European Federation of Pharmaceutical Industries and Associations

# Annual Regulatory GMP/GDP Inspection Survey 2022 Data

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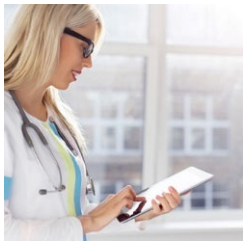
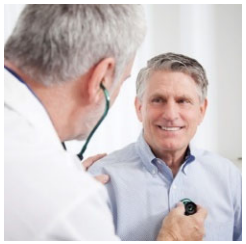





Summary


# Background and history

## History

- The annual inspection survey was initiated in 2003

## Intention

- Monitor trends and new focus areas
- Promote reliance optimizing the use of inspection resources
- Materialise the benefits of PIC/S membership

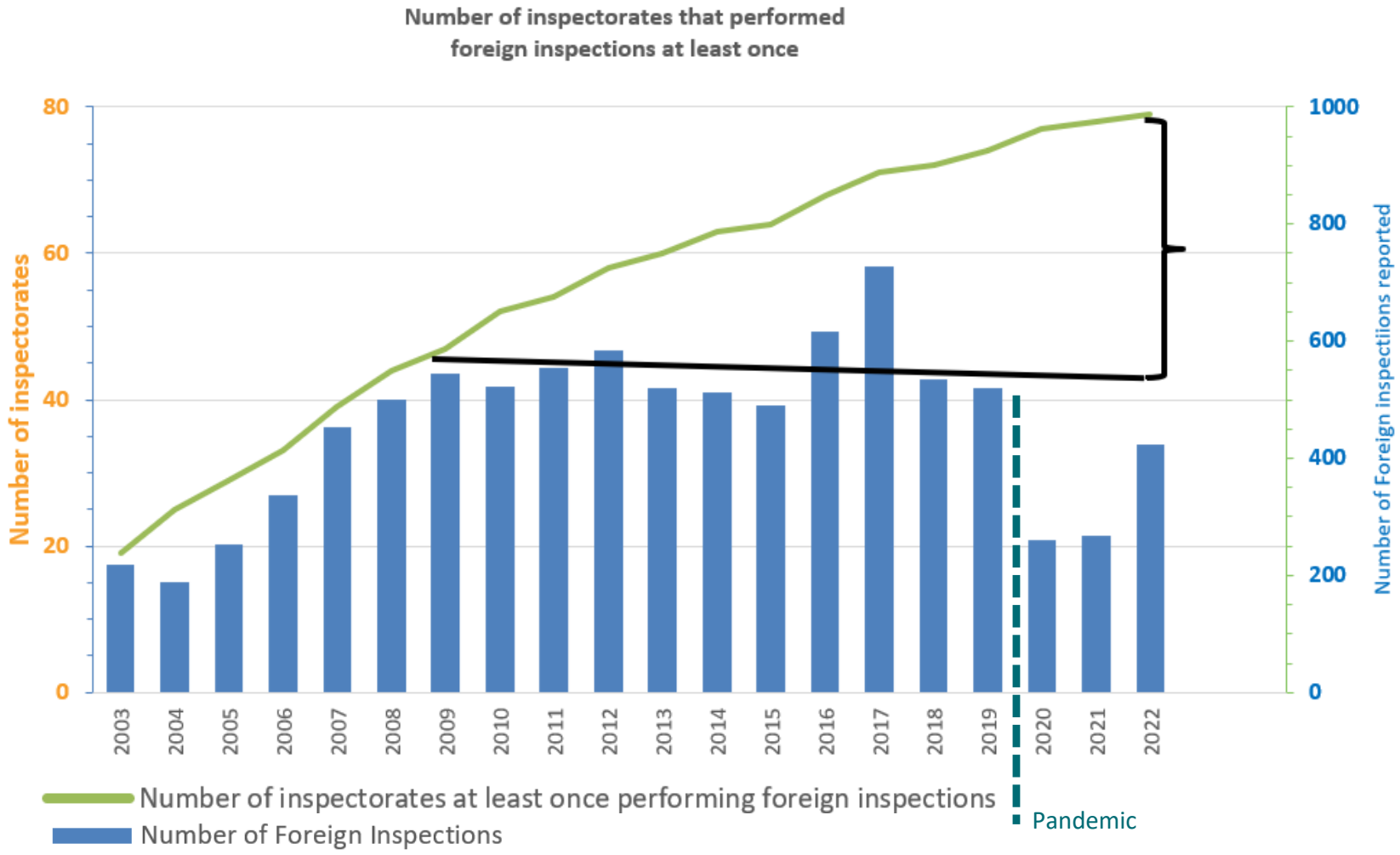
## Scope

- Regulatory GMP/GDP inspections
- Notified Bodies certifications for devices is used in Medicinal Products
- Manufacturing sites and commercial affiliates worldwide
- Inside and outside the own borders (domestic and foreign*)
- Inspection modes used and combinations of them

* 'foreign inspections' are inspections performed in a 3rd country to the inspectorate

## 20 YEARS OF THE ANNUAL INSPECTION SURVEY

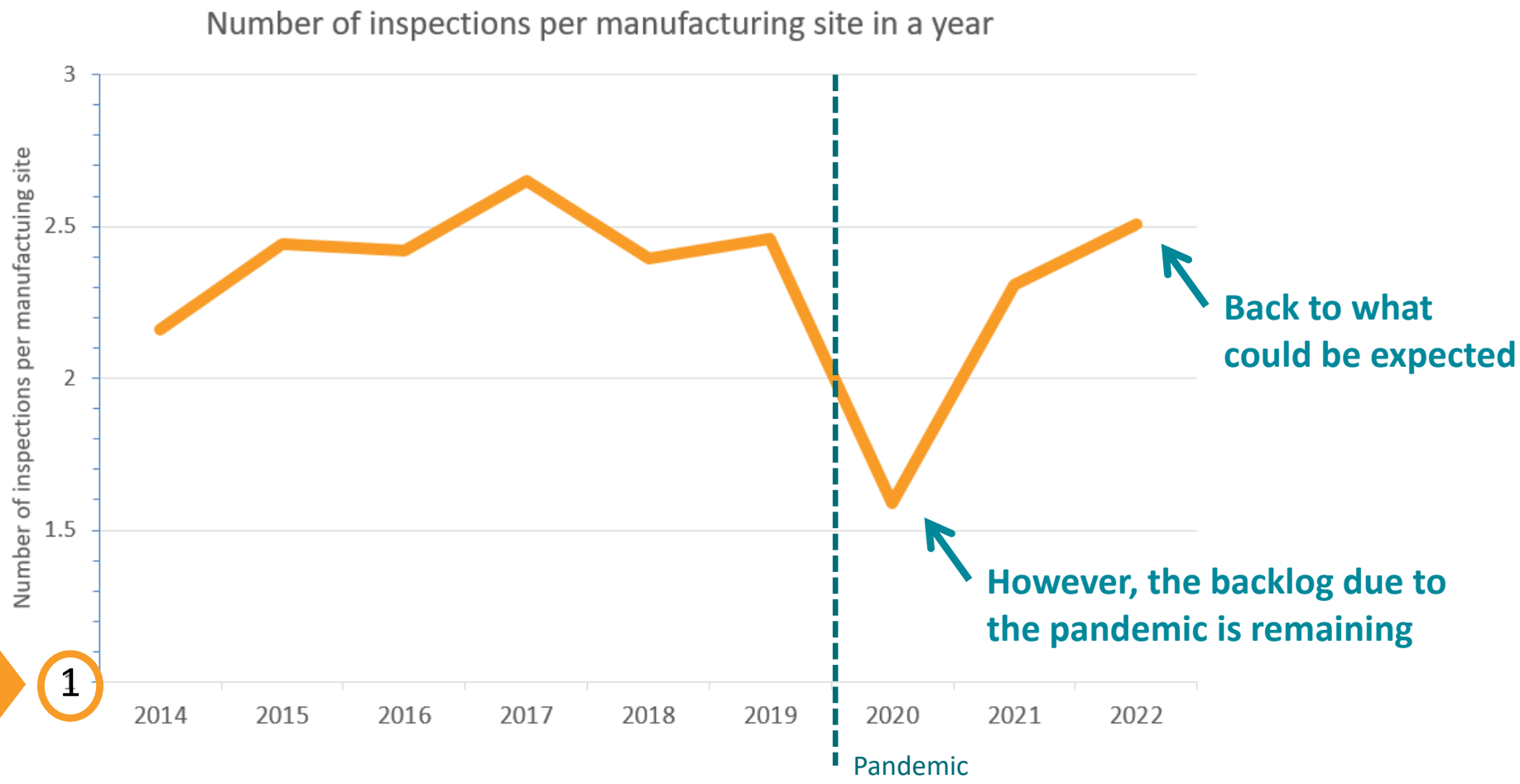
# We broke the trend




Can we continue the trend post pandemic?

## INSPECTION SURVEY - 2022 DATA

# The number of inspections at manufacturing sites in 2022 is similar to before the pandemic



# Outcome of the data

## At Manufacturing sites

- Inspectors are back on site and the numbers are similar to 2019
- The percentage of sites with no inspection has remained stable for 7 years
- Opportunities for a better risk-based approach on inspections*1

**Data source: 23 Global research-based pharmaceutical companies + 7 sites reported by two National Trade Associations**

## At Affiliates - worldwide

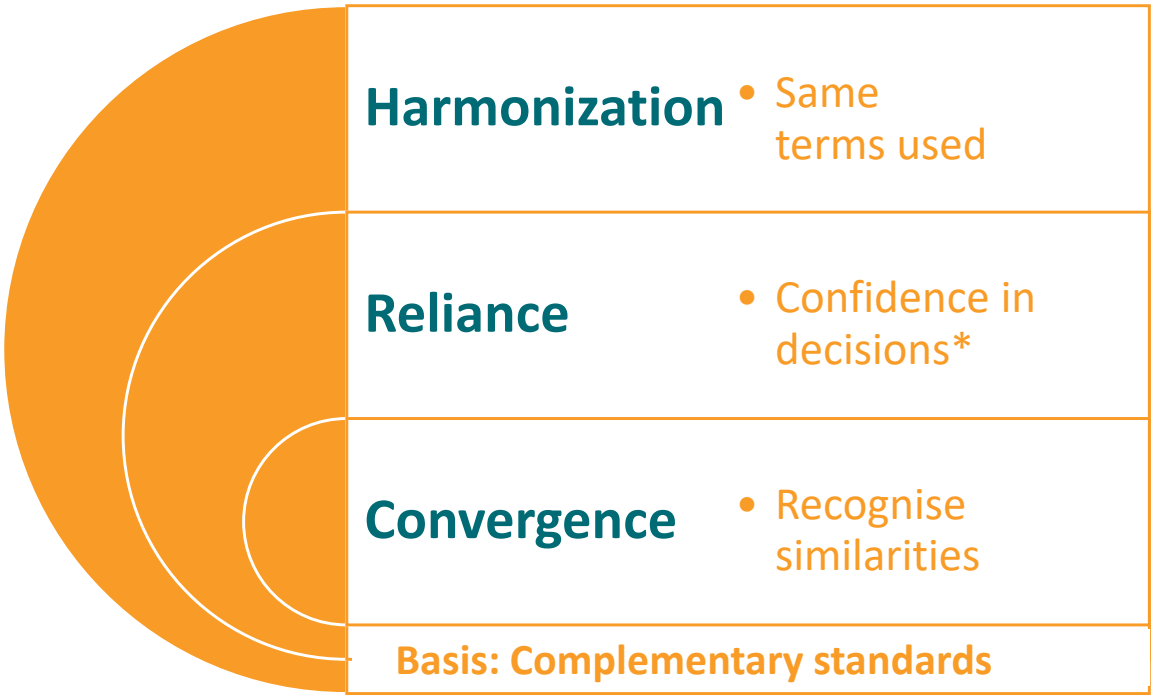
- More inspections than ever*2
- Very limited impact by the pandemic on the number of inspections
- The role of 'MAH and GMPs' is a key topic in Europe

*1 Countries may include Russia, Republic of Korea, USA, Japan, EU, Mexico, Brazil, Türkiye, Belarus, Libya

*2 Note: only 23% of all affiliates had an inspection; a reason can be the inspection frequency of about 4-5 years

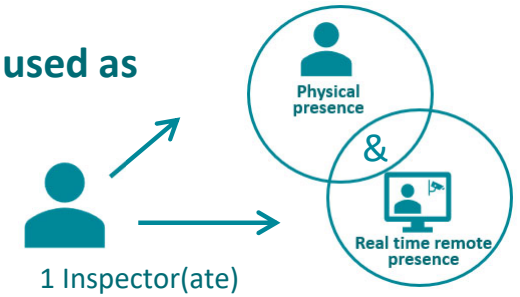
## UNDERSTANDING THE TERMINOLOGY

# Make sure everybody is aware on what is discussed

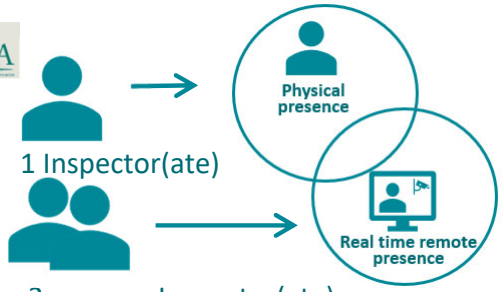



## 'Hybrid' Inspections

**A: often used as**




**B:** ICMRA



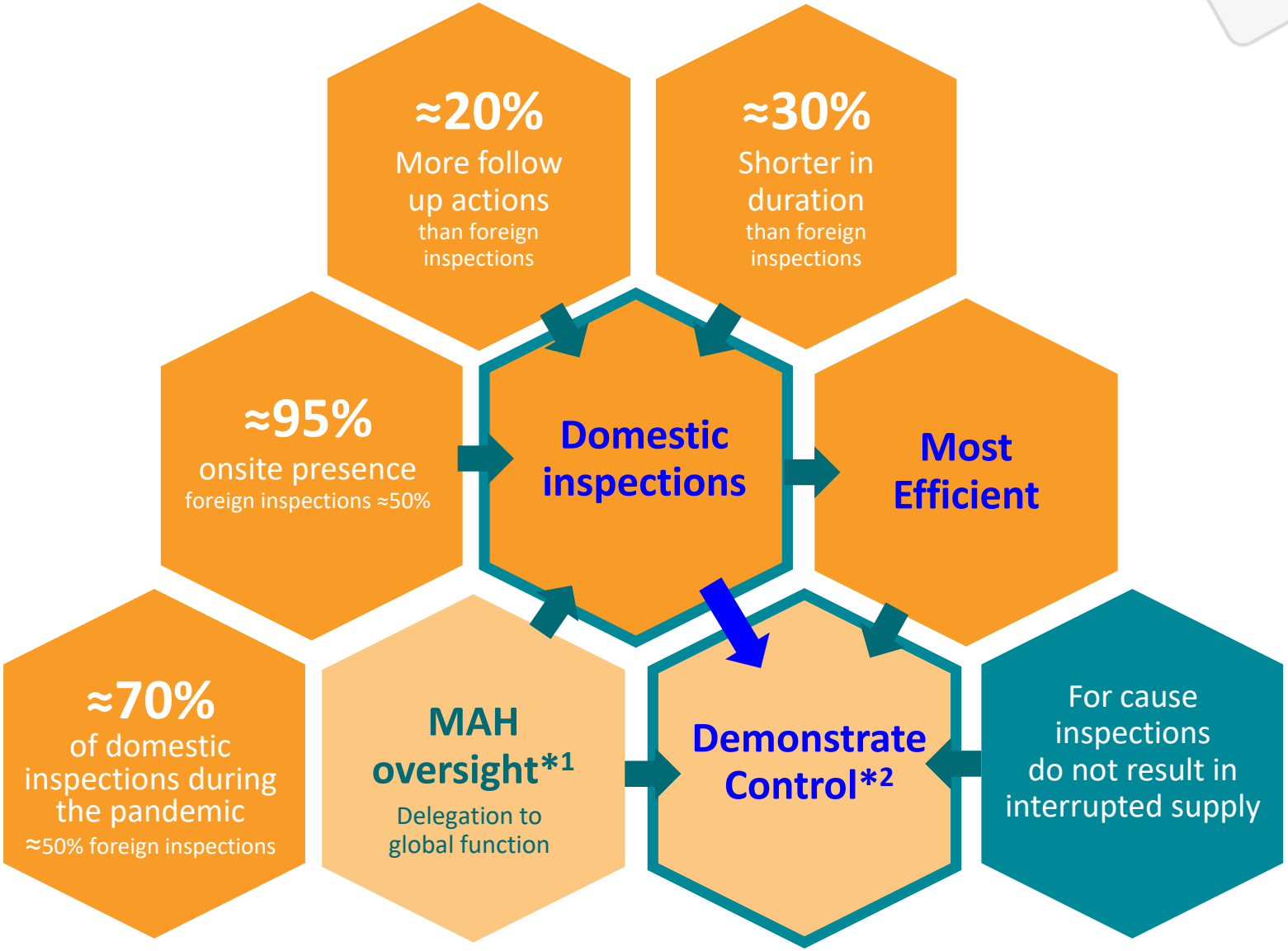

'Collaborative Hybrid Inspection Pilot' (CHIP)

**Inspection mode** = Different inspection tools used
**Real-time remote** = Using virtual tools= Distant assessment (EU) = Remote Interactive Evaluation (RIE; US)
**Document review** = Paper-based = Desktop assessment (EU) = Remote Record Request (RRR, US)



* Significant weight on the evaluation of recognised other National Competent Authority in the risk-based inspection approach

# Domestic Inspections are most efficient & demonstrate control

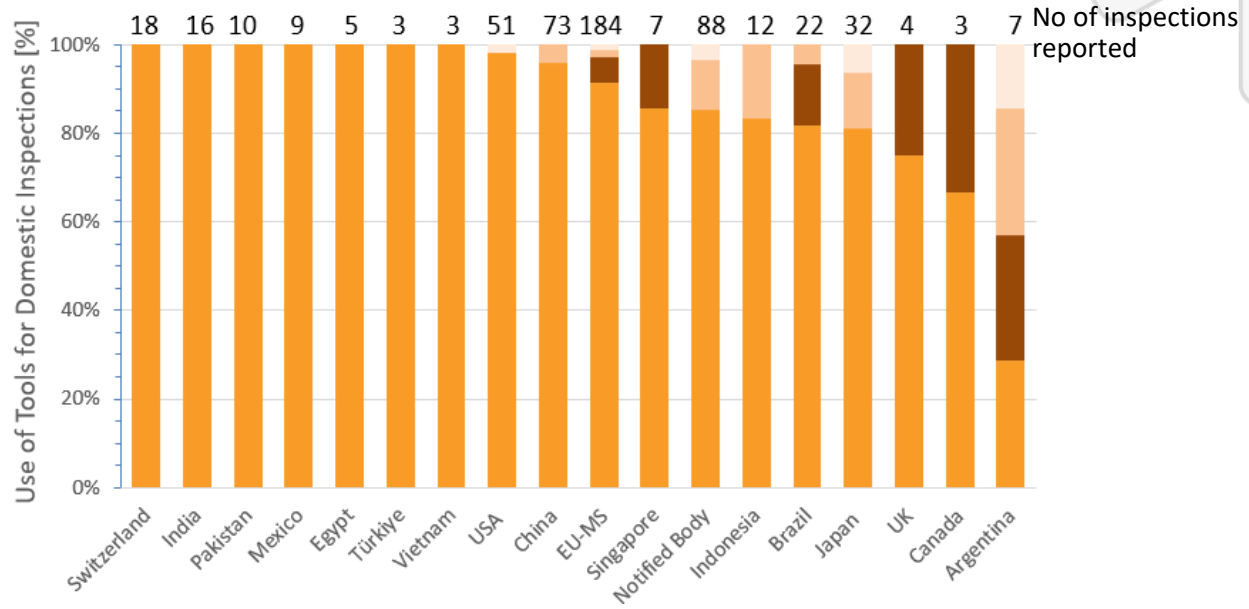



*1 a) Questions focuses on e.g., PQR, contractor oversight, supply chain end-to-end
b) Confirmed by authorities beyond EEA-MS e.g., China, Mexico, Russia

