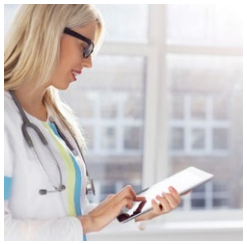
European Federation of Pharmaceutical Industries and Associations

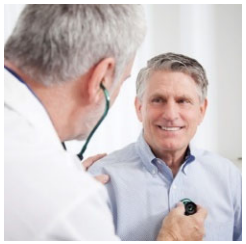
Annual Regulatory GMP/GDP Inspection Survey 2023 Data

Author: MQEG Inspections topic team

Date: 15. May 2024

Version: 1






Summary

EFPIA'S ANNUAL INSPECTION SURVEY

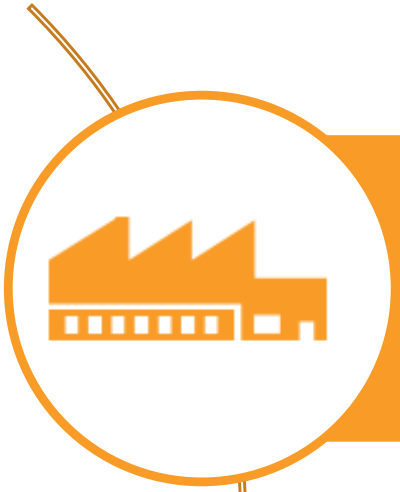
Background and history

- **History**
  - The annual inspection survey was initiated in 2003
- **Scope**
  - Regulatory GMP/GDP inspections
  - Notified Bodies certifications for devices 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
- **Intent**
  - Monitor trends and new focus areas
  - Promote reliance optimizing the use of inspection resources
  - Materialise the benefits of PIC/S membership and MRAs

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

Outcome of the data

Provided by 26 global research-based pharmaceutical companies and two National Trade Associations



At Manufacturing sites[1]

- Opportunities for a better risk-based approach on inspections*
- The number of inspections are reported to be at a maximum
- Inspectorate focus on foreign rather than domestic inspections in 2023

At Affiliates

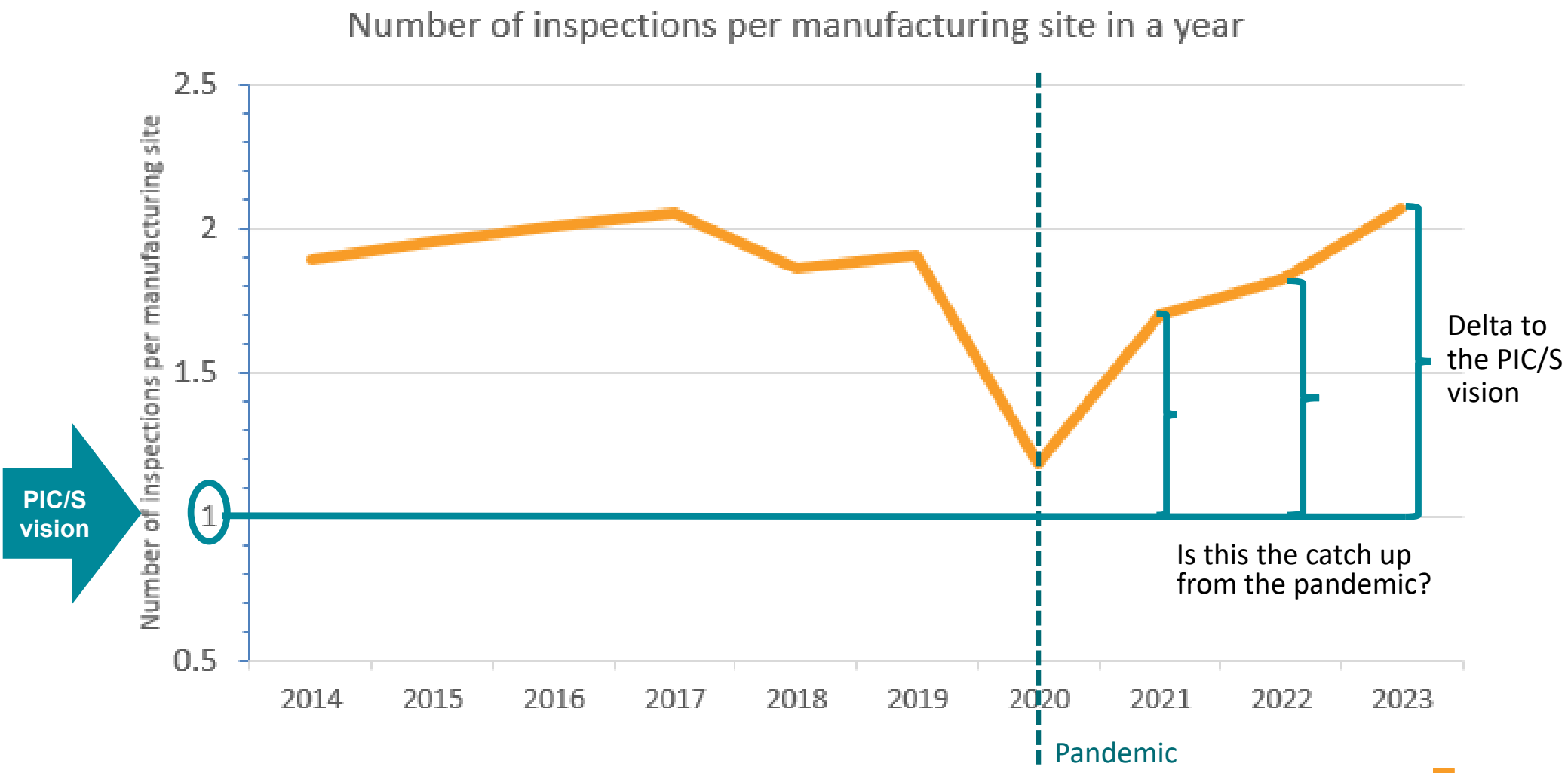
- Constant high numbers of inspections – mostly domestic
- Very limited impact by the pandemic on the number of inspections
- 80% without inspections – assumption: inspections every 5 years

