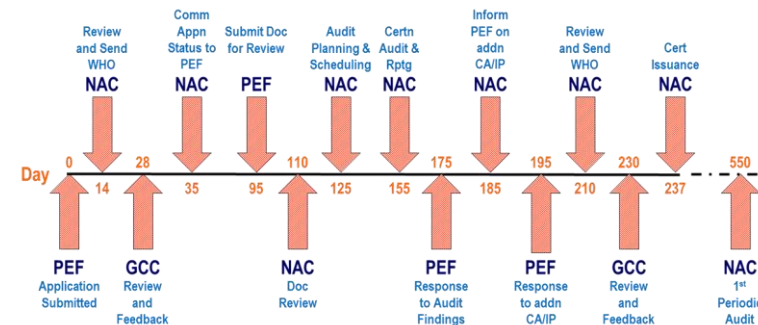
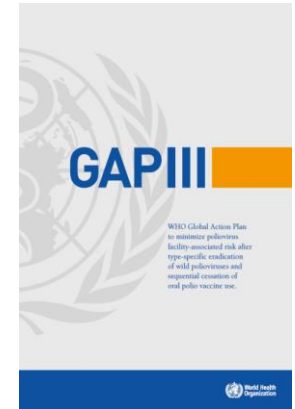
## ➤ Well established Surveillance System