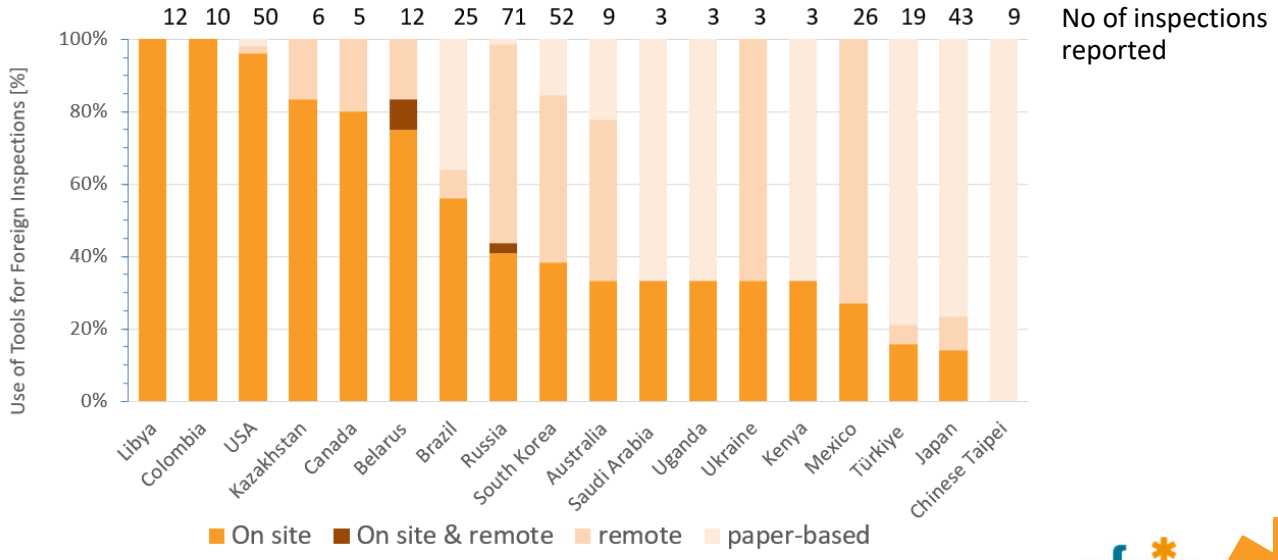
*2 Environmental aspects are covered by inspections / ISO 14000 certifications executed by governments acting outside the pharmaceutical sector

# Different inspection modes are used by country

Domestic




Foreign






The graphic show only inspectorates performing more than three domestic inspections
The graphic show only inspectorates performing more than four foreign inspections

## STILL ON A LEARNING CURVE AND IMPROVING

# Comparison of efforts using the on-site or real-time remote inspection mode

| Being on-site | Area | Real-time remote |
|---|---|---|
| Experience … Feel good | Perception | Stressful … Routine |
| 8-10 h/day | Way of working*1 | 4-6 h/day |
| | Communication | |
| | Prework | |
| | Preparation*2 | |
| • Domestic 3.3.(2.9) d<br>• Foreign 4.6 (5.0) d | Duration | • Domestic 2.4(2.8)d<br>• Foreign 4.5(4.8)d |

*1 Opportunity to perform day-to-day business while at a real-time remote inspection
*2 Is there really a need to pre-prepare so many documents in advance of a real time remote inspection when they could be made available faster by sharing the electronic file

# Opportunities in the inspection process – post pandemic

| Data | Opportunities |
| --- | --- |
| Stable number of real-time remote and more on-site inspections 2021/2022 | Permanently accept different inspection modes for compliance decisions |
| Foreign inspections reduced by 50% in 2021 (100% in 2019) | Trend of foreign inspections to be flat at least; based on data pre-pandemic |
| Significant increase of foreign inspections 2022*1 | Ensured reliance on compliance decisions by stringent domestic inspectorates |
| Increase in information requested prior to an inspection | Standardise pre-inspection information package*2 |

*1 After a reduction of 50% in 2020 already back in 2022 to the baseline from 2006/7

*2 e.g., by PIC/S incl. e.g., Site Master File (SMF), Annual Product Quality Review, Site Quality Manual, Additional information e.g., list of inspections / audits

## PAPER - BASED INSPECTIONS - MESSAGE FROM EFPIA

# Information provided by the site can follow a commonly agreed standard for paper-based inspections

| | |
|---|---|
| **Site** | • Site Master File (SMF)* |
| **Product** | • Annual Product Quality Review |
| **Pharmaceutical Quality System** | • Site Quality Manual |
| **Additional information** | • List of inspections / audits |

Adobe Acrobat Document

Enhanced GMP/GDP Inspection Efficiency, EFPIA, Position Paper 19. May 2014.

Adobe Acrobat Document

Optimising the GMP paper-based Inspection Process EFPIA, Position Paper 26. June 2019.

*EXPLANATORY NOTES FOR PHARMACEUTICAL MANUFACTURERS ON THE PREPARATION OF A SITE MASTER FILE, PIC/S PE 008-4, Annex 1, January 2011

# Pathways to unilateral reliance

**EMA**

- EFPIA member companies welcome the EMA pilot on unilateral reliance on inspections by PIC/S participating authorities incl. issuing GMP-certificates

**PIC/S**

- Provides the foundation; how to overcome (legal) implementation issues?
- There is opportunity for continual improvement on reliance*1
- Opportunity to enhance training for assessors/reviewers on GMPs

**MRA**

- Continue to maintain the current MRAs execution*2
- Support implementation of existing MRAs (e.g., US/EU)
- Continue expansion to vaccines and ATMPs

**Ask**

- Recognise domestic inspections; if mature inspectorate
- Adopting scope and length of inspections
- Request a defined, focused set of documentation in advance

Risk-based principles apply

*1: 63% (265 of 423) of foreign inspections are amongst PIC/S participating authorities
*2: e.g., EU/US: PAI; EU/CH on MDR

# Learnings from the survey questions

- **Enabling reliance on inspections and its processes**
  - It is reported that EMA asked FDA to follow-up on a method approval while they were on-site in US conducting an inspection
- **About inspection practices**
  - Regulations are similar but not the interpretation between inspectorates
  - Paper-based inspections growing in frequency and complexity
  - Additional questions / observations added after the inspection closure and/or final report
- **Of note on inspection practice**
  - Varying degree of acceptance for using electronic files
  - Industry asks regulators to continue GMP/GDP inspections based on regulatory guidance rather than for-profit standards developed by experts which may have conflict of interest (e.g., ISO, ASTM)

## CONCLUSION: ENCOURAGING FOR INDUSTRY AND REGULATORS

# Opportunities to manage the workload of inspections

**Reliance**

- Evaluate & recognise inspection reports by stringent domestic inspectorates (e.g., PIC/S participating authorities)
- Expand convergence as success is proven

**Risk-based approach**

- Adapting scope, length and frequency of inspections
- Real-time remote inspections* for a focused surveillance

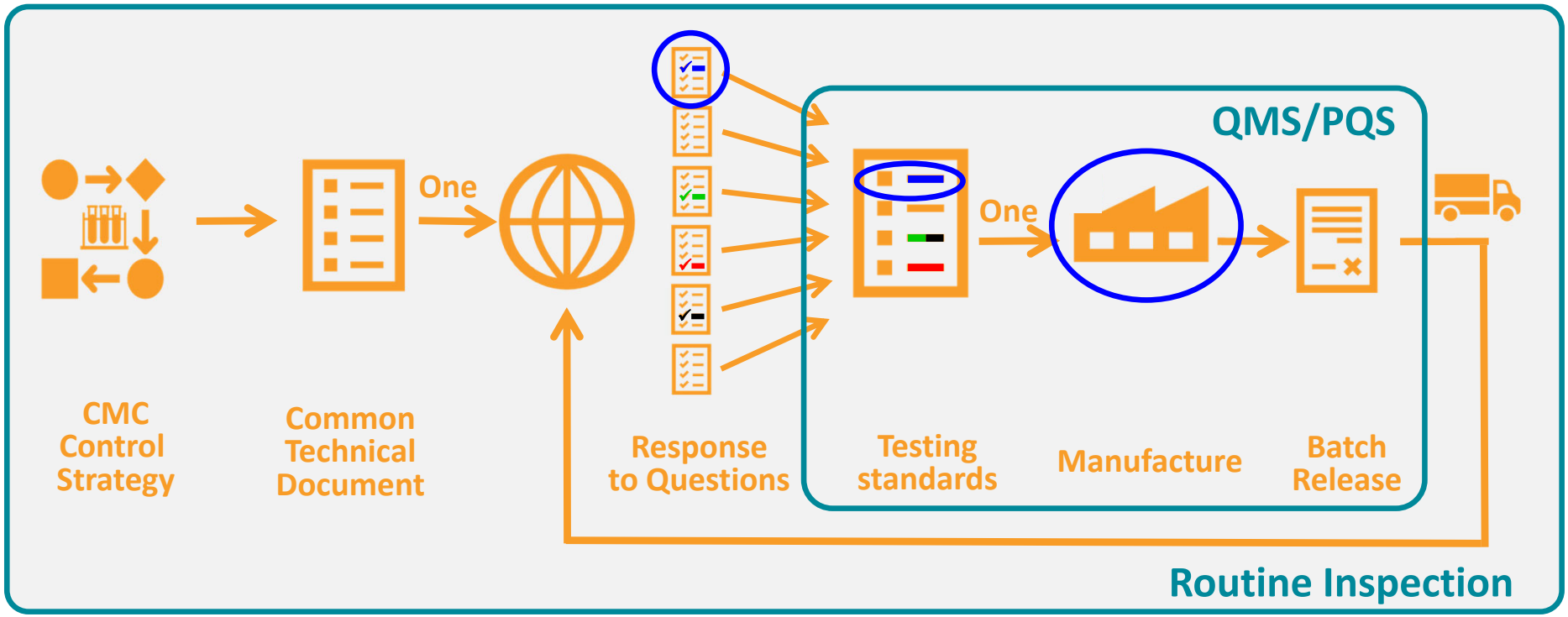
**Communication**

- With industry and / or between inspectorates
- Standardise requested documentation packages
- Reviewers to agree that GMPs aspects are fully covered in inspections and reliance on QMS / PQS

*They are a valuable contribution towards a comprehensive understanding to allow a decision on compliance. It is acknowledged that remote interactions do not offer the same insights as on-site inspections.

# Proposal to rely on routine inspections of the QMS/PQS instead of additional product specific PAIs

Routine domestic inspections can verify the robustness of the QMS/PQS processes managing local regulatory commitments to ensure respective manufacturing and testing at the site. As the process is applicable throughout there is no need to access this matter on dossiers filed in other jurisdiction.




Experience: Pre-Approval Inspections (PAI) dedicate most of the time on inspecting the QMS/PQS and only briefly checking on the authenticity of submitted data and links to dossier.

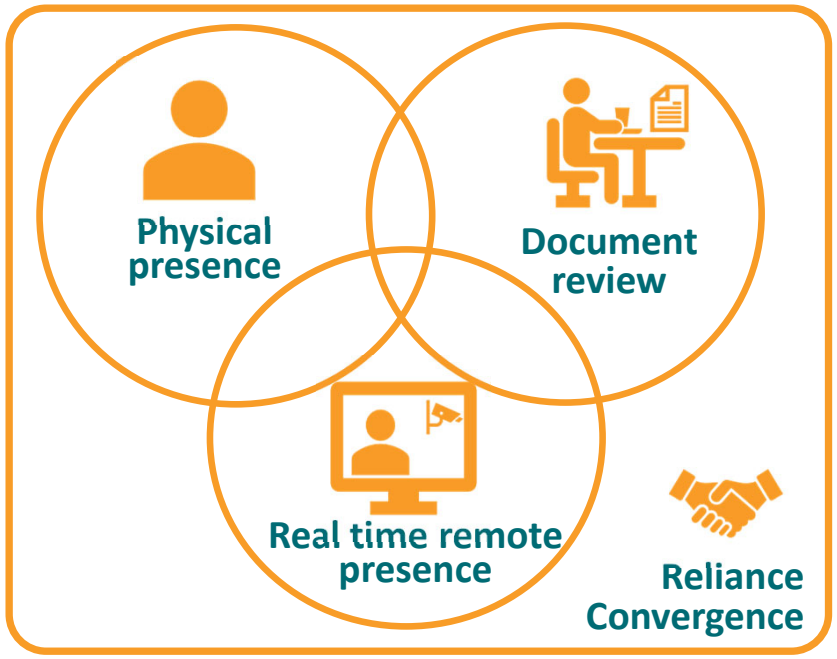
QMS/PQS: Quality Management System / Pharmaceutical Quality System

## CONCLUSION: KEEP IN MIND THE PURPOSE OF AN INSPECTION

# Is a site compliant?

**No difference in inspection types (PAI*, routine, surveillance, for cause)**

**Inspection**




- **C**apability — Manufacture
- **A**dequacy — Controls
- **S**uitability — Equipment
- **E**ffectiveness — QMS/PQS

**Enabled by risk-based approaches**

**Alternative Modes** → Risk-based → **Decision on compliance**

* Experience: Pre-Approval Inspections (PAI) dedicate most of the time on inspecting the QMS/PQS and only briefly checking on the authenticity of submitted data and links to dossier.

# Opportunities, as the trend in increased inspections was broken during pandemic

## Domestic Inspections are most efficient and demonstrated control

- Continue focusing on the effective domestic inspections by trusted inspectorates
- Unilateral reliance can be the concept of the future
- We support the PIC/S vison of one inspection per manufacturing site

## Risk-based inspections approaches can be optimised

- Standardise pre-inspection information package
- Adapting scope, length and frequency of inspections based on compliance history
- Permanently accept different inspection modes for compliance decisions

## Requirements are implemented in one QMS/PQS

- Based on comparable and complementary local regulatory expectations
- Train for comparable interpretations between inspectorates
- Reviewers to agree: GMPs aspects are fully covered in inspections of Quality Systems

## ACKNOWLEDGEMENTS

# Contributors to the EFPIA inspections survey 2022

- AbbVie
- Almirall
- Amgen
- Astra Zeneca
- Bayer
- Bial
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Eli Lilly and Company
- Grünenthal GmbH
- GlaxoSmithKline
- Johnson & Johnson
- Lundbeck
- Merck
- MSD
- Novartis
- Novo Nordisk
- Pfizer
- Roche
- Sanofi
- Servier
- Teva
- UCB

### National Trade Associations

- Apifarma (Portugal) 2
- Farmindustria (Italy) 5

efpia

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# Further data analysis

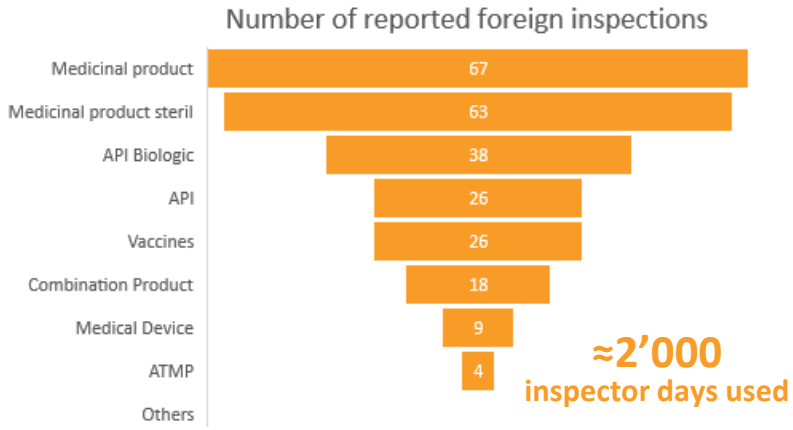
1. Opportunities for risk-based inspection approaches and reliance
2. How and where inspections are executed
3. Domestic inspections of site and affiliates
4. Data on foreign Inspection practice

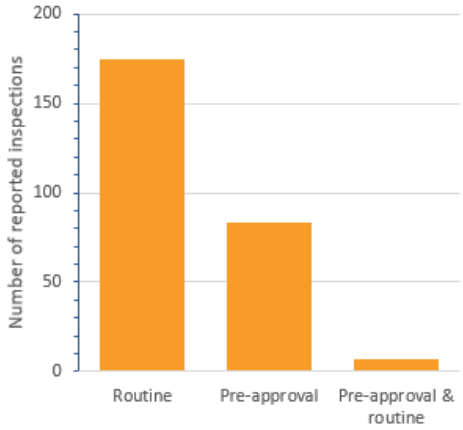
# Opportunities for risk-based inspection approaches and reliance

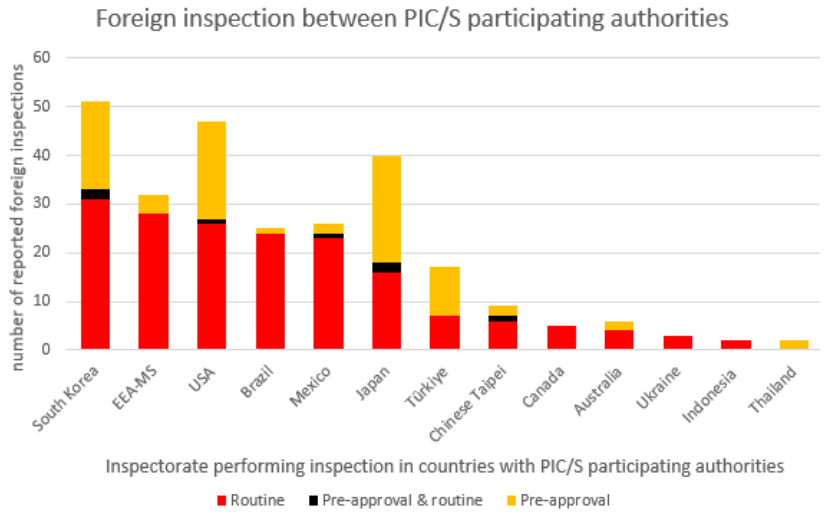
## INSPECTION SURVEY - 2022 DATA

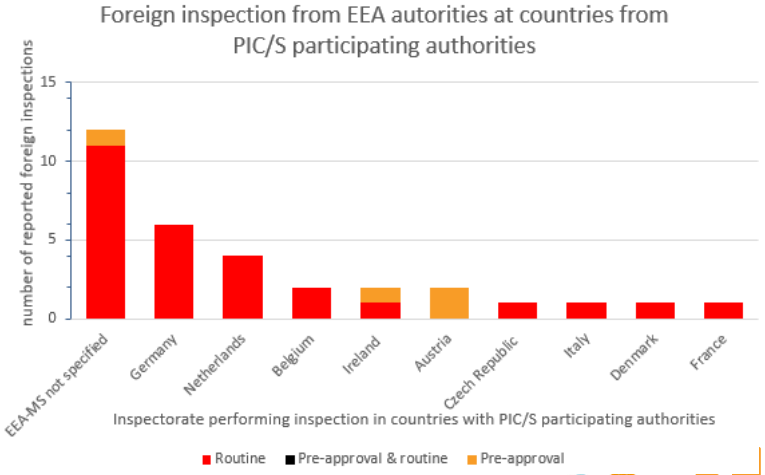
# PIC/S Participating Authorities

- **265/423 (= 63%) of the reported foreign inspections at manufacturing sites are amongst the PIC/S participating authorities**