* Countries may include USA, Russia, Türkiye, Japan, Republic of Korea, Libya (potential PIC/S candidate?), EU, Brazil, Mexico. We encourage to establish a legal basis, if needed, to allow acceptance for inspection reports from PIC/S participating authorities.

[1] See infographic: https://efpia.eu/media/lsbbeaze/20230914_efpia-leaflet-compressed.pdf

INSPECTION SURVEY - 2023 DATA

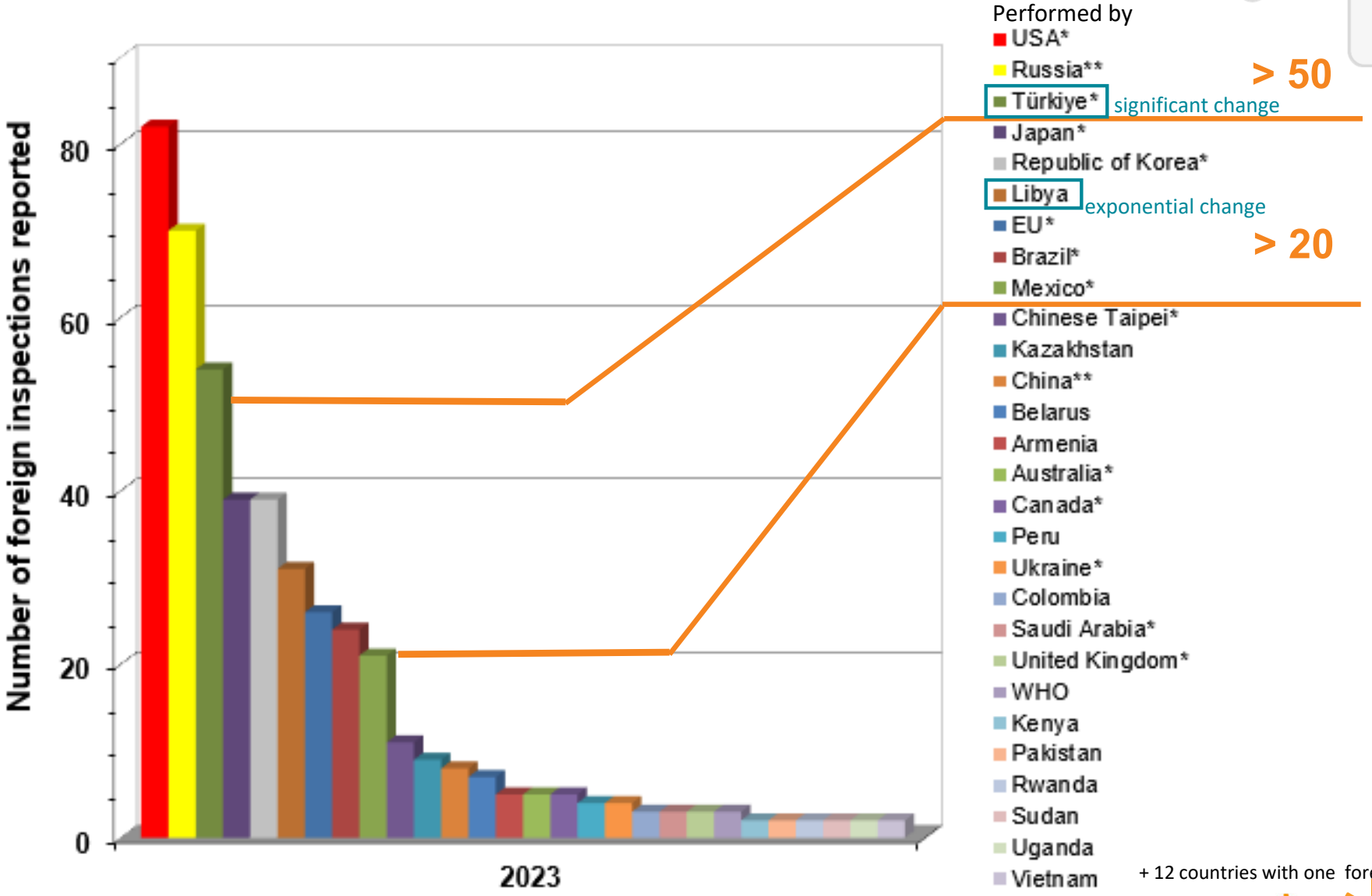
The number of inspections at manufacturing sites are at a maximum in 2023



Correction: Data reviewed and updated as of a feedback to the last year's graph

Number of foreign inspections at manufacturing sites

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



+ 12 countries with one foreign inspection

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

What do the data tell us on foreign inspections?