## ➤ Risk Assessment

## ➤ Biosecurity und Biosafety Aspects

## ➤ Emergency schedule in case of release

## ➤ **TIME:** Containment Certification Scheme takes 18-24 month

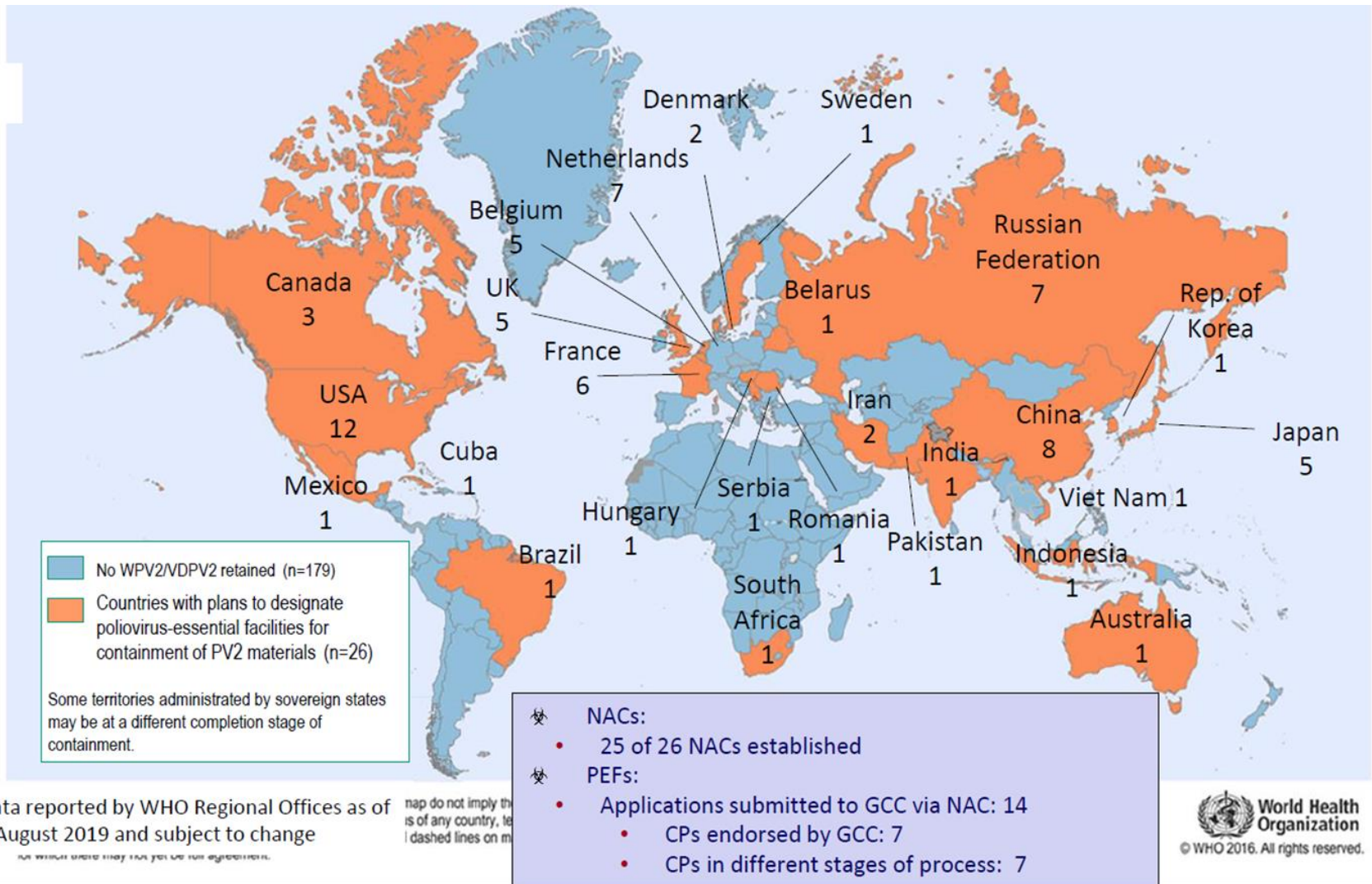


Source: WHO

**GLOBAL  
POLIO ERADICATION  
INITIATIVE**



# 26 Countries: 74 designated PEFs (PV2\*)



Data reported by WHO Regional Offices as of 1 August 2019 and subject to change

map do not imply the is of any country, te dashed lines on m



# Containment reference documents



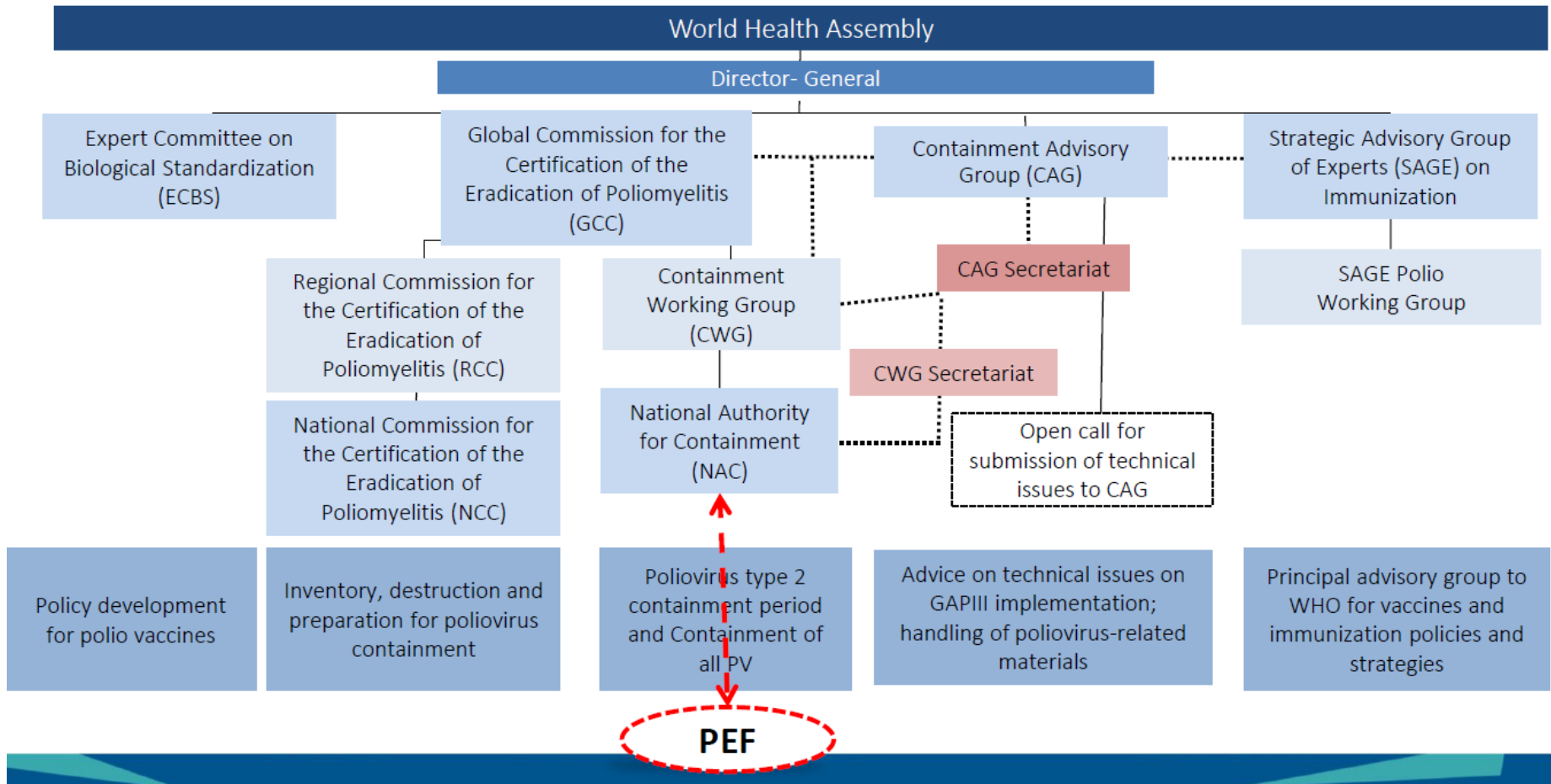
- **Global Action Plan (GAPIII)**
  - ✘ World Health Assembly 2015
- **GAPIII Containment Certification Scheme (GAPIII-CCS)**
  - ✘ SAGE 2016
  - ✘ Supersedes Annex 4 of GAPIII
- **Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious materials for polioviruses (PIM guidance)**
  - ✘ Published in April 2018
- **Resolution WHA 71.16 on PV containment**
  - ✘ Published in May 2018
- **Global Certification Commission (GCC)**
  - ✘ Expectations with regards to progress with containment for global eradication certification
- **Technical Reports Series (TRS 926) on the production and control of polio vaccines**
  - ✘ Revision endorsed (ECBS meeting, October 2018)