# Facts and opportunities to unleash the benefits of reliance

## Data

Reliance mechanisms can be beneficial to save resources

- A lower number of duplicated inspections of manufacturing sites was observed during the pandemic
- Foreign and domestic inspection covers about the same sites, product types and quality systems
- The number of sites eligible for inspection remain stable for EFPIA member companies

## Approach

Industry practice to be recognised

- EU-GMP-certificates are used in 3rd countries: additional statements were requested to be issued by MAH or the respective health authority*
- Manufacturing sites follow global QMS which is complemented by local SOPs stating and explaining links to specific local requirements

## Foundation

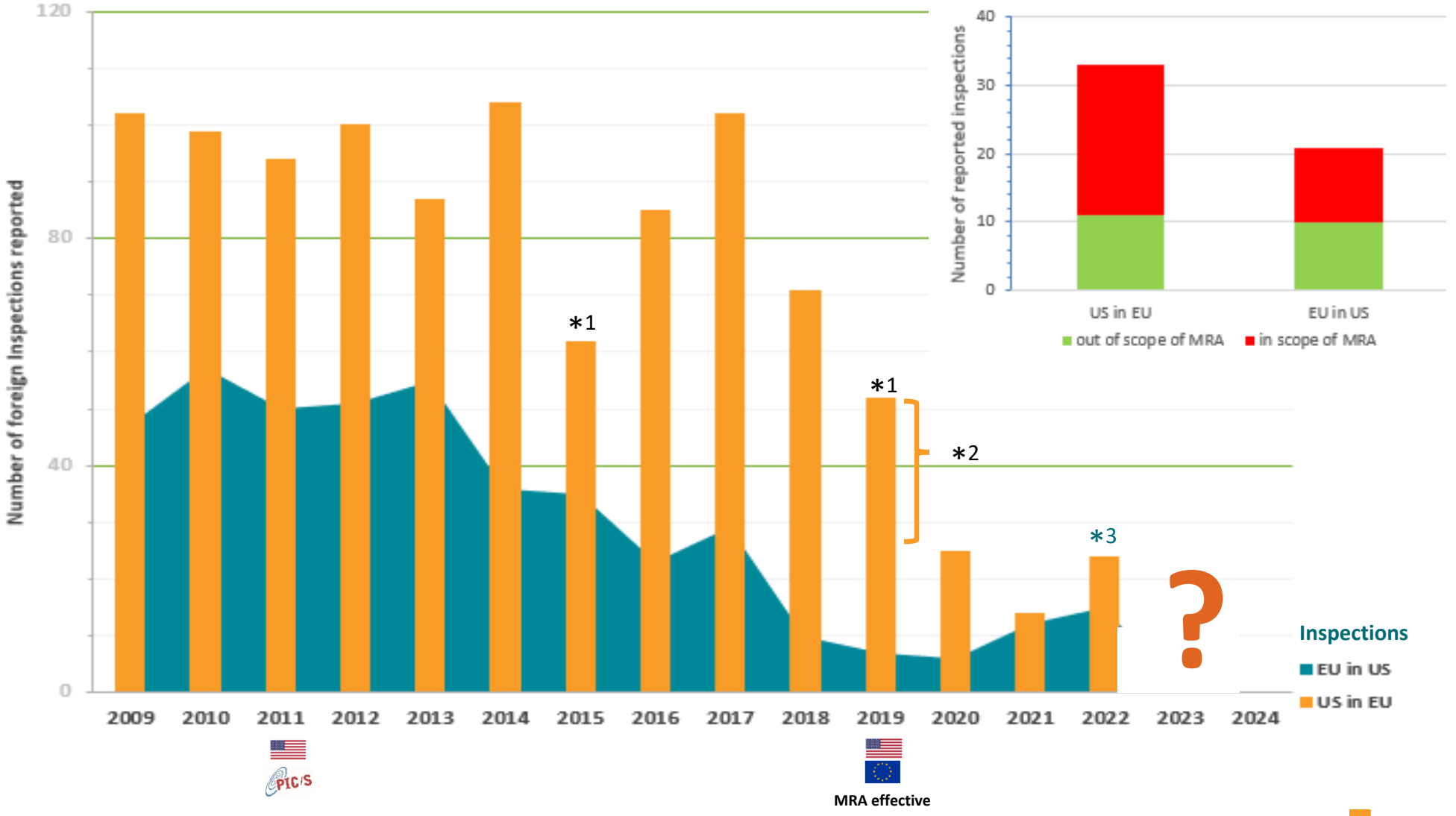
Legal bases

- We encourage to establish a legal basis, if needed, to allow acceptance for inspection reports from PIC/S participating authorities
- Industry asks regulators to continue inspections based on regulatory guidance rather than for-profit standards (e.g., ISO)

*Delays in applications / renewals were reported in many cases for countries outside EU

## DATA ON THE MRA EU/US

# Full EU / US MRA implementation could leverage further benefits



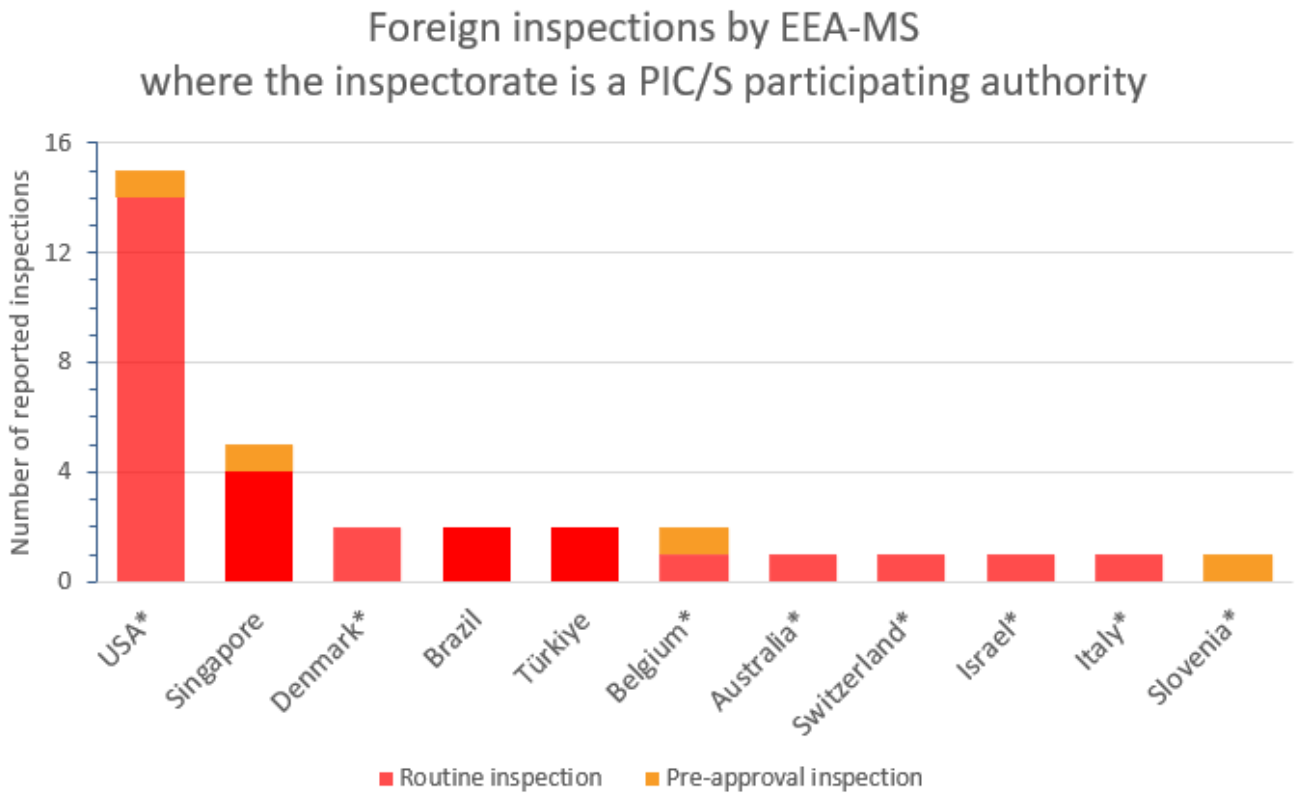

*1 Government shut down in US >20 days

*2 Effect may only result from the general reduction of foreign inspections in 2020 (~50%)

*3 7 out of 15 inspection from the EU in US had been reported to be for vaccines or ATMP

# EU Inspection reliance initiative

- **EFPIA member companies welcome the EMA pilot on unilateral reliance incl. issuing GMP-certificates**
  - Opportunities of 322 inspector days (≈ 65 weeks)



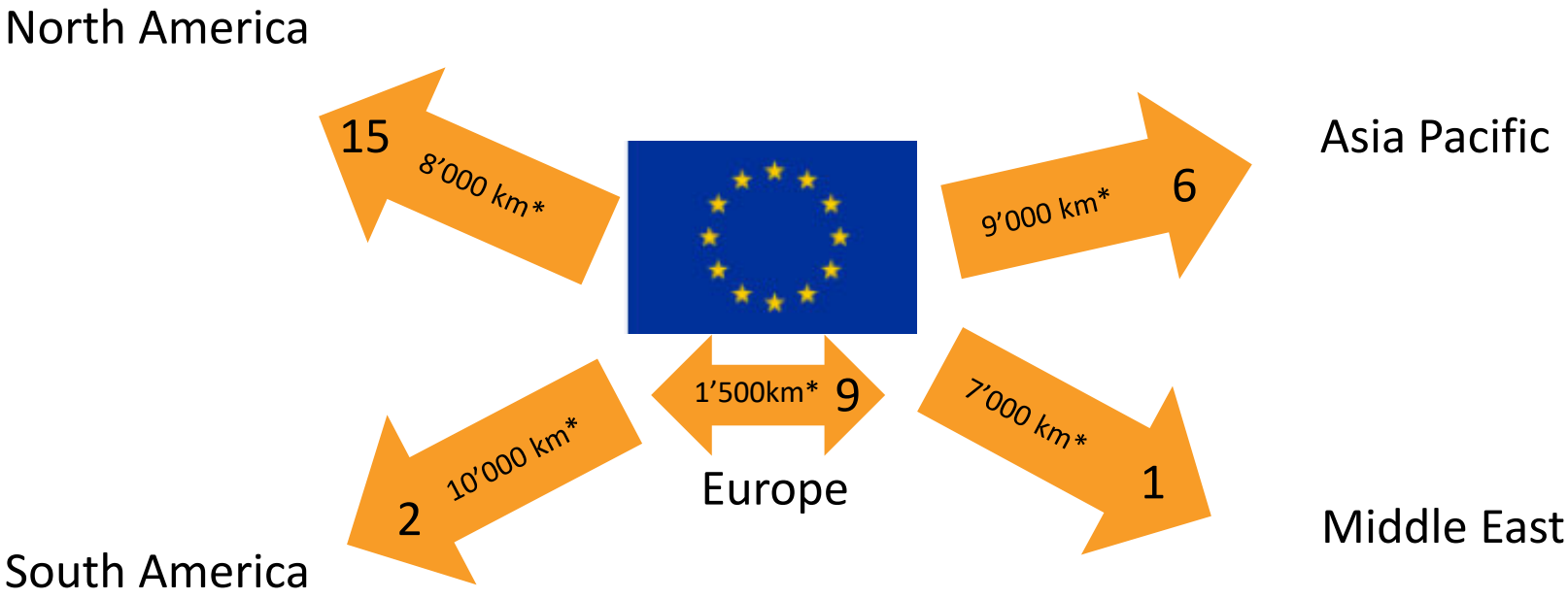



*MRA / AACA Country
Note: scope of the MRAs recognised; no for-cause inspections

## OPPORTUNITIES FOR EEA INSPECTORS

# Reducing environmental footprint by reliance on PIC/S

≈ 600’000 km/y*




Assumption per inspection: 2 inspectors & return flights

*on average

# Case study: When a remote inspection can be utilised

Source: Christina Baccarelli, EDQM at DIA Europe March 2023

## INSPECTIONS

# Explaining reliance in the inspection landscape

- **Enhanced Good Manufacturing and Good Distribution Practices (GMP/GDP) Inspection Efficiency**, EFPIA position paper, 19. May 2014.
- **A Concept for Harmonized Reporting of Inspections**, 29. May 2015; addendum of the PhRMA White Paper: 'Mutual Recognition of Drug GMP Inspections by U.S. & European Regulators', 15. May 2015.
- Alternative GMP/GDP Inspection **Practices in a Pandemic Situation** (COVID-19) and Beyond EFPIA position paper, 28 May 2020.
- **Opportunities for Optimising the GMP Inspection Process post pandemic,** in publication based on 'Request for Optimising the **GMP paper-based Inspection Process** by Regulatory Authorities', EFPIA position paper, 26 June 2019.
- Proposals for Quality and GMDP aspects: **Regulatory response to Covid 19 crisis**, 30. Mar. 2022
- **Opportunities and Challenges with MRAs on GMP,** EFPIA Reflection Paper, 21. December 2022
- EFPIA: Annual Regulatory GMP/GDP Inspection Survey's

efpia

- Guidance on good practices for **desk assessment**… for medical products regulatory decisions, WHO, TRS 1010 (2018), Annex 9.
- **Good reliance practices** in the regulation of medical products: high level principles and considerations, WHO, TRS 1033, Annex 10, 2022, 237-267.
- International regulators recommend use of remote inspections as complementary tool beyond pandemic, EMA-News, 13. Dec 2022.
- Guidance related to GMP/GDP and PMF: **distant assessments**. EMA/335293/2020, 15. Oct. 2020
- **Remote Interactive Evaluations** of Drug…, FDA , Guidance for Industry, FDA-2020-D-1136, April 22
- **Conducting Remote Regulatory Assessments,** Q&A, FDA draft guidance for industry, July 22
- Joint Audit Programme for EEA GMP inspectorates - JAP Procedure (Rev.3)
- **Report on the review of regulatory flexibilities/agilities as implemented by National Regulatory Authorities during Covid-19 pandemic - December 2020,** WHO & ICDRA, published November 2022
- **Reflections on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 Pandemic.** ICMRA, 26 November 2022. Inspection pilot

- **Considerations for effective regulatory reliance,** 21. June 2019
- **Convergence of Good Manufacturing Practice (GMP) standards and Related Inspections**, IFPMA Position paper, v2, January 2020.
- **Points to Consider for Virtual GMP Inspections – an Industry perspective**, 5 Feb 2022, update in progress with Annexes on
  - 'best practices' and
  - 'IT considerations'
- Inspections **Infographic**
- Related: import testing

IFPMA

- **EC-PIC/S Co-operation agreement** EC Ares(2022)5237302-19/07/2022
- **EC-PIC/S Working arrangement for the exchange of non-public information**, EC Ares(2022)5725920-12/08/2022
- **GMP-Inspection reliance**, PIC/S guideline PI 048-1, 1 June 2018
- **Risk-based inspection planning**, PIC/S guideline PI 037-1, 1 Jan. 2012
- **Classification of GMP Deficiencies**, PIC/S guideline PI 040-1, 1 Jan. 2019.

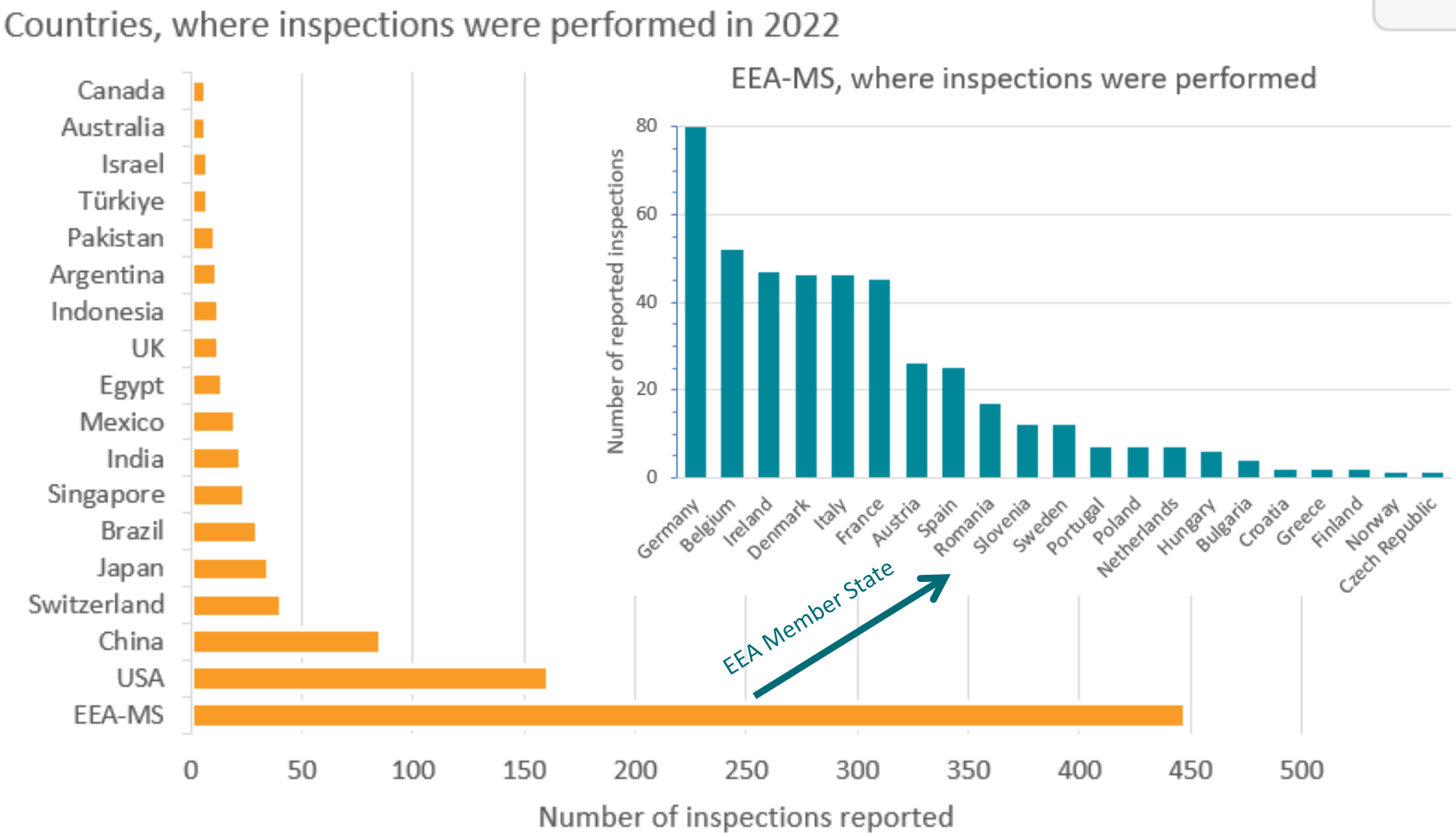
PIC/S


- EMA, WHO, TGA, US-FDA, EDQM, Council or Europe, ANSM, DMA, HPRA AIFA, MHRA, **Report on the International Active Pharmaceutical Ingredient Inspection Programme** 2011 – 2016, March 2018, 1-13.
- H. Jin, N. Carr, H. Rothenfluh, TGA, **Medicines Regulations: Regulating Medicines manufacturers: Is an onsite inspection the only option?**, *WHO Drug Information*, 31/2, 2017, 153-157.
- S. Rönninger, J. Berberich, V. Davoust, P. Kitz, A. Pfenninger**, Landscape of GMP/GDP inspections in research-based pharmaceutical industry, Part I: Data**, *Pharm. Tech. Europe*, January, 2017, 6-10; **Part II: Considerations and Opportunities**, *Pharm. Tech. Europe*, February, 2017, 5-9.
- S. Rönninger, P. Gough, V. Davoust, **Opportunities for Saving Resources in the Regulatory Inspection Process: MRA Example EU/US,** *Pharm. Tech. Japan*, 35, **2019,** 15-25.
- A. Meshkovskij, S. Rönninger, **National GMP Inspection Practice for Biotech Pharmaceuticals: Communalities, Differences, Opportunities**, CIS GMP News, 2018, *1,* 26-31.
- S. Rönninger, A. Kurz, and F. Raya, **GMP/GDP Inspections: Challenges and Opportunities from COVID-19**, Pharmaceutical Technology Europe, *33 (11) 2022,* 36-39; print version; full version