Increasing and now reaching the level before the pandemic

- **They are at a peak**
  - Trend continues when the pandemic (2020 & 2021) is disregarded

	Tendency	Inspectorates from
	Exponential increase	Libya
	Back to high rates before the pandemic, or even higher	US, Turkey, EU, Brazil, Mexico
	Increasing	EAEU-MS (beside Russia)
	Stable	Russia
	Decreasing	Japan (less document inspections)

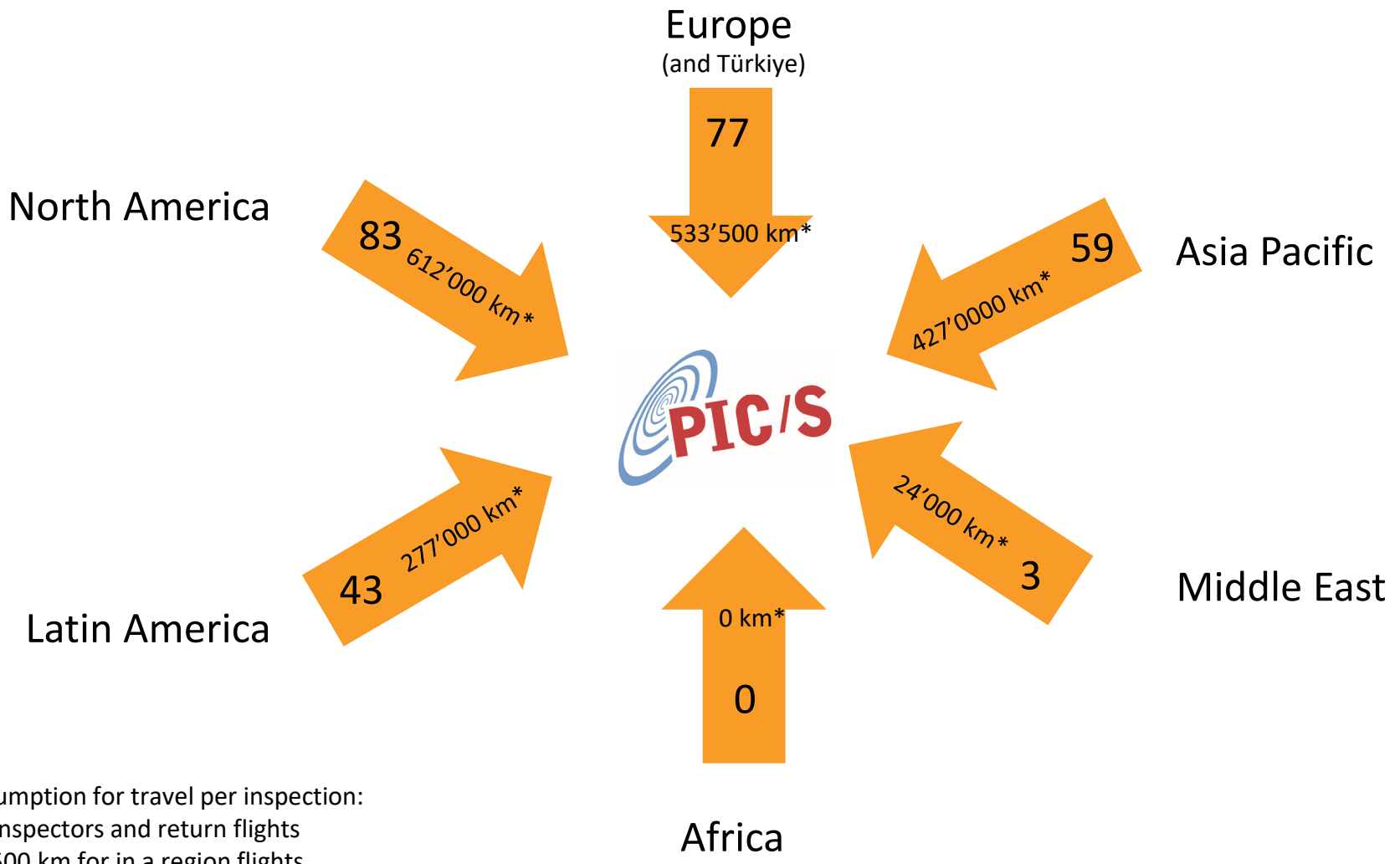
- **We observe an increasing average of inspector days***
  - Increasing inspectors' days used for foreign inspections (8.2 days)
- **About 80% of the foreign inspections are conducted in EU/EEA, US and Switzerland**
  - 62% of inspections between PIC/S members with a shift from pre-approval inspections (PAI) towards surveillance/routine inspection