Source: WHO



# Containment oversight and advisory bodies





# PEF ≠ PEF

- Risk assessment results differ between PEFs around the globe
- Depending on:
  - Kind of material: **WPV2/VDPV2** > OPV2/Sabin2
  - Amount of materials: **manufacturer** > Labs
  - Vaccination rate : **low** (PV2 >90%)
  - Standard of Hygiene: 95% of population with access to good standards

## Reported PEF incidents since 2014

Year	Location	Virus	Comments
Sep 2014	BEL (GSK, Rixensart)	WPV3 (Saukett)	Accidental release of 45 liters of concentrated PV ( $10^{13}$ virus particles) into sewage system with consecutive release of the water (after treatment plant) into the river Lasne. No PV detected in the samples available; no PV spreading in communities with less than 80% of vaccination coverage.
Apr 2017	NET (BBio)	WPV2 (MEF-1)	Accidental spill with 2 operators exposed. One operator was continuously excreting WPV2 during 28 days after exposure; some of the sewage samples collected around his residence were PV- positive (in RT-PCR) up to day 30 after exposure.
Nov 2018	FRA (Sanofi Pasteur, Val de Reuil)	OPV3	Accidental spill with 5 operators exposed. All pharyngeal and all except one stool samples collected on day 5 and day 15 were PV-negative. One PV-positive sample has 100% homology with OPV3.
2017/2018	NET (BBio)	WPV3 (Saukett) /none	Two additional events. One has not been reported because it was not related to PV2. The other did not involve infectious material.



# What is PV Potential Infectious Material (PIM) ?

- Stool and respiratory samples, collected at any purpose and any time and place with:
  - WPV / cVDPV Circulation → destroy, transfer or contain (in PEF, exception: RNA)
  - OPV vaccination → PIM “light”
- Products (from material above) on PV-permissive cells
- Uncharacterised Enterovirus-similar cell-culture isolates
- Respiratory and enteral stocks from virus, handled under PV propagating conditions
- Examples for “non- PV Labs “ having a PIM-Risk:
  - Measles
  - Rotavirus/Norovirus
  - Enteric Viruses
  - Hepatitis
  - Influenza a.o. resp. Viruses
  - Enterobacteria
  - Waste water testing
  - Nutritional science



# Collections with potential only for OPV/Sabin and related strains

Risk	Type of PIM	Procedures used with PIM
<b>1 moderate</b>	Faecal samples or concentrated sewage	Inoculation into poliovirus-permissive cells
	Extracted nucleic acid from faecal samples or concentrated sewage	Transfection into poliovirus-permissive cells
<b>2 low</b>	Faecal samples or concentrated sewage	No cell culture inoculation
	Respiratory tract samples	Inoculation into polio-permissive cells
	Extracted nucleic acid from respiratory tract samples	Transfection into poliovirus-permissive cells
<b>3 lowest</b>	Respiratory tract samples	No cell culture inoculation
	Extracted nucleic acid from faecal samples, concentrated sewage or respiratory tract samples	No transfection into polio-permissive cells
<b>Non-PIM</b>	CSF, serum/blood and other clinical material, materials inactivated by a validated method (e.g. formalin)	Not applicable



# Risk mitigation strategy

Risk Mitigation Strategies	Level 1 Moderate	Level 2 Low	Level 3 Lowest	Storage Only <sup>2</sup>
Declare PIM in National Survey and maintain working inventory	X	X	X	X
Biosecurity (locked freezers, limited access)	X	X	X	X
Good laboratory/microbiological practices, including documentation and validation of methods/SOPs	X	X	X	n/a
Risk assessment for specific procedures being used	X	X	X	n/a
Polio immunization for staff: Required	X	X	-	n/a
Recommended	-	-	X	n/a
Accreditation to a national or international biorisk management standard	X	n/a	n/a	n/a

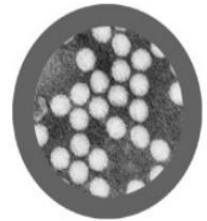


# Thanks for your attention



## Polio

(Poliovirus)



Dieser Artikel ist ausverkauft und wird derzeit leider nicht mehr nachproduziert.

[www. Riesenmikroben.de](http://www.Riesenmikroben.de)

## Questions...?

More Information:

Diagnostic: NRZ Poliomyelitis und Enteroviren, RKI, [polio@rki.de](mailto:polio@rki.de)

Containment: Geschäftsstelle der Poliokommission, RKI, [EVSurv@rki.de](mailto:EVSurv@rki.de)  
[https://www.rki.de/DE/Content/Kommissionen/Poliokommission/Poliokommission\\_node.html](https://www.rki.de/DE/Content/Kommissionen/Poliokommission/Poliokommission_node.html)