# How and where inspections are executed

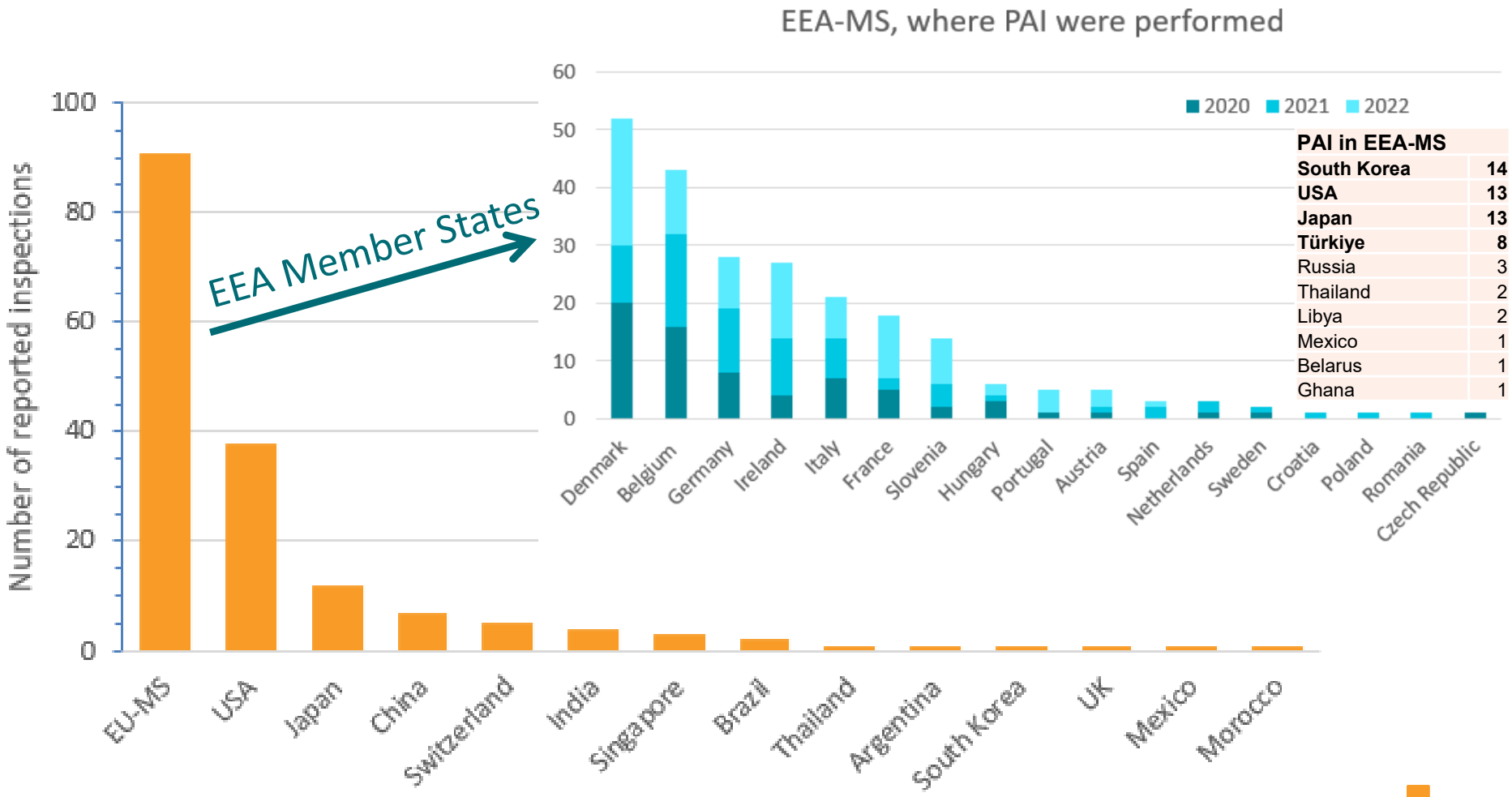
## INSPECTIONS AT MANUFACTURING SITES

# Locations of manufacturing facilities




+ 15 other countries with 7 or less inspections

# Locations of manufacturing facilities reporting PAI demonstrating where innovative products are manufactured



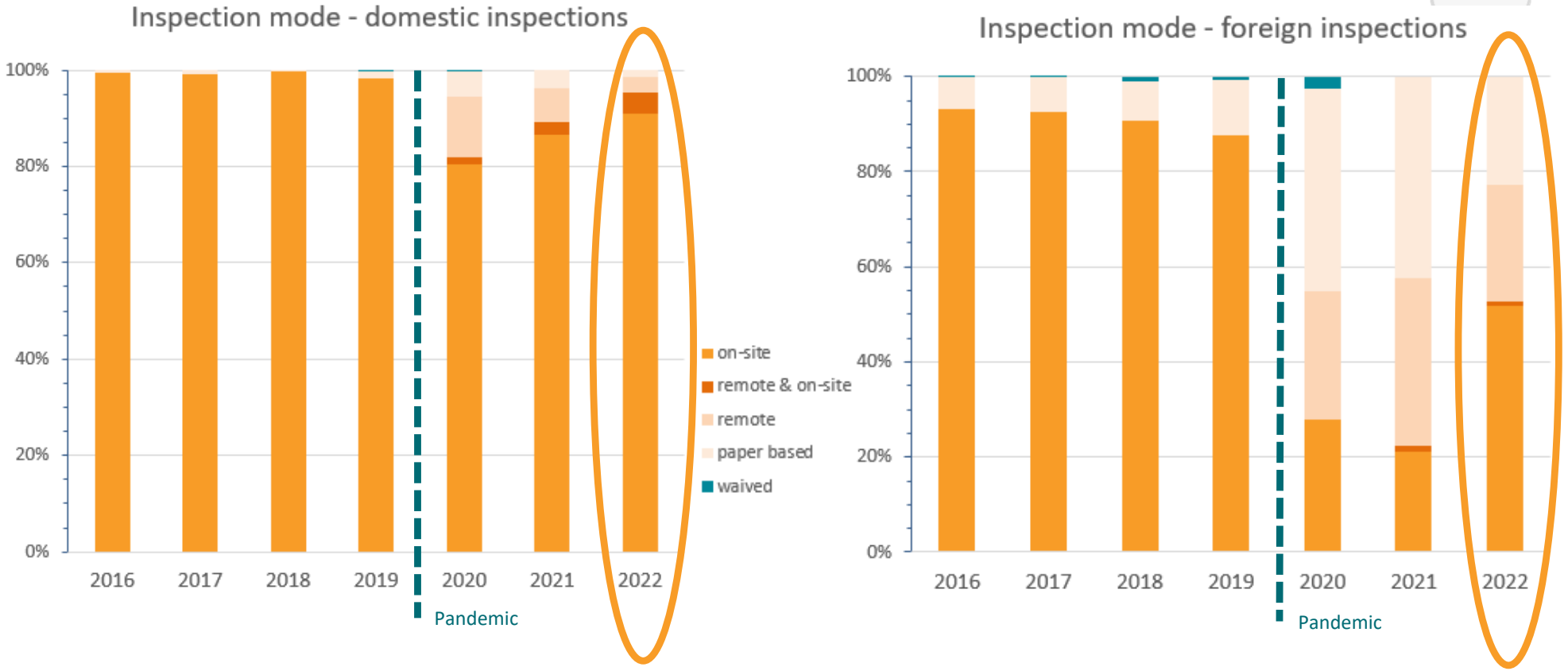

| PAI in EEA-MS | |
|---|---|
| South Korea | 14 |
| USA | 13 |
| Japan | 13 |
| Türkiye | 8 |
| Russia | 3 |
| Thailand | 2 |
| Libya | 2 |
| Mexico | 1 |
| Belarus | 1 |
| Ghana | 1 |

PAI: Pre-Approval Inspection

## USE OF INSPECTION MODES

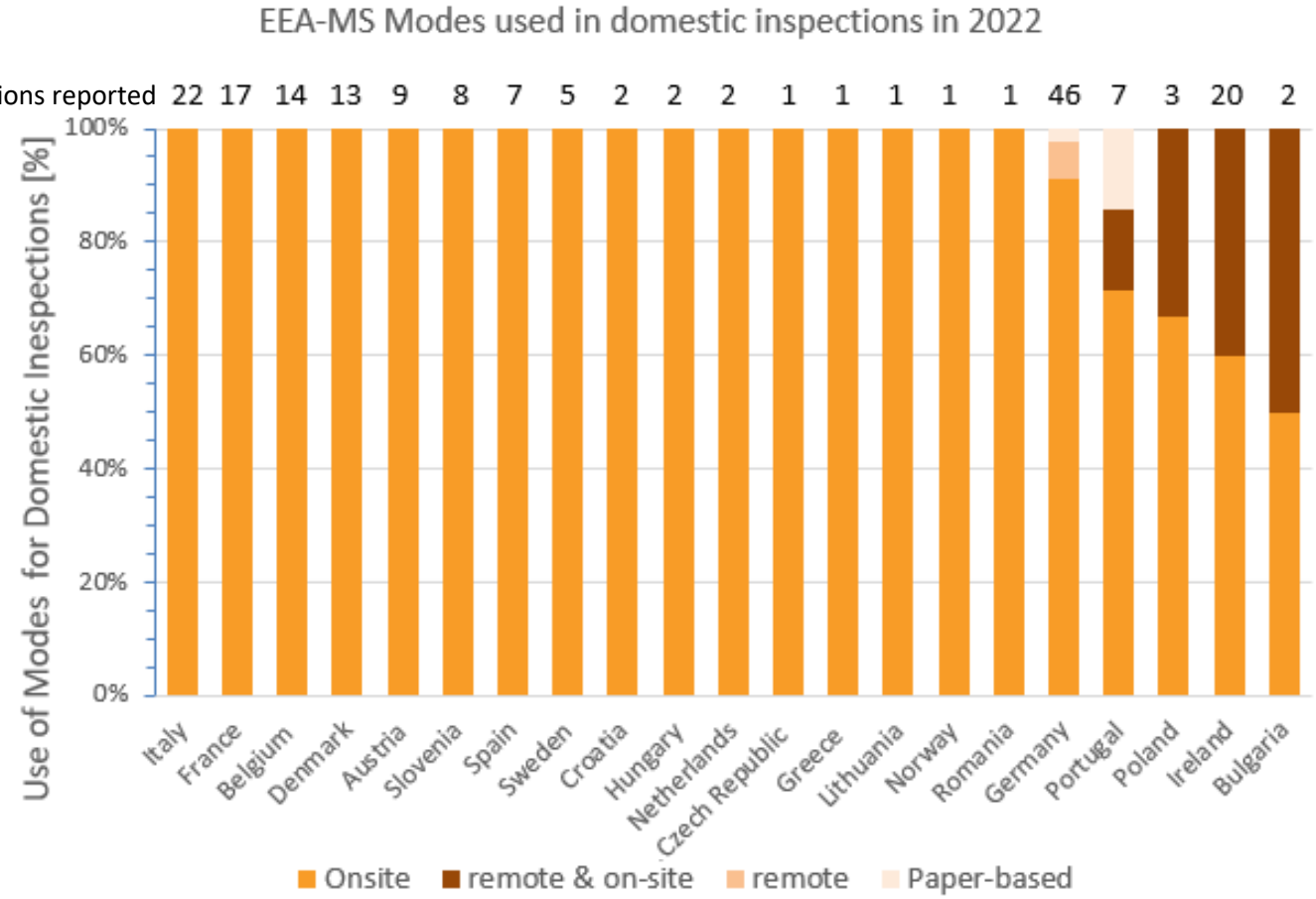
# The number of onsite inspections is back to pre-pandemic level

***Can we minimise the number of foreign inspections as deemed necessary?***

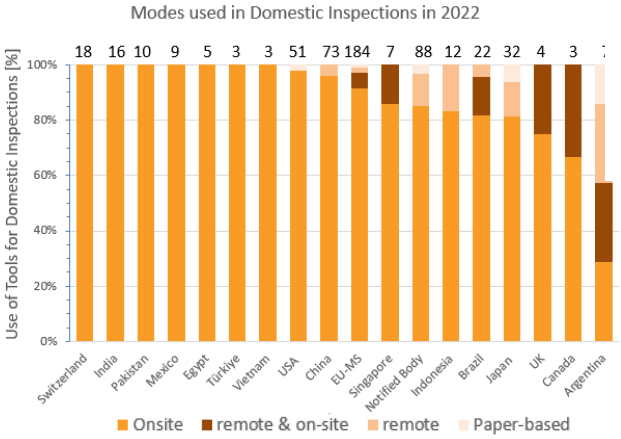



- **About 95% of the domestic inspections have had at least a partial on-site presence**
  - The data seems to show an evolving trend of more combinations of real-time remote and on-site at domestic inspections
- **About 50% of the foreign inspections have been conducted with on-site presence**

# Inspection modes used by inspectorates in domestic inspections



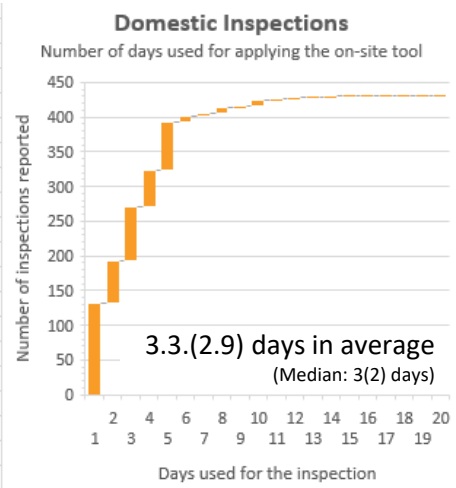

EEA-MS

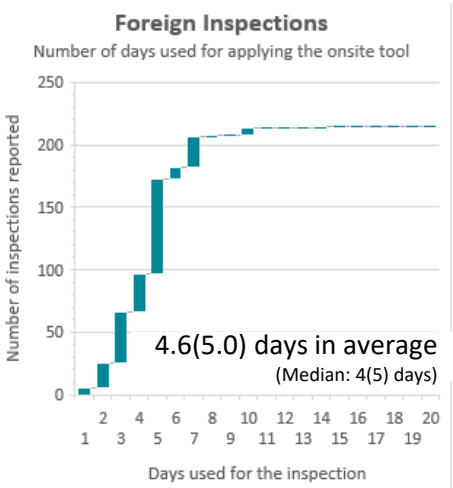


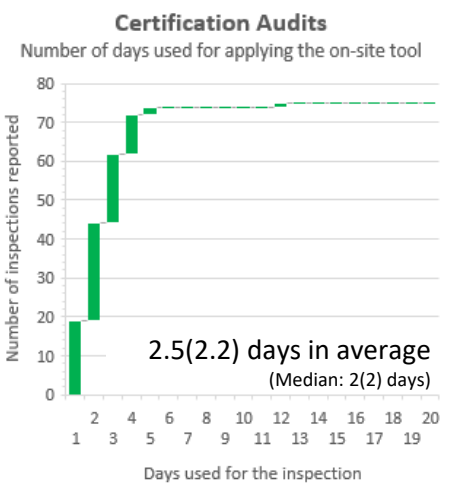
## USE OF INSPECTION MODES

# Average inspection duration for different inspection modes

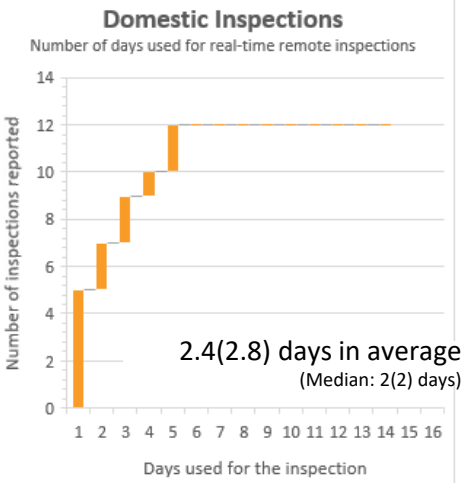
**Physical presence**

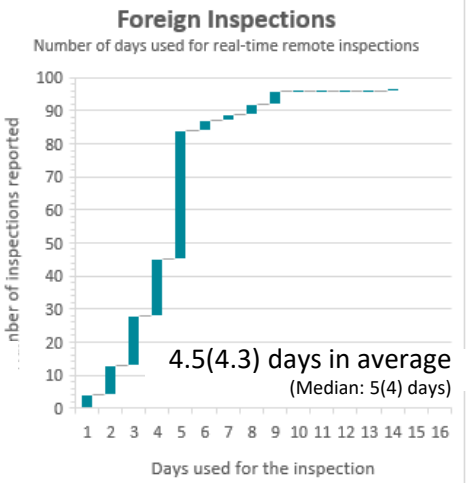


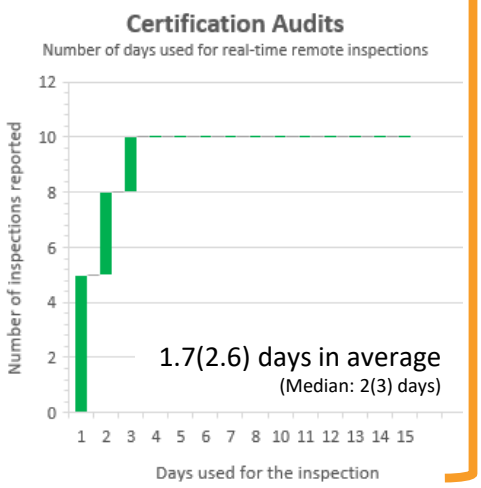



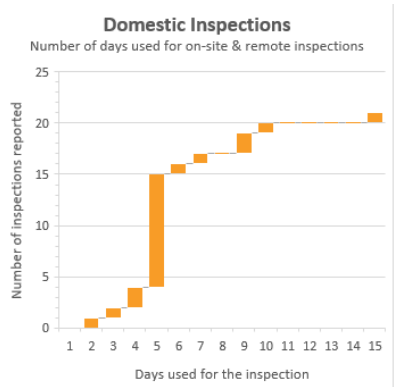

**Real-time remote presence**




**Real-time remote presence & Physical presence**



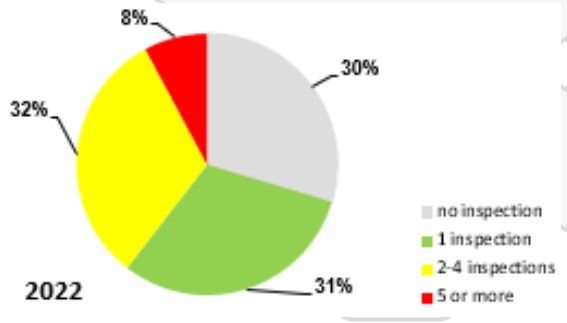

5.9 days in average
(Median: 5 days)