*Assumption: having additional inspectors for training purposes

OPPORTUNITIES FOR PIC/S PARTICIPATING AUTHORITIES

Reducing environmental footprint by reliance on PIC/S

≈ 1’900’000 km/y* ≈ 26’000’000 kg CO_2

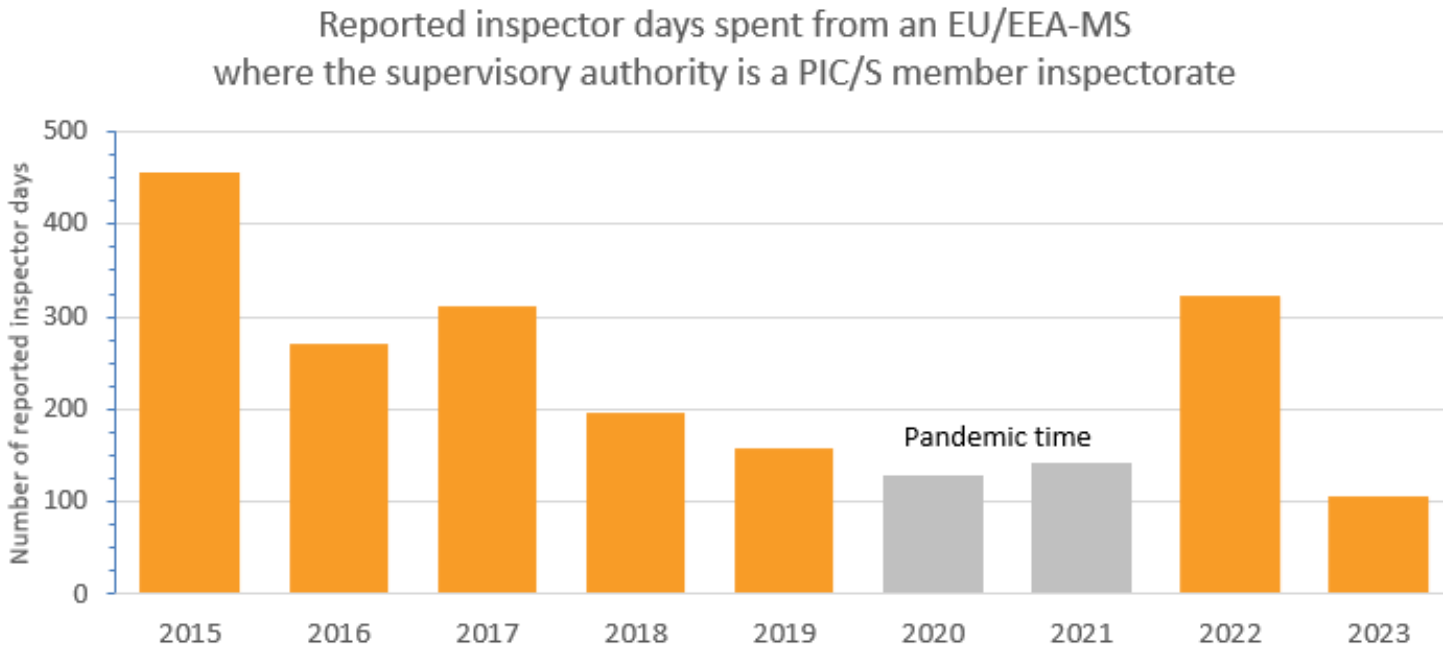


Assumption for travel per inspection:
- 2 inspectors and return flights
- 500 km for in a region flights
- 8’000 km for interregional flight

*on average; 0.0658 kg CO_2 / flight km
Switzerland: Bundesamt für Zivilluftfahrt (BZL)

EU Inspection reliance initiative seems to start materialising

- **EFPIA member companies welcome the EMA pilot on unilateral reliance**
  - We also welcome the issuing of new GMP-certificates after decision on reliance
- **It seems to materialise**
  - 106 inspector days reported in 2022 vs. 322 days in 2022



What do the data tell us in general?

- **Inspections at manufacturing sites of research-based companies**
  - Do not end in interrupted supply
  - For more than 80 % no follow up actions were needed
  - No difference in outcomes between domestic and foreign inspections
  - Inspections of IMP manufacturing sites are reported to be domestic only
- **Increasing trend towards more inspections at the same manufacturing site**
  - Currently at the level of 2014-2019
- **The number of 'for cause' inspections doubled from 2022 to 2023**
  - However, this did not result in interrupted supply or more follow up actions
- **Scheduled (≈90%) versus unannounced (≈10%) inspections have similar outcome**
  - The number of unannounced inspections are significantly high by US and China
  - No influence of the pandemic
- **China**
  - Sourcing APIs from China is not a supply chain priority for research-based companies
  - The inspection data demonstrate that many companies may manufacture in China for the domestic market only

ANNUAL EFPIA INSPECTION SURVEY - INSPECTION MODES

Back to physical presence while there is a decreasing number of alternative modes

* Some inspectorates (e.g., Australia, Mexico, Rep. of Korea, Russia) still see remote inspections beneficial and a valid alternative in foreign inspections