Insufficient data for foreign inspections
(about 5.2 days +/-1 day)

Data bases: 250 data sets with inspection times < 14 days
Note: a) Travel time to site in 3rd countries is not included; b) Median count only full days; c) certification audits are for ISO 13485

## INSPECTIONS AT MANUFACTURING SITES

# Examples of multiple inspections at a manufacturing site



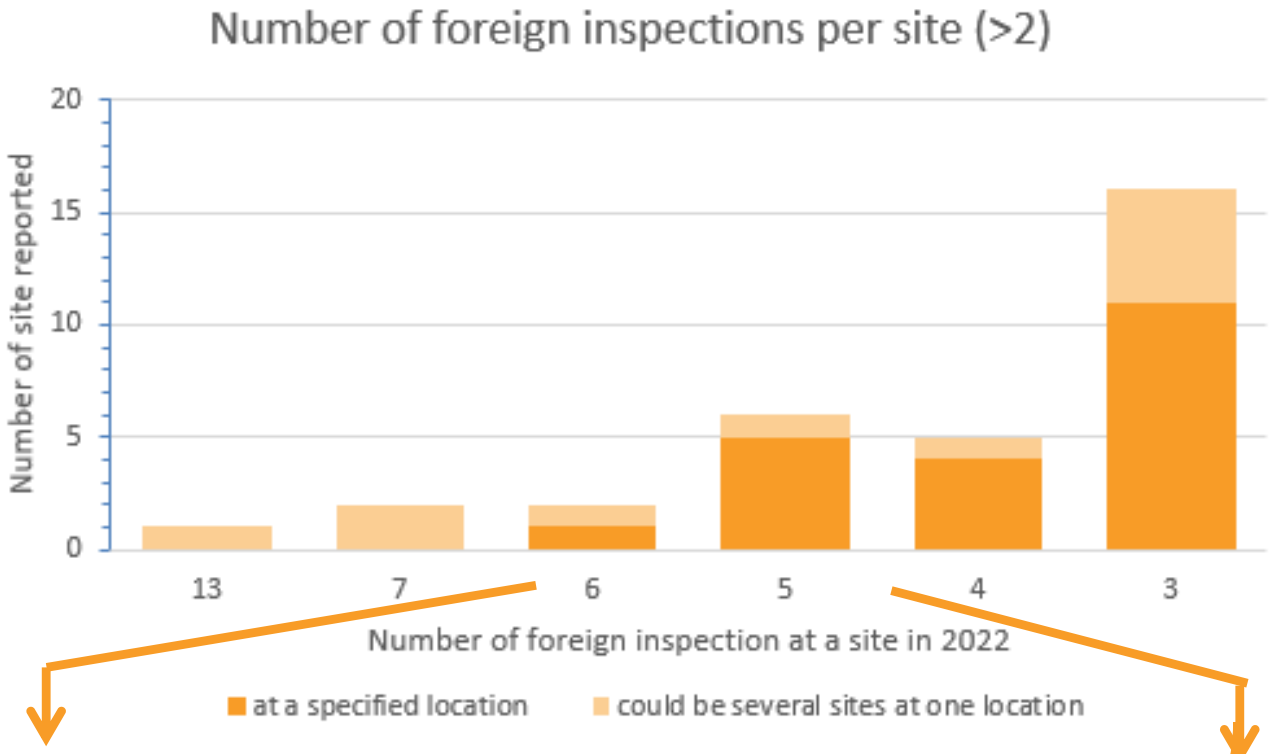

| A site in country | Domestic inspections | Foreign inspections | Sum | Foreign inspectorates |
|---|---|---|---|---|
| Denmark*[1] | 4 | **13** | 17 | Japan (4), Türkiye (4), South Korea (2), Brazil, Russia, US |
| Romania*[2] | 1 | **13** | 14 | South Korea (3), Australia (2), Indonesia (2), Brazil, Chinese Taipei, Japan, Jordan, Türkiye, Uganda |
| Japan | 7 | **2** | 9 | South Korea, Belarus |
| USA | 2 | **6** | 8 | Russia (2), Japan (2), Brazil, South Korea |
| USA | 2 | **6** | 8 | Japan (3), South Korea, Türkiye, Brazil |
| Ireland | 6 | **2** | 8 | Russia (2) |
| Germany | 4 | **4** | 8 | Japan, United Arab Emirates, Lybia, Belarus |
| India | 7 | **0** | 7 | n.a. |
| Indonesia | 7 | **0** | 7 | n.a. |
| Belgium | 2 | **5** | 7 | Mexico, South Korea, Australia, EEA, India |
| Italy | 2 | **4** | 6 | South Korea, Russia (2), US |
| Germany | 5 | **1** | 6 | Russia |
| Italy | 3 | **3** | 6 | Mexico, US (2) |

- **Three sites with 7 domestic inspections in Japan, India and Indonesia**
- **Countries with opportunities for a better risk-based approach include**
  - Japan, Türkiye, Russia, South Korea, Türkiye, Australia, US

***Consideration:*** *Notified body certifications are reported site several times (up to 9) at the same site. Then product wise certification requirement may drive to duplication in the oversight of the Quality System (for devices) at a specific manufacturing site*
***Note:*** *Not all companies are sharing details on specific manufacturing sites in a country*

*1 A variety of manufacturing units located at the same site
*2 No details indicated on the site

# Multiple foreign inspections at one manufacturing site




Only max. 4 different inspectorates at one manufacturing site when there are 5 or 6 foreign inspections

### Site in US

- Brazil / ANVISA
- Japan / PMDA (2)
- South Korea / MFDS
- Russia / MoIT-SID&GP (2)

### Site in UK

- Russia / MoIT-SID&GP (2)
- USA / FDA
- South Korea / MFDS
- Brazil / ANVISA

### Site in Ireland

- Japan / PMDA
- USA / FDA
- South Korea / MFDS
- Chinese Taipei / TFDA (2)

### Site in Austria

- Belarus / MoH
- Japan / PMDA (2)
- USA / FDA
- Türkiye / TMMDA

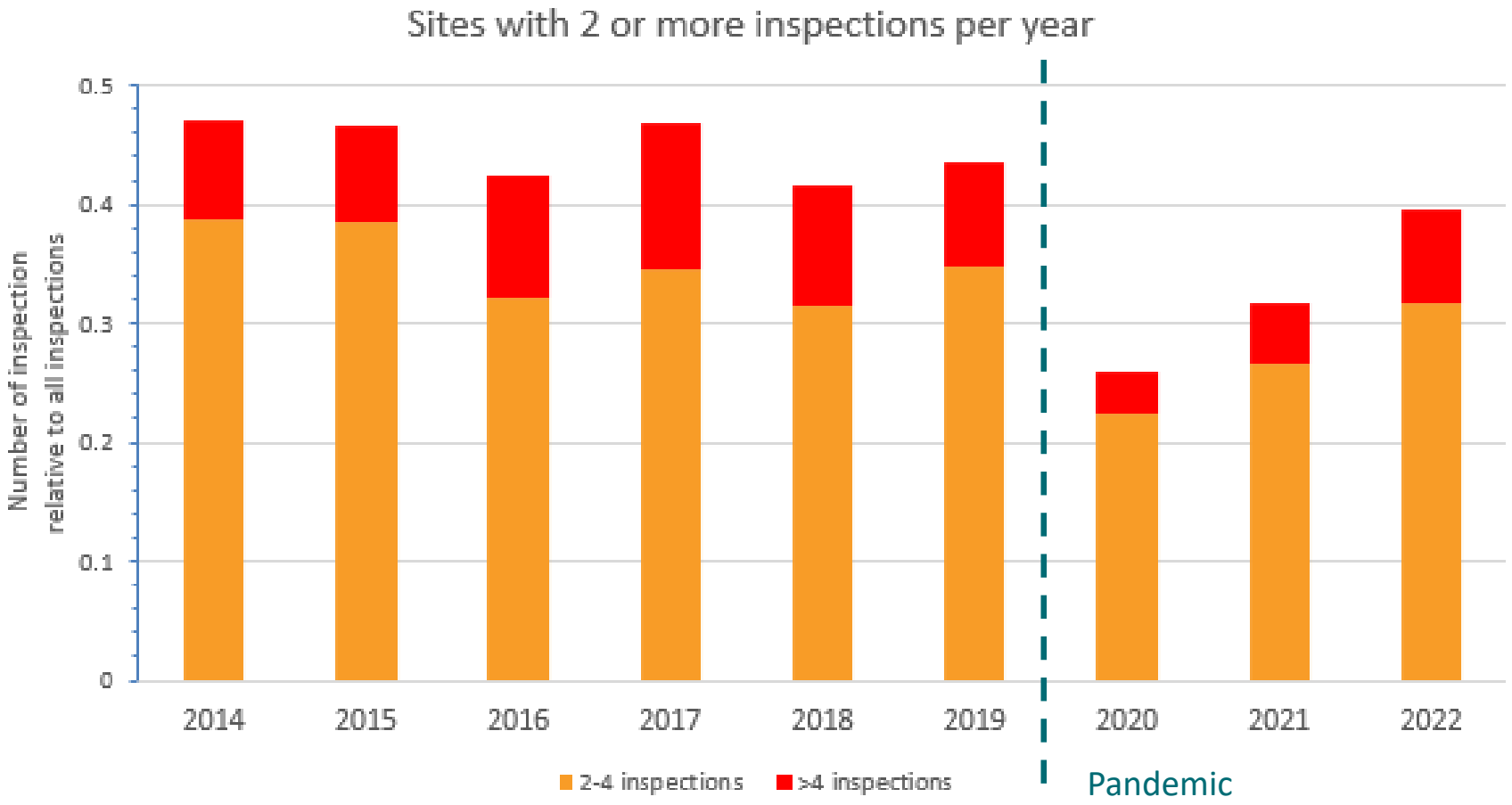
### Site in Germany

- Japan / PMDA (2)
- Russia / MoIT-SID&GP
- South Korea / MFDS (2)

### Site in Belgium

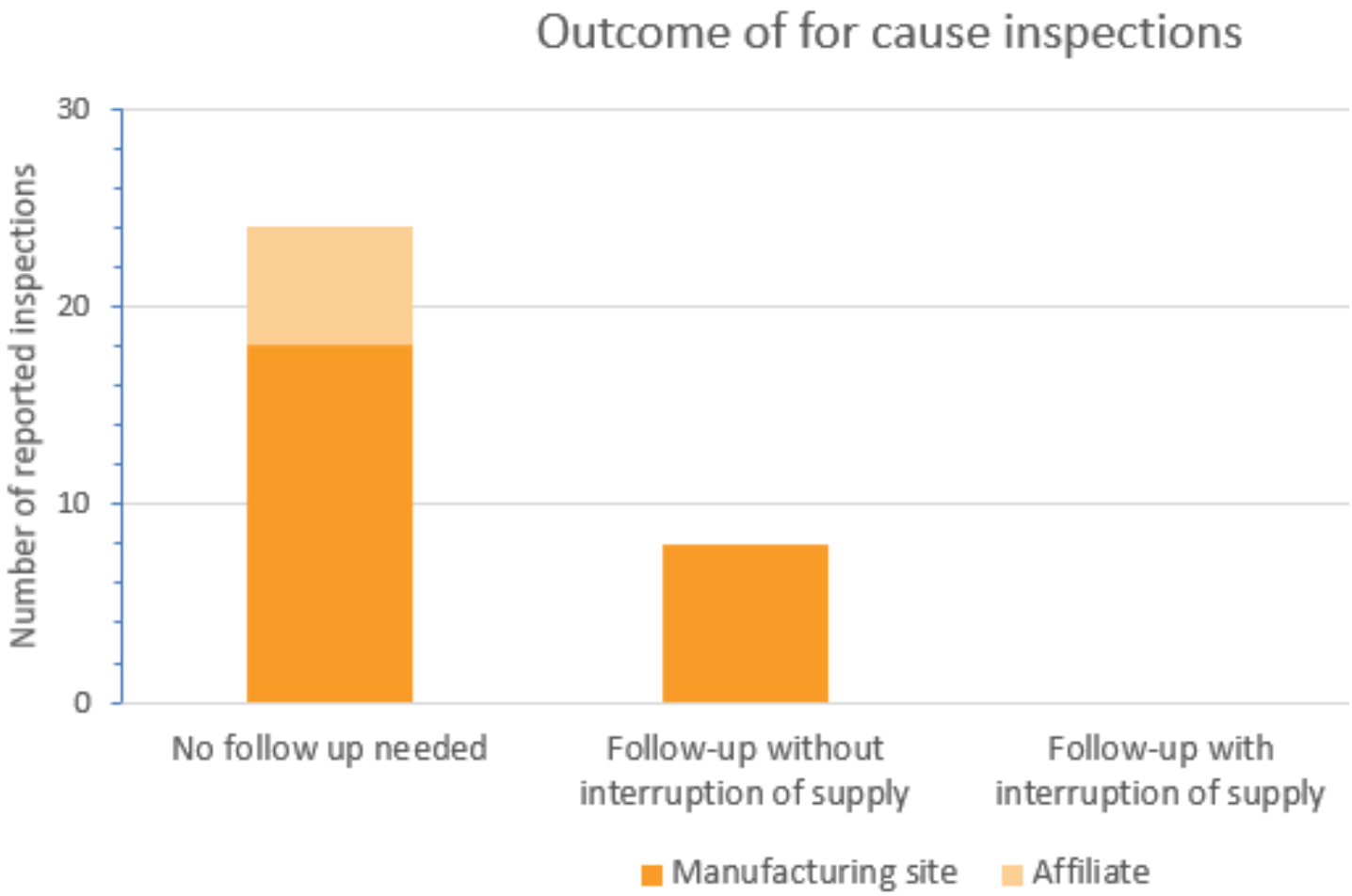
- Mexico / COFEPRIS
- South Korea / MFDS
- Australia / TGA
- Austria / AGES
- India / CDSCO

# Lower number of duplicated inspections during the pandemic observed



## OUTCOME OF INSPECTIONS

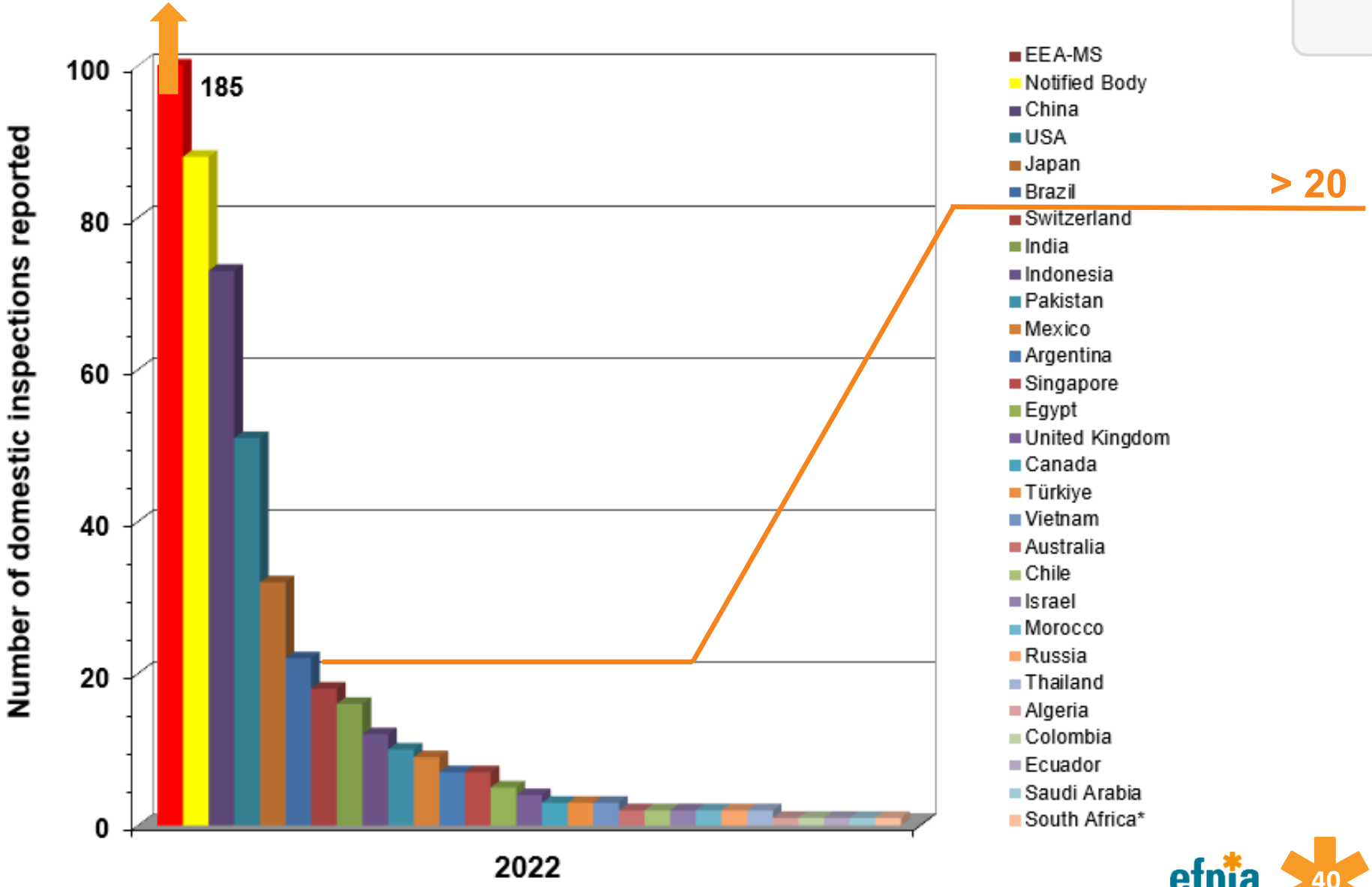
# For cause inspections do not result in interrupted supply