What do the data tell us on the presence of assessors

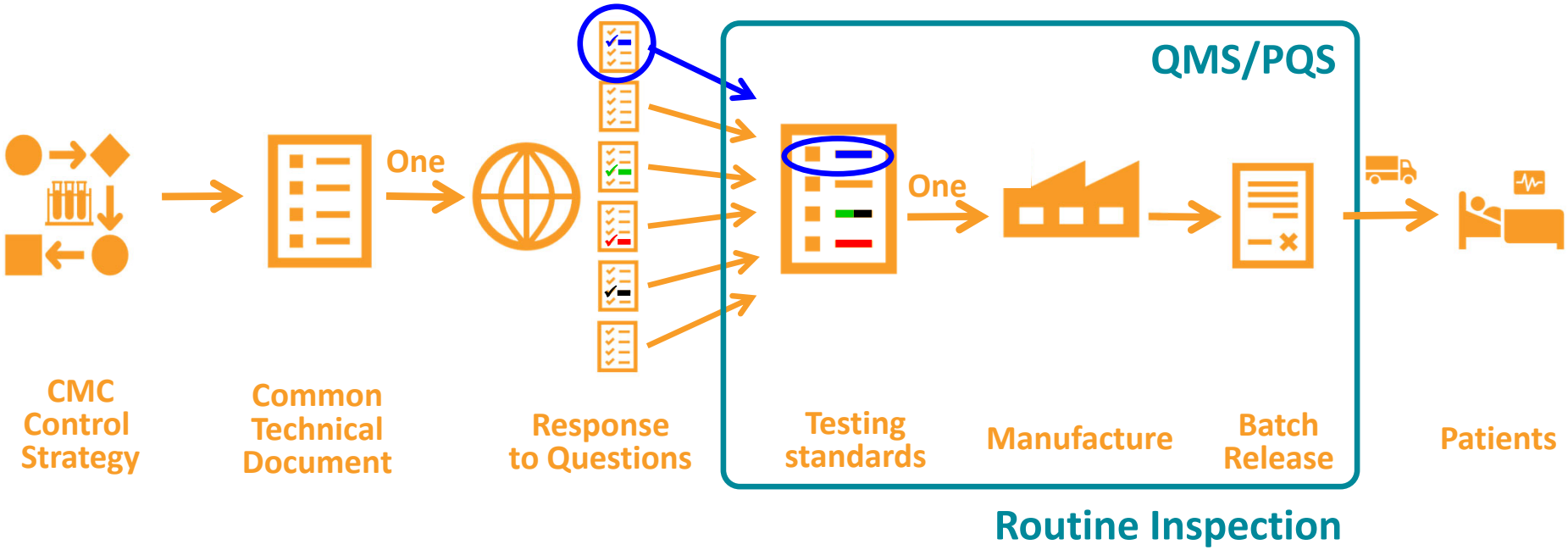
- **New data this year indicates that regulatory assessors are present during inspections**
  - However, the data does not tell if there was a discussion between inspectors and assessors prior to an inspection
- **Presence of regulatory assessors in**
  - Foreign inspection worldwide
    - Routine — average 51% (US-FDA 48%)
    - PAI — average 76% (US-FDA 25%*)
  - Routine inspections by EU/EEA
    - Domestic inspections — average 42%
    - Foreign inspections — average 26%

* note: the US-FDA has field inspectors in the Office of Regulatory Compliance (ORA) while members of CDER/CBER/CDRH can be part of the inspection team

About 50% of the companies answered only

743 INSPECTOR DAYS ARE REPORTED FOR FOREIGN PAI IN 2023*

Convergence opportunity to rely on inspections of the QMS/PQS instead of additional product specific PAIs



*639 in 2022

QMS/PQS: Quality Management System / Pharmaceutical Quality System

REALITY CHECK

Expectations and reality in regulatory approval

Inspections cover PQS/QMS

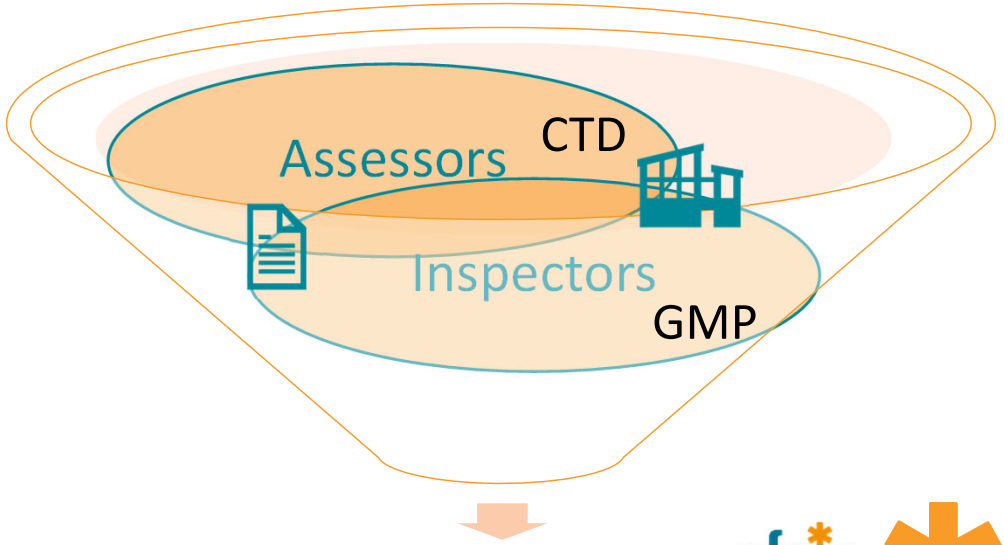
- GMP aspects are covered by the inspectorate in routine and PAI
- Early collaboration of assessors and inspectors can facilitate understanding

What companies see

- GMP aspects in the registration dossier

What companies expect

- Mutual understanding of the assessor's and inspector's domains



ICMRA COLLABORATIVE HYBRID INSPECTION PILOT (CHIP)

Initial thoughts on learnings and future benefits

About the pilot

- Physical presence of domestic, other inspectorates / observers remotely
- Opportunity to use prior knowledge of the site
- Align inspection approaches
- Flexible but not binding

Benefits

- Outcome is one inspection with a consolidated list of observations and response process (aligned assessment and timelines)
- Allow for legal acceptance of the process and outcome

Learnings

- Collaboration is key
- Roles and responsibilities defined and understood
- IT platforms and set-up to be well prepared