# Domestic inspections of site and affiliates

# Number of domestic inspections

## ordered by country (>1 inspections; EU as one entity; manufacturing sites; all modes)

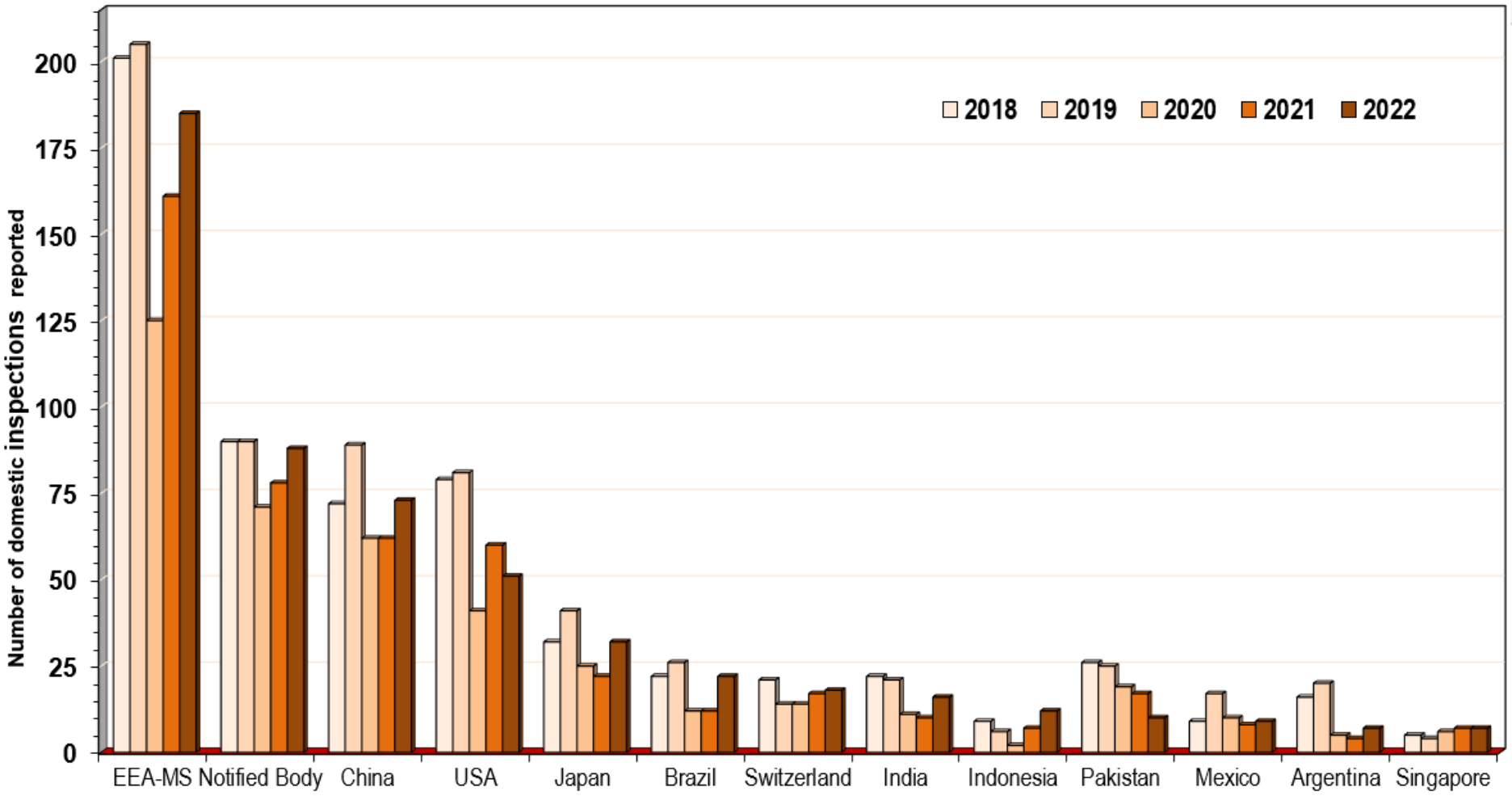





Note: Notified Bodies doing certifications for devices included in Medicinal Products

## INSPECTIONS AT MANUFACTURING SITES

# Number of reported domestic inspections



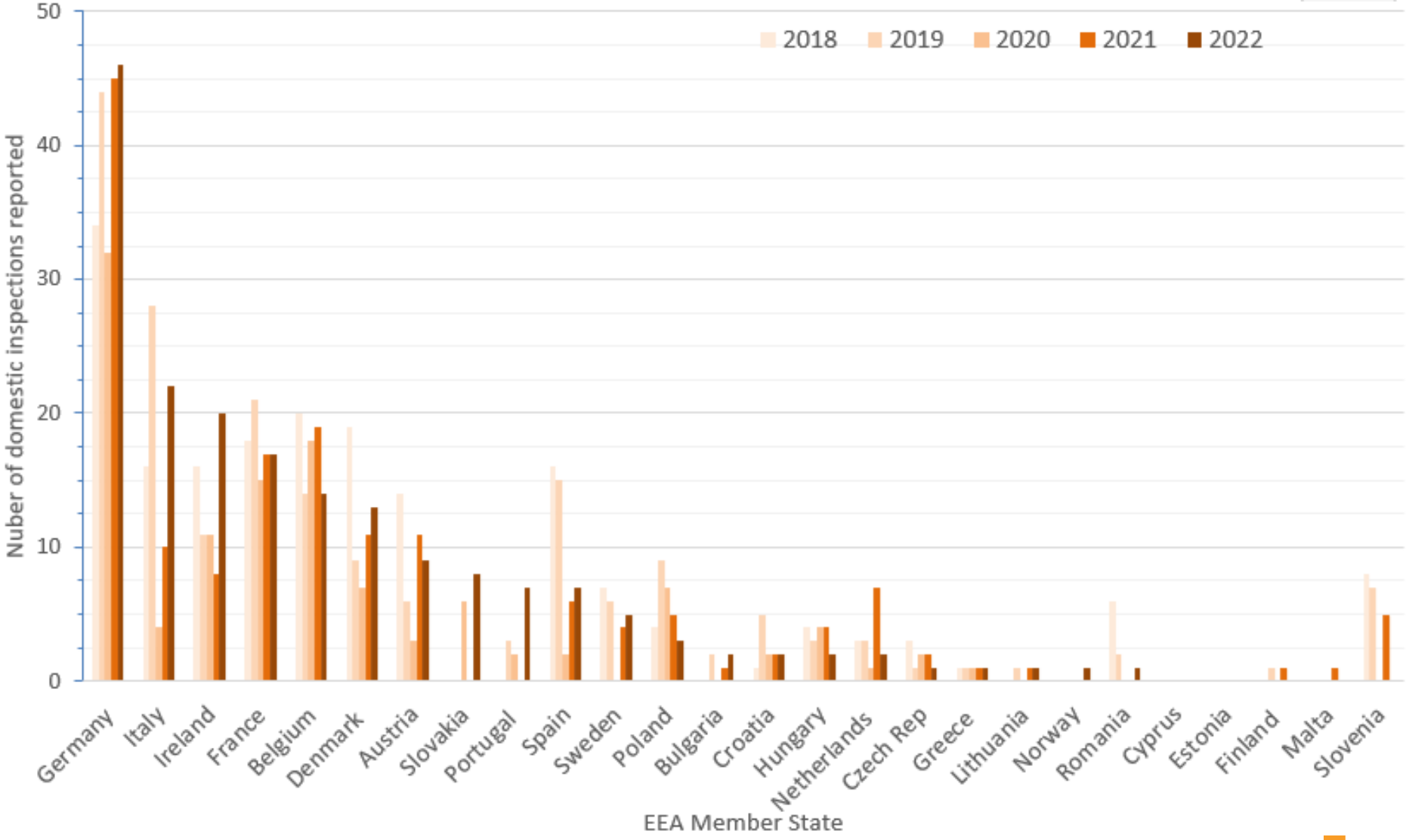

We noted only 30% less domestic inspections of manufacturing sites during corona 2020-2022 in comparison to the average 2014-2019

Only listed if more than 5 domestic inspections reported

*Note: the UK does not count for the EU-MS any more since 2021

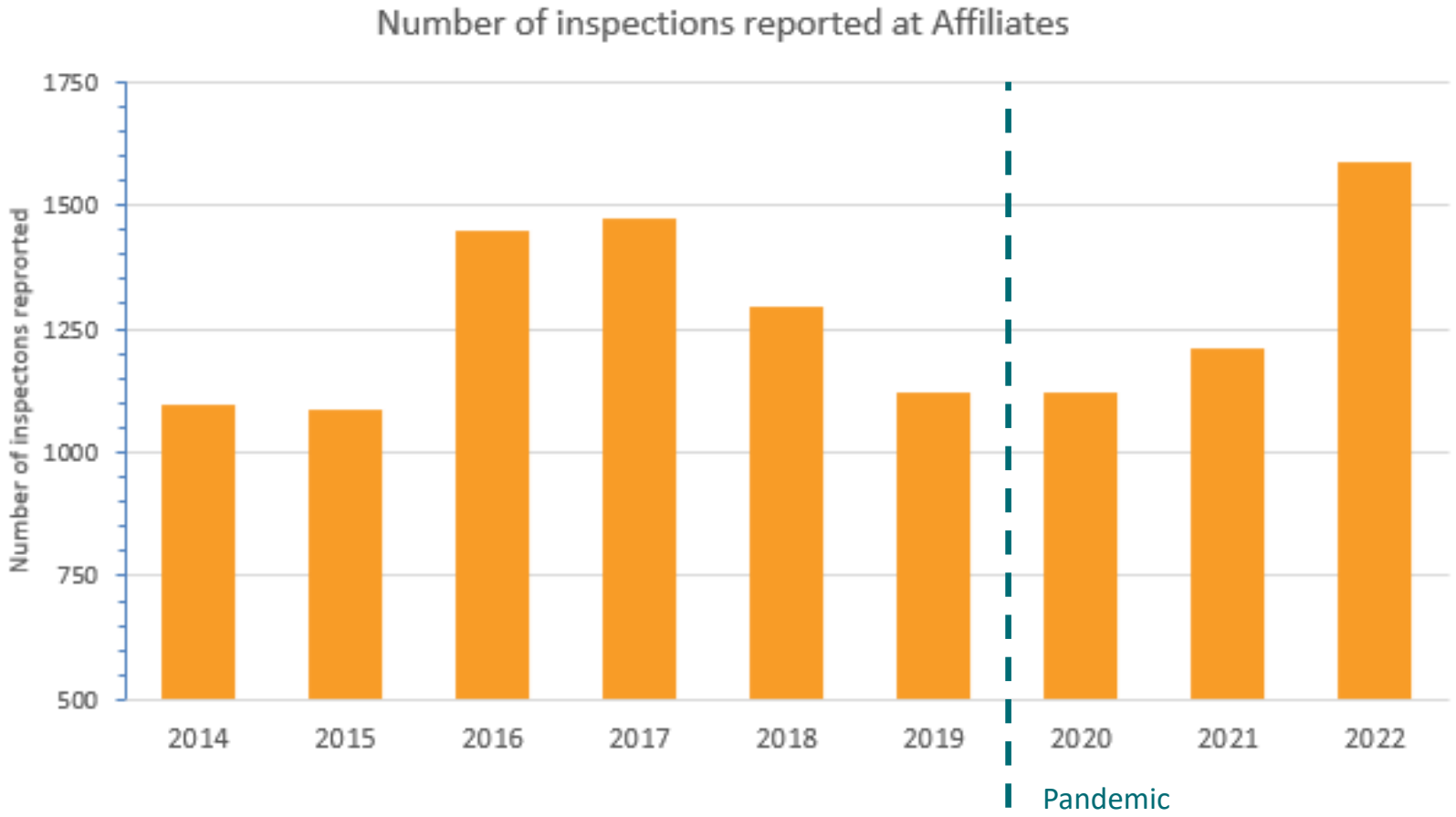
Note: Notified Bodies doing certifications for devices included in Medicinal Products

# Number of reported domestic inspections by authorities in EEA Member States



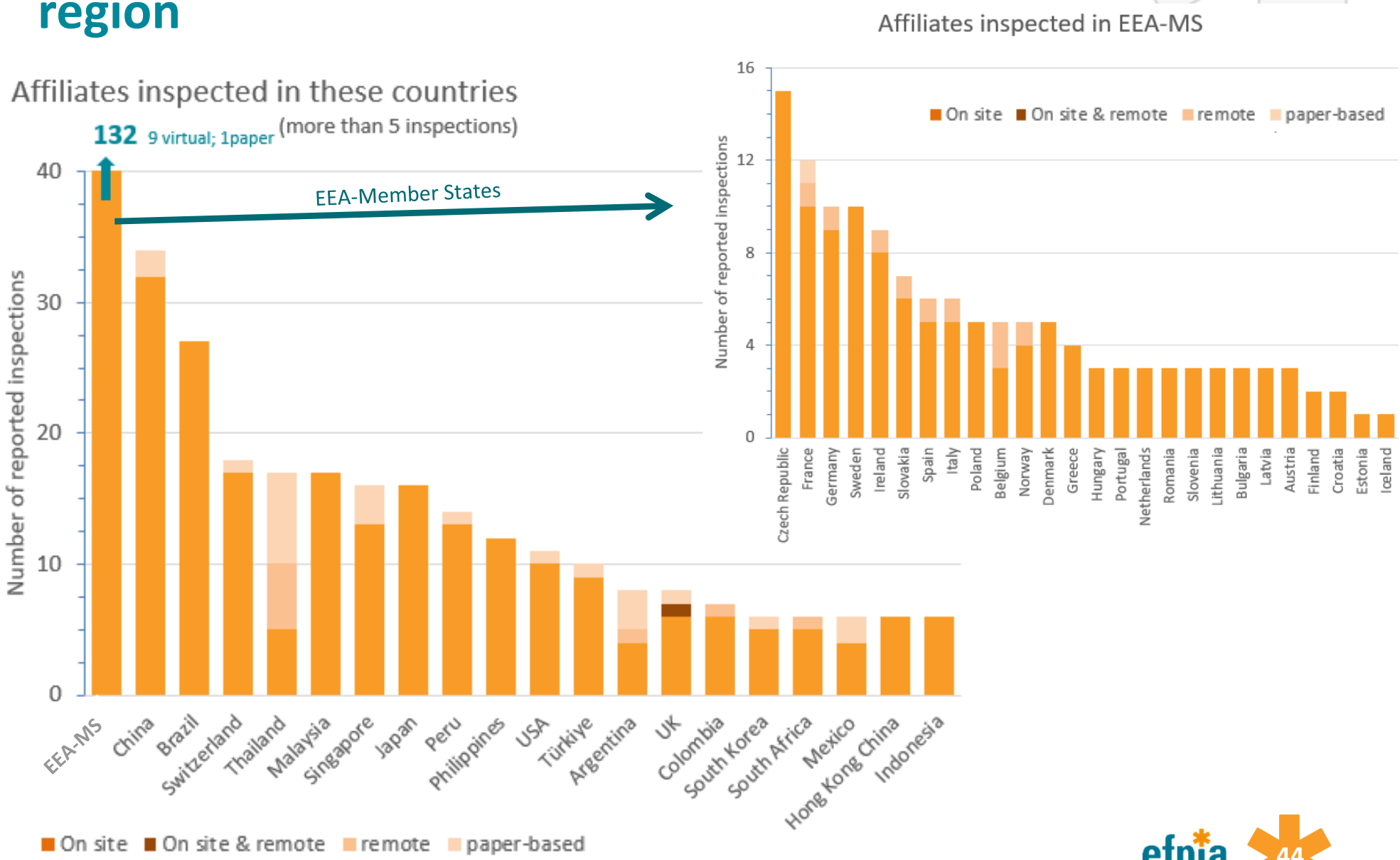
## INSPECTIONS AT AFFILIATES

# An all time high of inspection at affiliates with very limited influence by the pandemic



## INSPECTIONS AT AFFILIATES

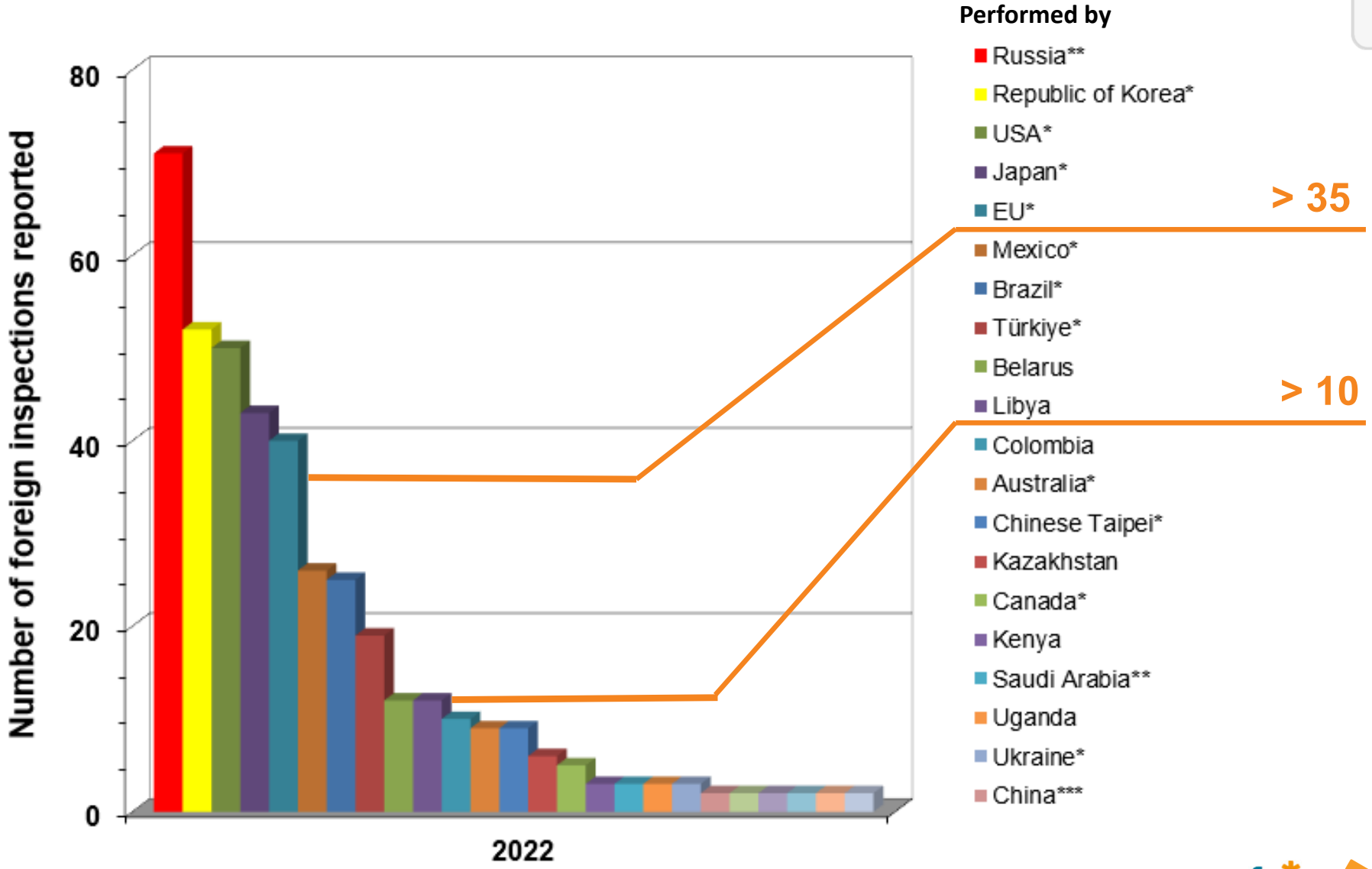
# Local affiliates have received inspections – no trend by region