Challenges

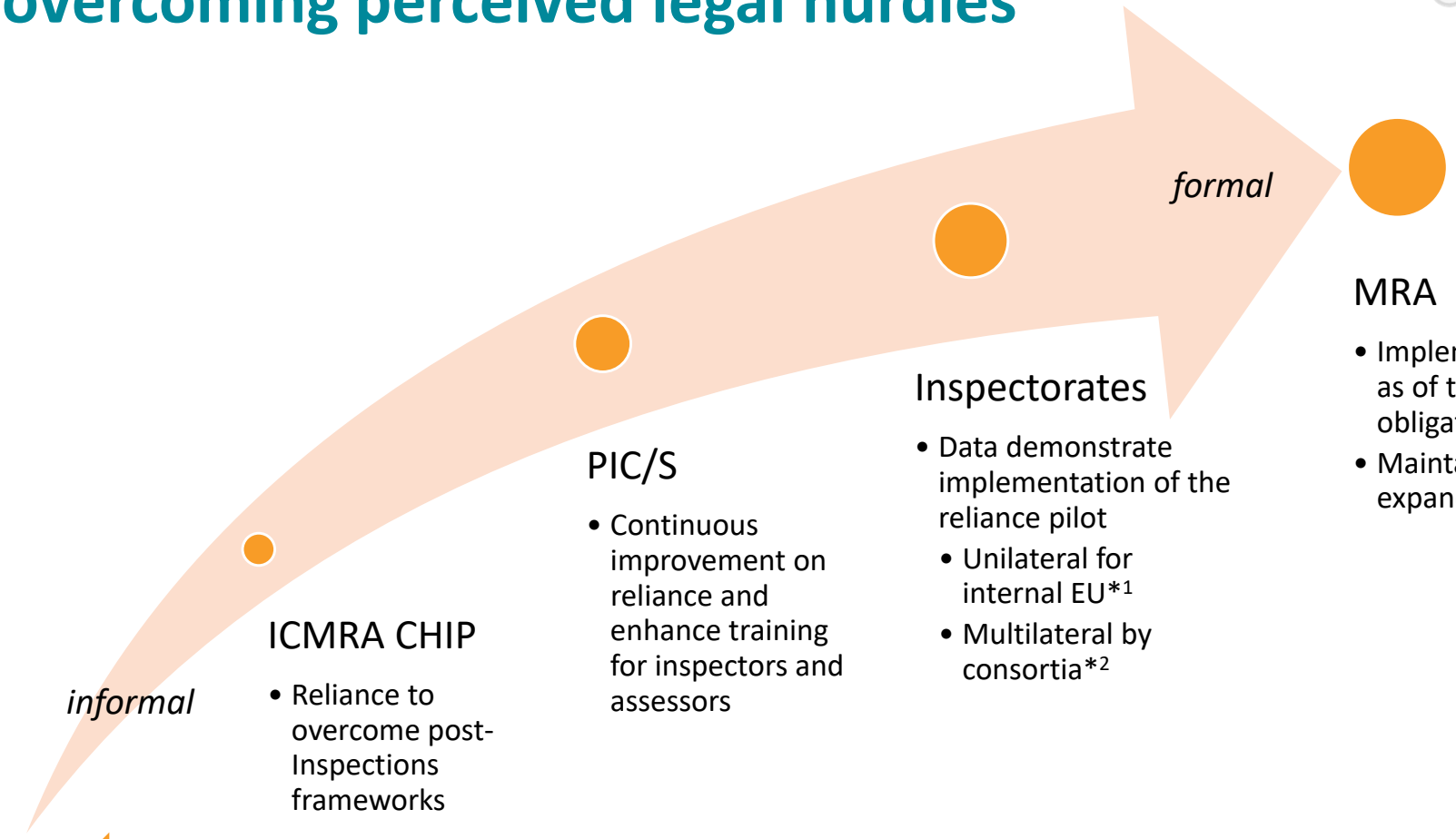
- Amount of pre-requested documentation
- Time zone differences

To fully materialize the benefits of the CHIP pilot

- ICMRA member countries to rely on the CHIP inspection report – *join as observer if needed*

For more details see: https://www.icmra.info/drupal/en/strategicinitatives/pqkms/inspection_expectations