# Data on foreign inspection practice

# Number of foreign inspections at manufacturing sites

## ordered by country (EU as one entity; all inspection types and modes)



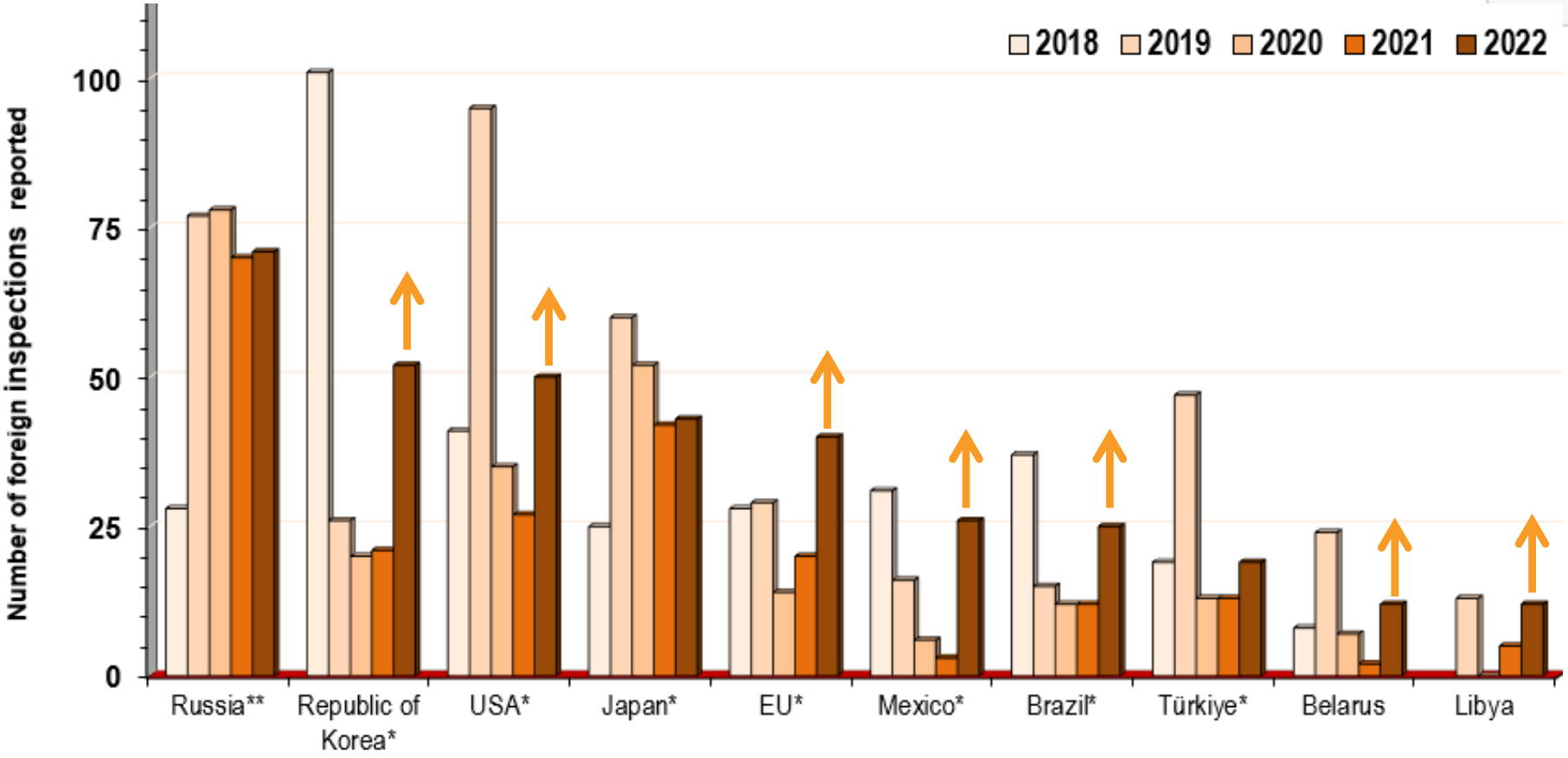

*Inspectorate is a PIC/S participating authority **PIC/S Applicant ***PIC/S Pre-Applicant



Reported foreign inspections on all countries listed

## FOREIGN INSPECTION ACTIVITY

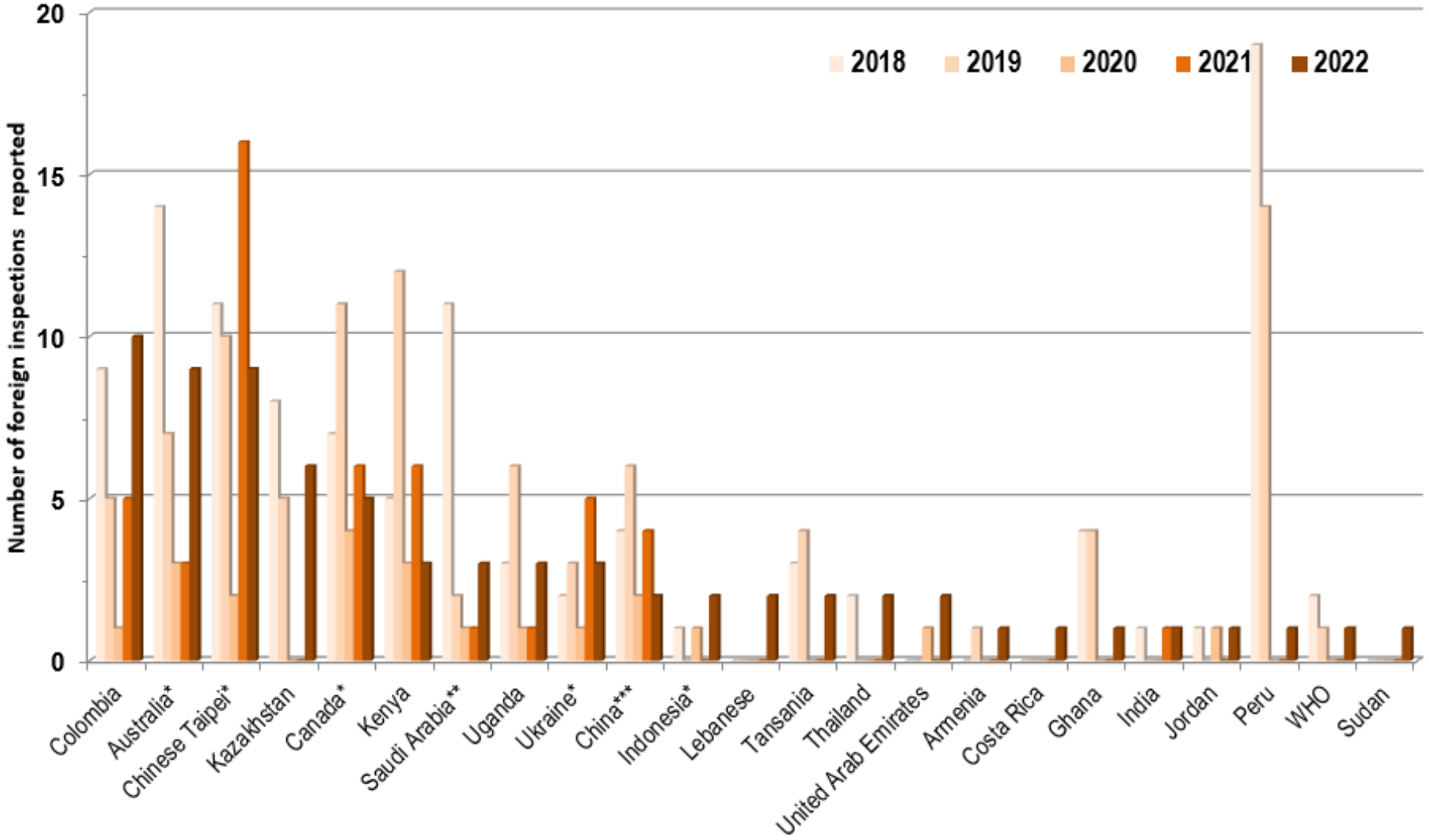
# Number of foreign inspections by country 1/2




## Most countries resumed foreign inspection programs

*Inspectorate is a PIC/S member **PIC/S Applicant ***PIC/S Pre-Applicant

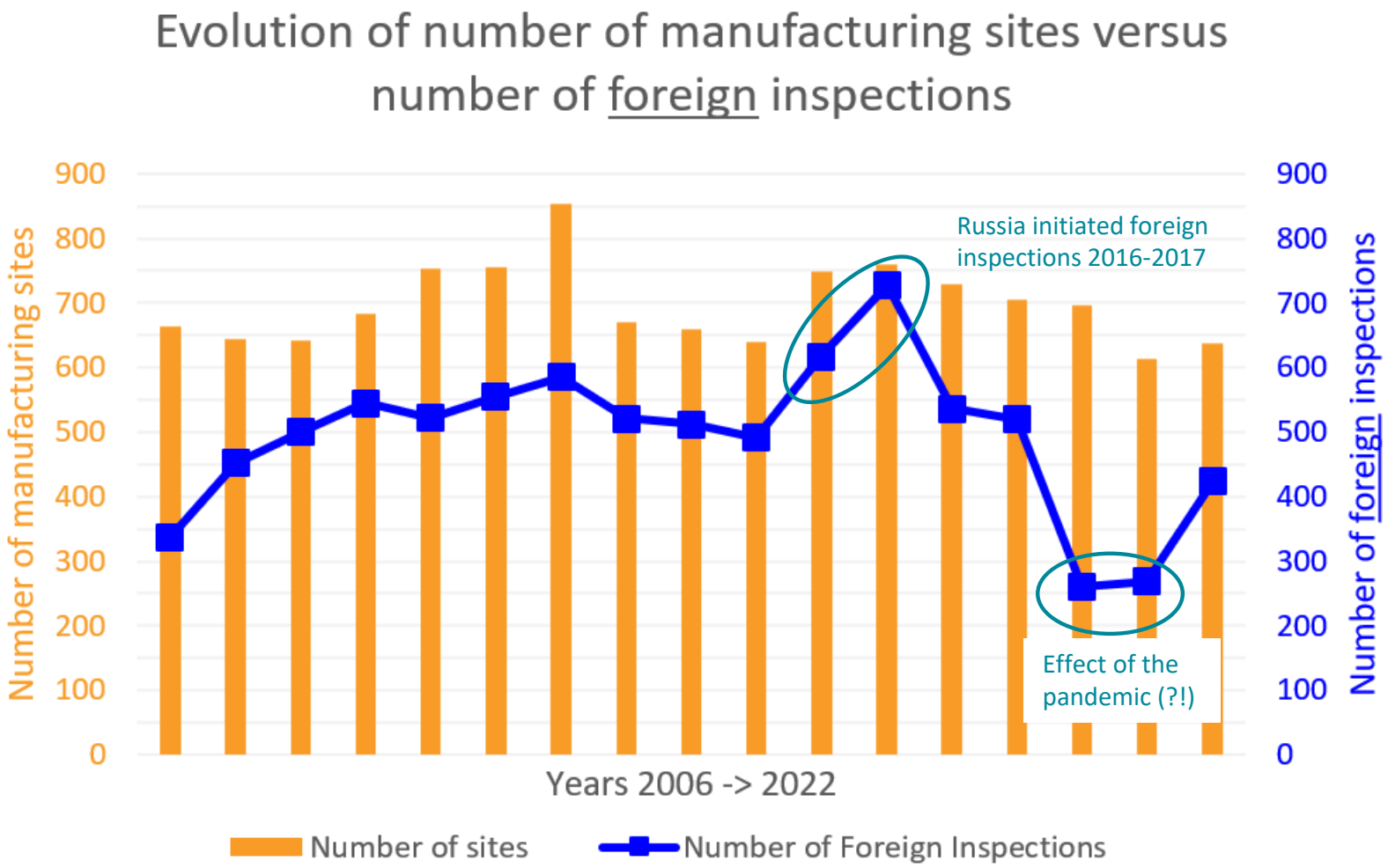
# Number of foreign inspections by country 2/2




*Inspectorate is a PIC/S member **PIC/S Applicant ***PIC/S Pre-Applicant

Note: No foreign inspection reported by the UK in 2021 and 2022

# Number of foreign inspections at manufacturing sites post pandemic is back to the baseline from 2006/7

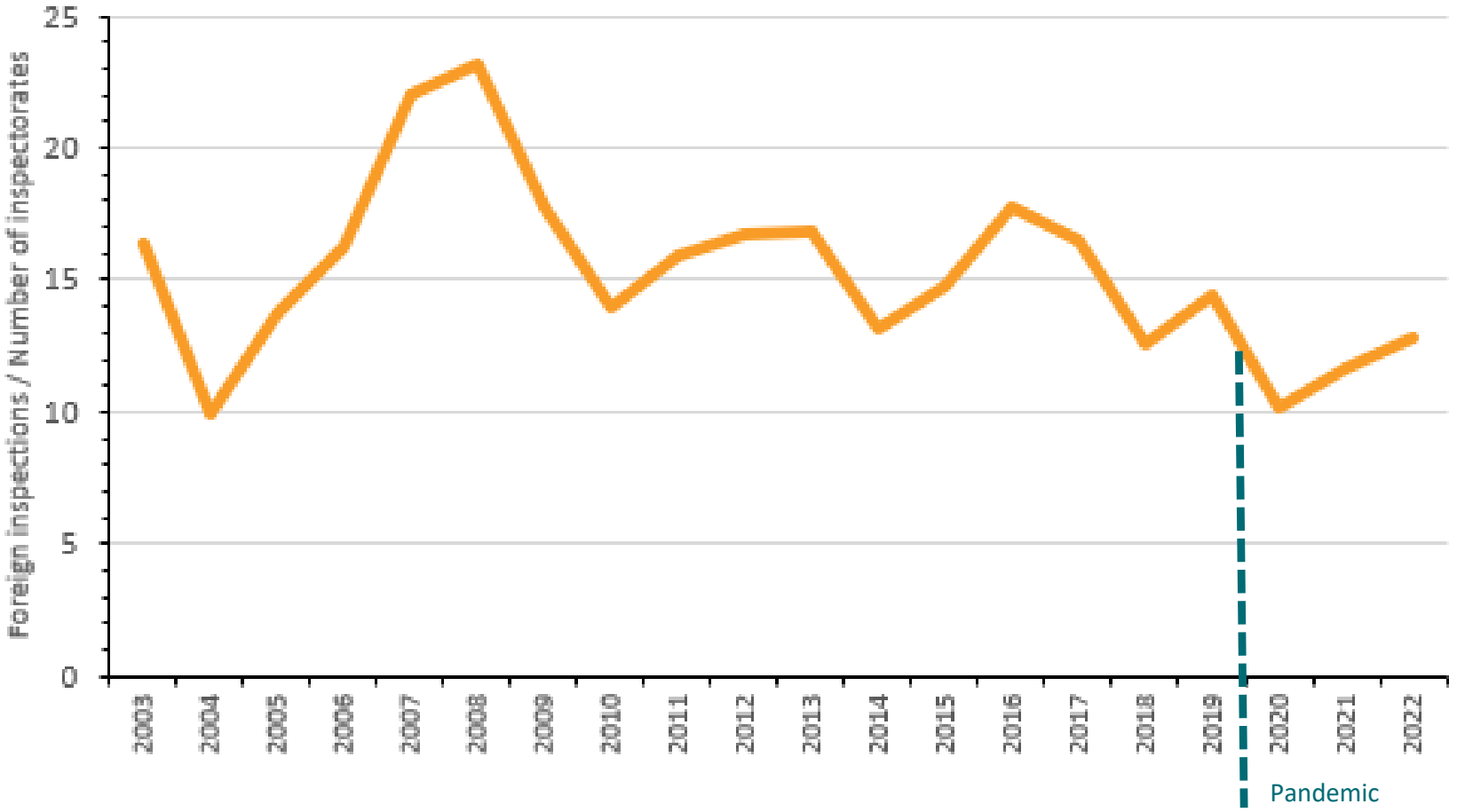



There are no indicators that oversight of the sites was impacted



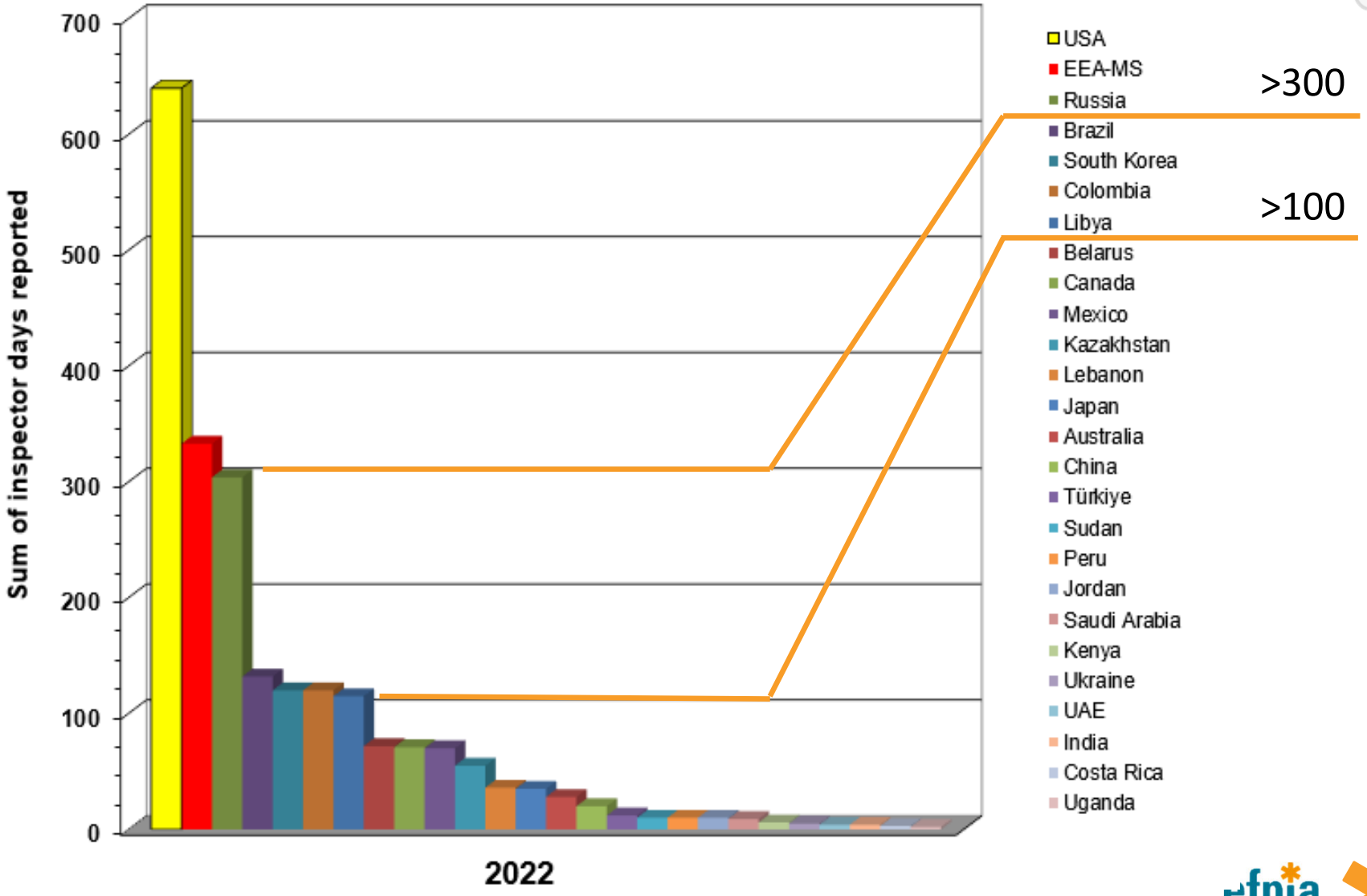
All inspections included independent of the mode used

# Trend in the number of foreign inspections per inspectorate going to 3rd countries

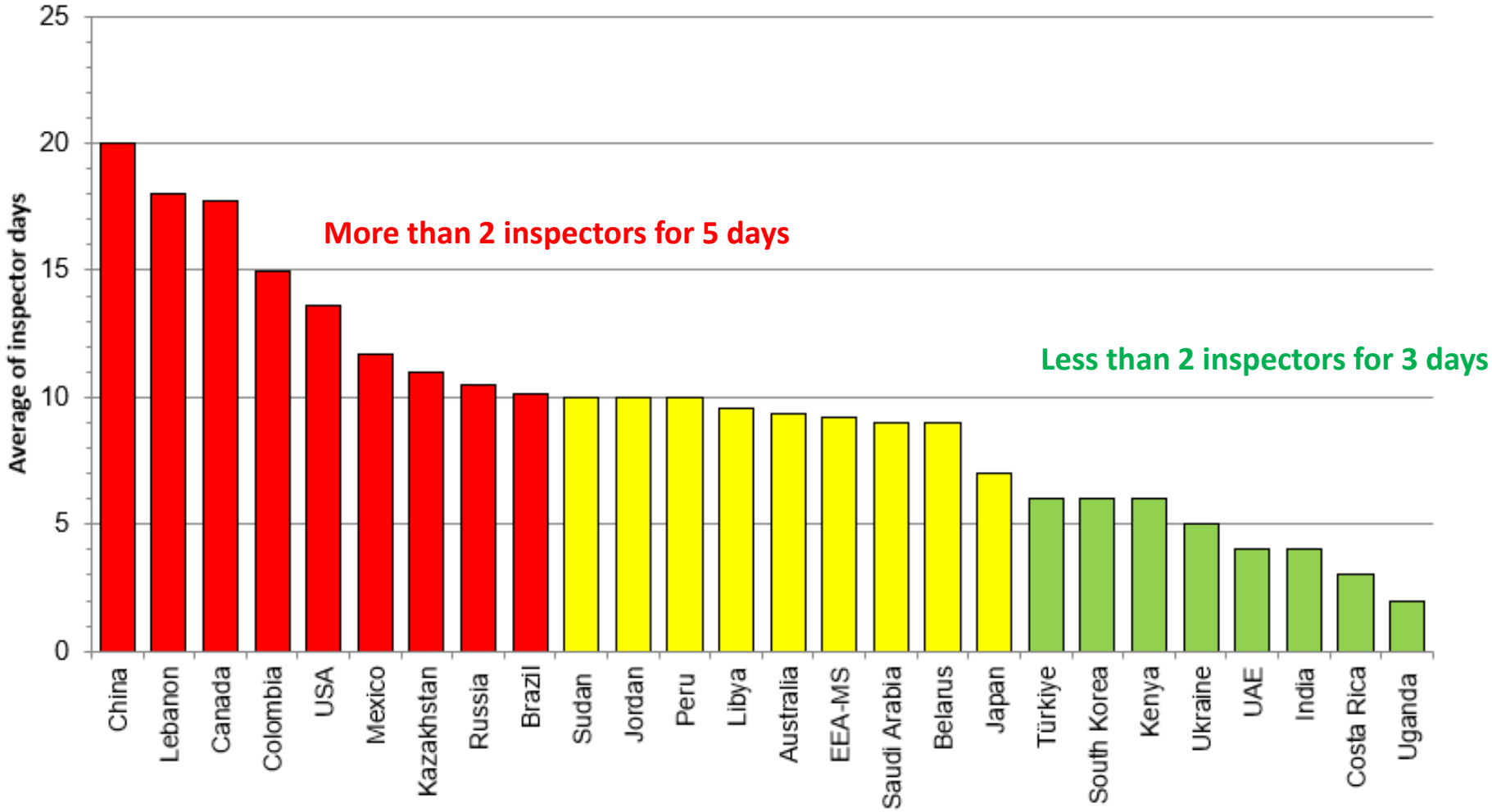



Can we continue the trend post pandemic?

# Inspector days spent on foreign inspections at a manufacturing site (onsite only)

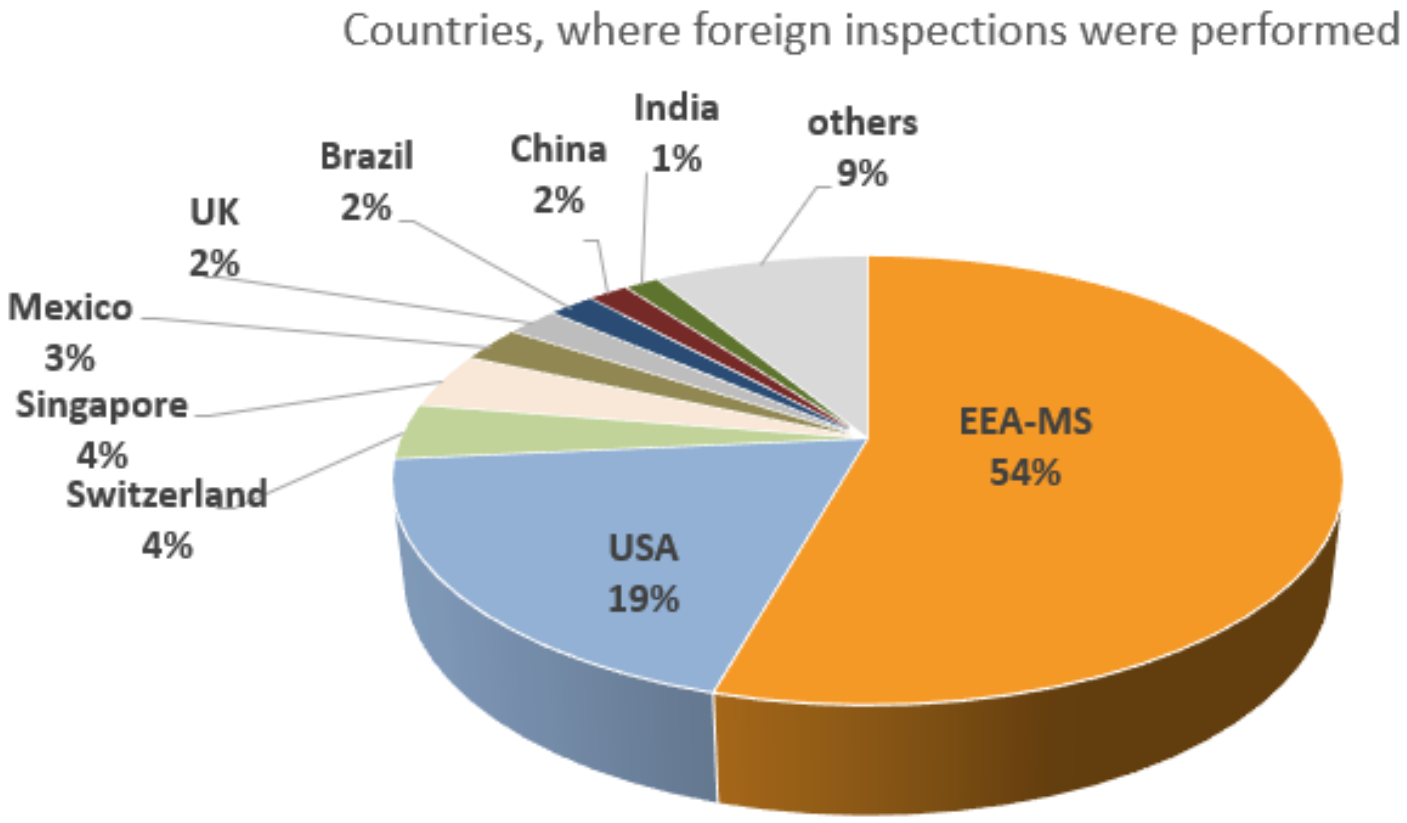


# Average inspector days for foreign inspections at a manufacturing site (onsite only)

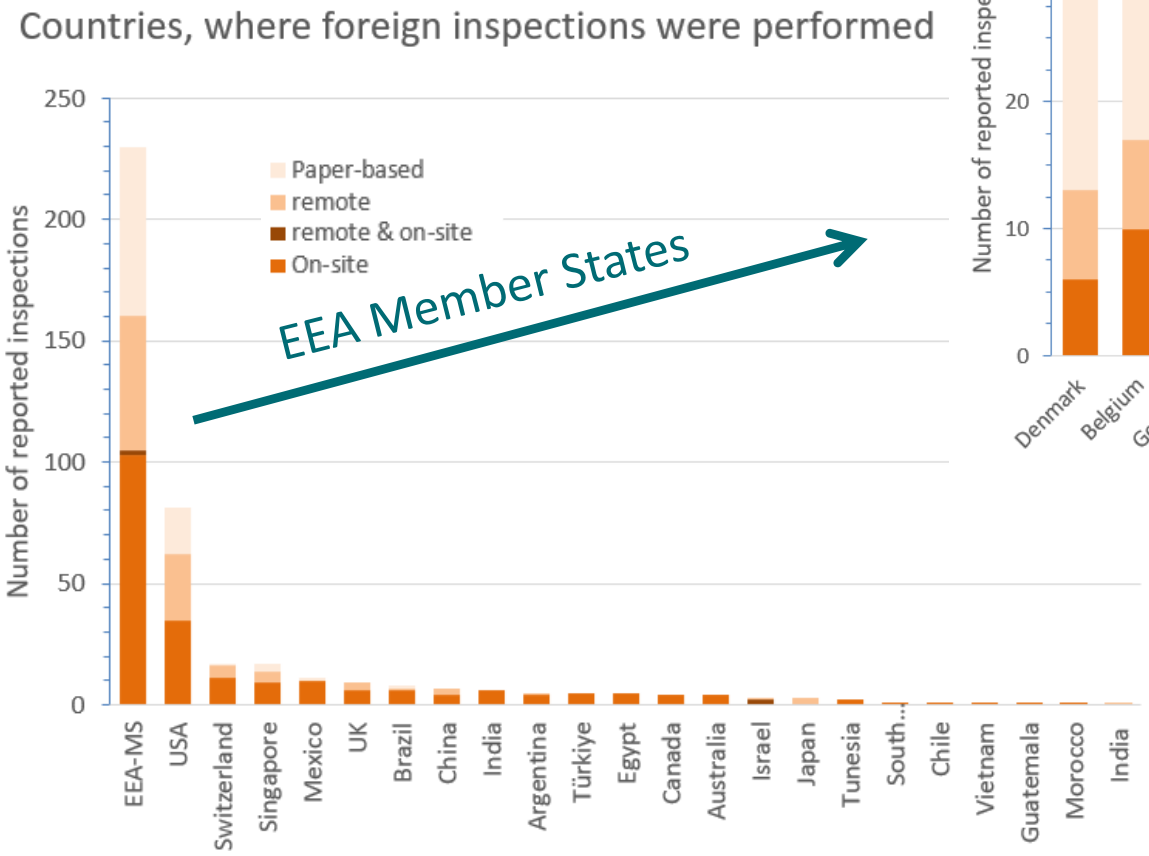


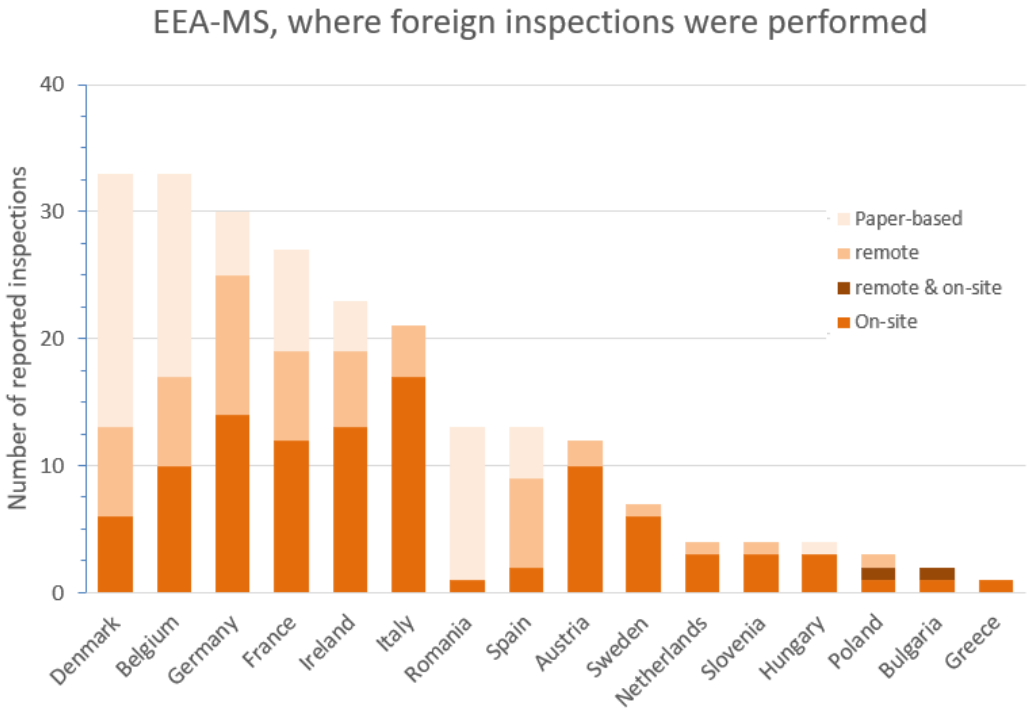
# Locations of manufacturing facilities hosting foreign inspections

- **The location, where conducting foreign inspections, demonstrate that research-based manufacturers are mainly based in**
  - EU
  - US
  - Switzerland
  - Brazil
  - Singapore
  - Mexico

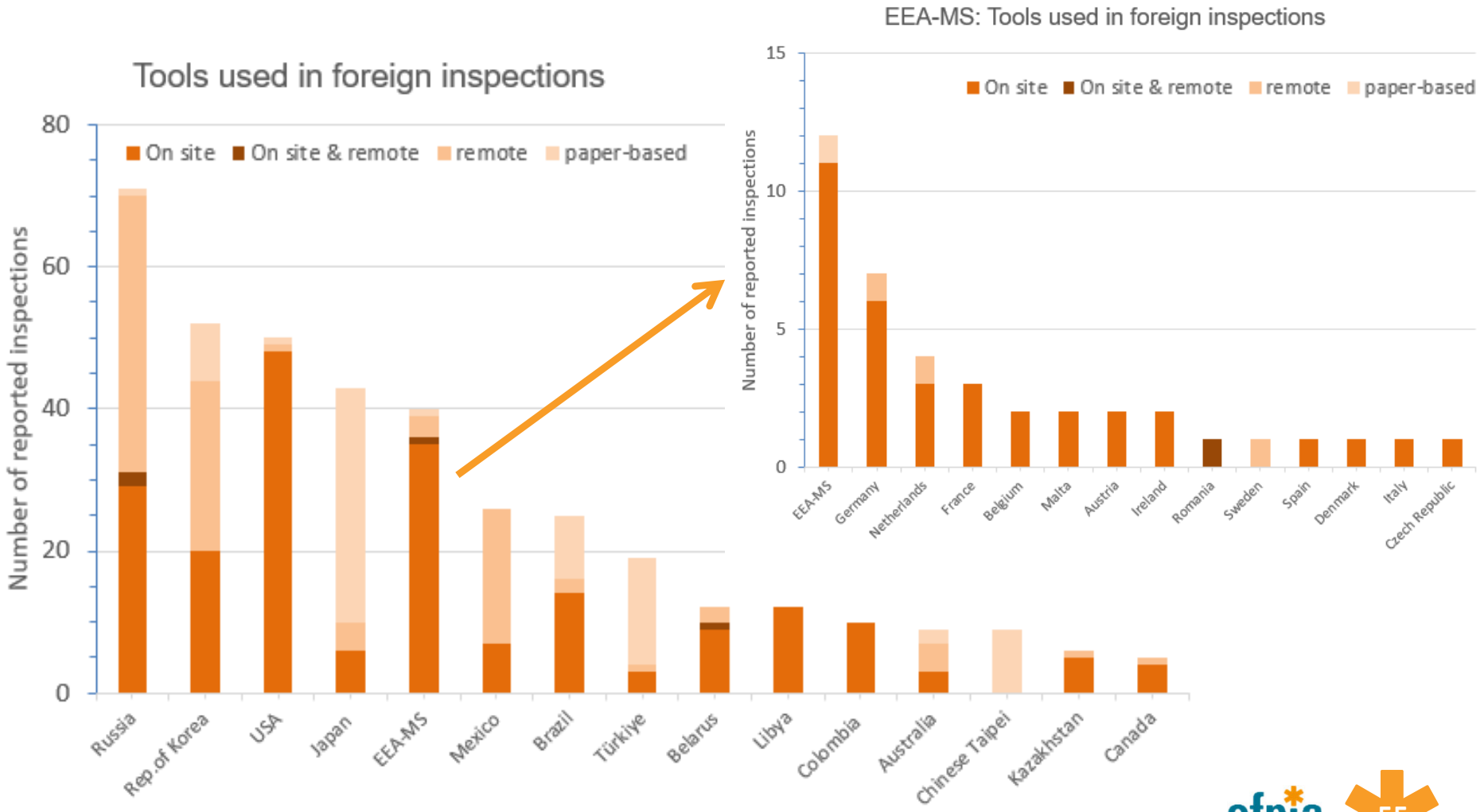


# Locations of Manufacturing Facilities Hosting Foreign Inspections



# Modes used by inspectorates in foreign inspections



efpia

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