Pathways to reliance on domestic inspections overcoming perceived legal hurdles

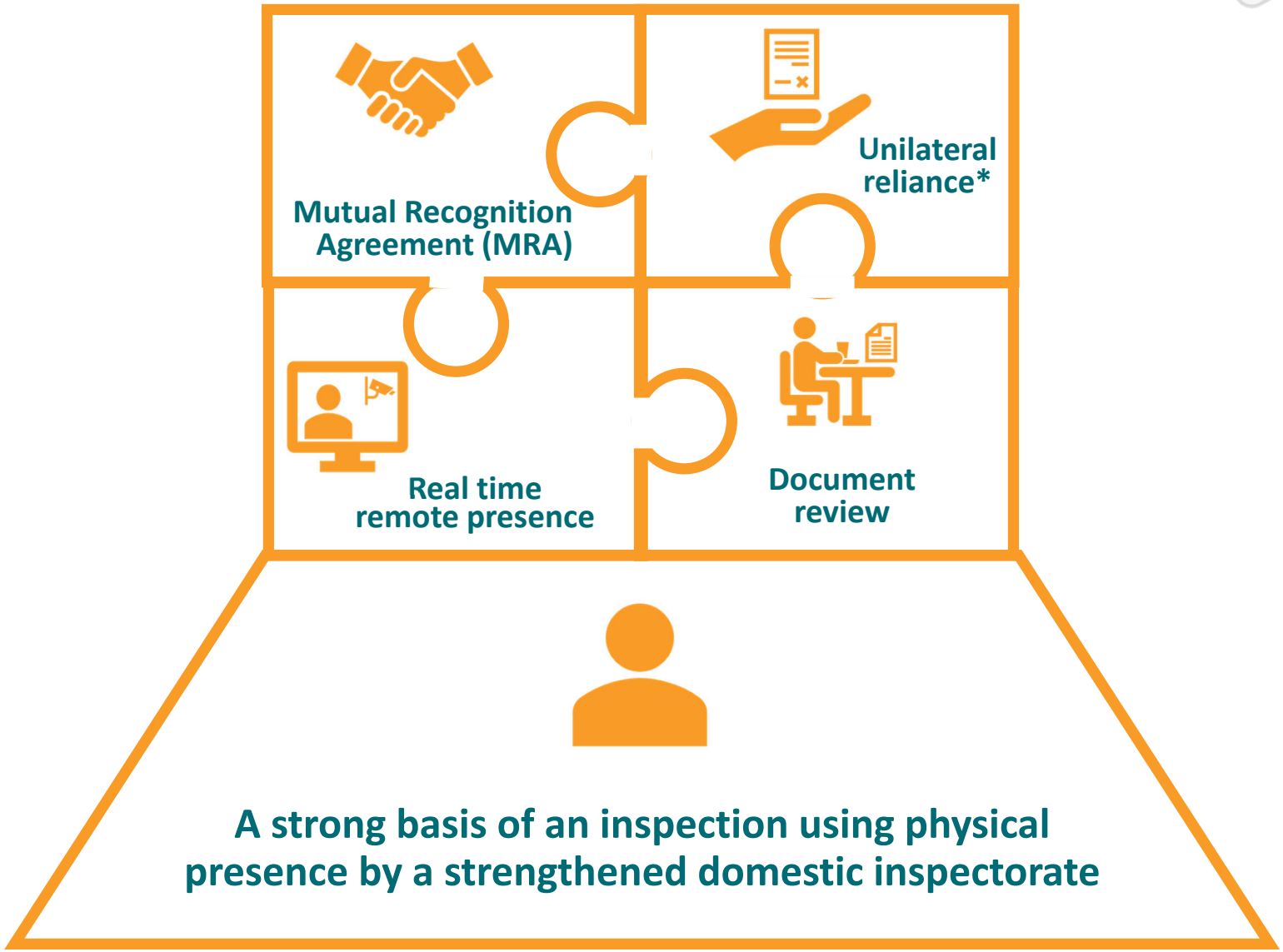


Implement prior knowledge to reduce inspections, length and topics

*1 Re-issuing GMP-certificates can be considered
*2 e.g., Australia-Canada-Singapore-Switzerland-United Kingdom (Access)
*3 MRA EU/US, see also new MRAs among ASEAN and Korea / Singapore

SCIENCE AND RISK-BASED INSPECTION APPROACH

Collaboration, Reliance, Recognition



*based on information from other stringent regulatory authorities

Call to action for reliance

Use reliance approaches

- Expertise gained jointly to allow for trust in the local inspectorate*1
- Consider deferring of an inspection*2
- Let industry know when a deferring of an inspection occurred

In support of reliance industry is open to proactively share information about inspection activities at sites

Materialise reliance

- Unilateral reliance based on mature and convergent regulatory system (e.g., PIC/S)
- Full implementation and expanding of existing MRAs
- Accept '*official GMPs documents*' including from all modes*3

*1: Interactions are in place e.g., PIC/S internal observed re-certifications of membership, MRA processes, CHIP pilot
*2: e.g., after sharing the inspection report
*3 i.e., by physical presence, real time remote presence, document review, reliance approaches etc. for unilateral reliance and within MRAs (change terminology in MRA US-EU Art 1.10)

Call to action on improving efficiency

Improve inspection practices

- Recognise documentation in local language*1
- Accept electronic files incl. e-batch records
- Coverage of several product types during one inspection

Can we enhance efficiency of inspections at the same site while it is assumed to be ≈ 80% redundant in average?

Gain Efficiency

- In-country inspectorates to align on their schedules*2
- Focus on sites / subject matters not yet inspected by others
- Reducing length and topics based on prior available knowledge about the site / products / process*3

*1: Domestic inspections may have covered it
*2 e.g., US-FDA: CDER, CBER, CDRH, OPQ, ORA; Republic of Korea: biologics/small molecule
*3 from stringent inspectorates e.g., MRA partners, PIC/S participating authorities

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

ACKNOWLEDGEMENTS

Contributors to the EFPIA inspections survey 2023

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

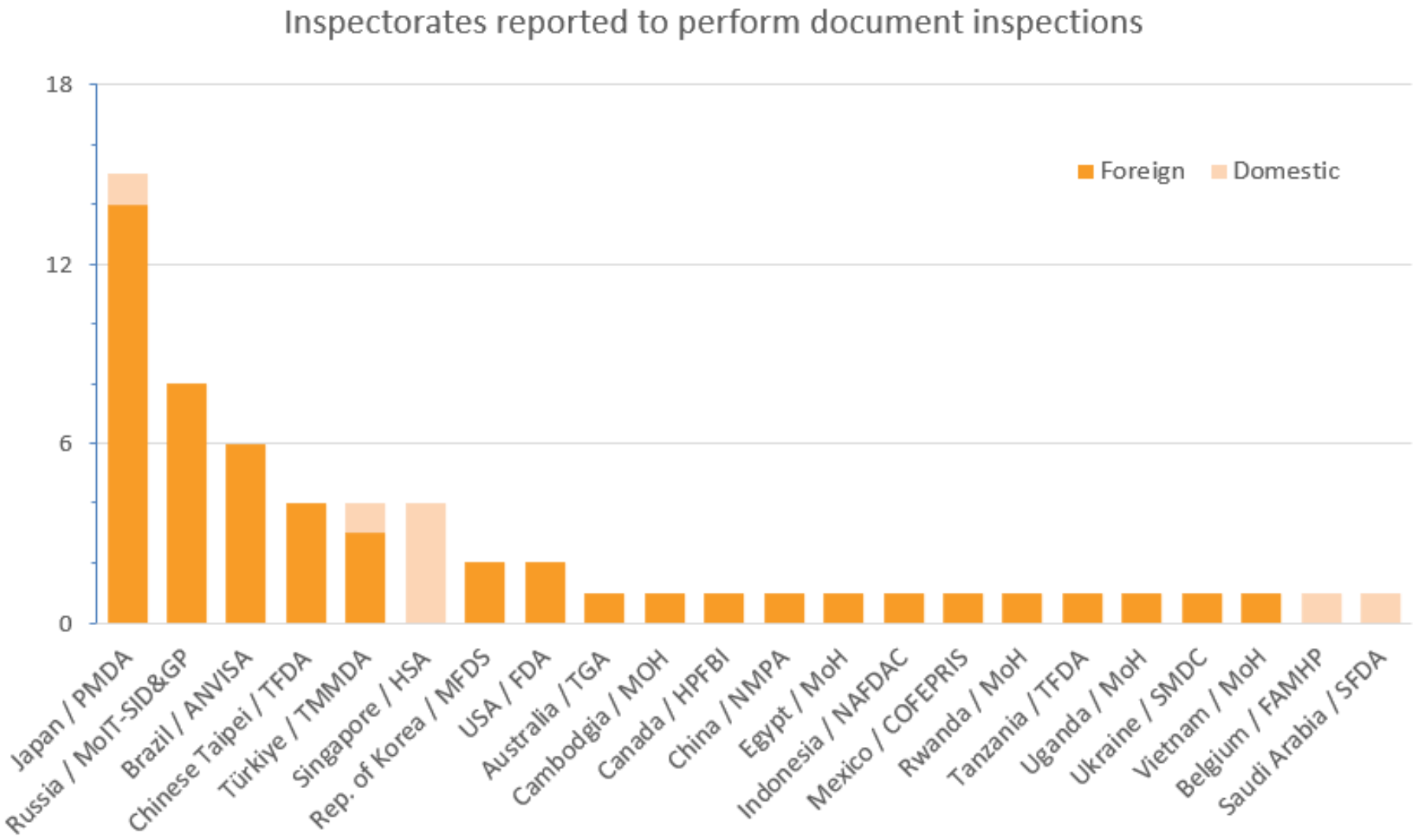
National Trade Associations

- Apifarma (Portugal)
- LEEM (France)

Additional data

Documents inspections

Inspectorates performing document inspections as an independent inspection mode



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

Check with survey results

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

Survey results 2023 of standard document packages requested prior to an inspection – any mode

- **Common documents requited in surveillance and pre-approval inspections**
  - Site Master File*
  - Annual Product Review*
  - Quality Manual*
  - Inspection History*
  - List of Deviations
  - List of Major Changes
  - List of Recalls
  - Quality Agreements
- **Additional documents usually requested in PAI**
  - Process Flow Diagrams
  - Product Specifications
  - Validation Documents
  - List of countries where the product is approved
  - List of Laboratory OOS results.

*Recommended as of the EFPIA 2014 position paper

Inspections at Manufacturing Sites

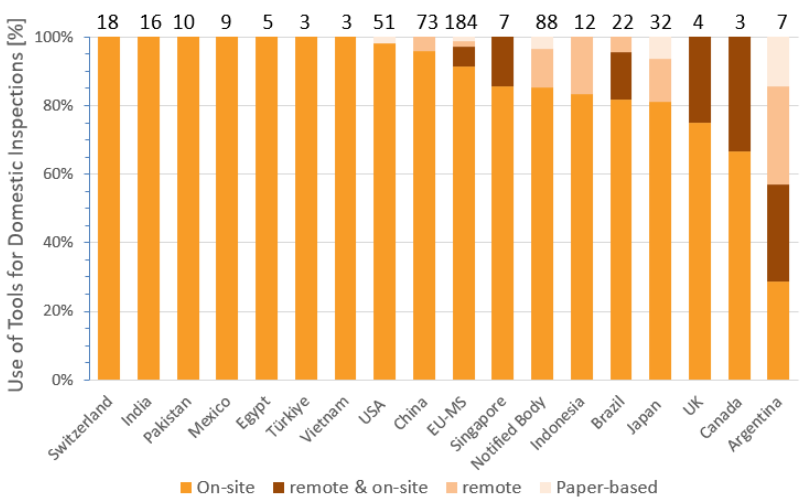
Back to physical presence while there is a decreasing number of alternative modes

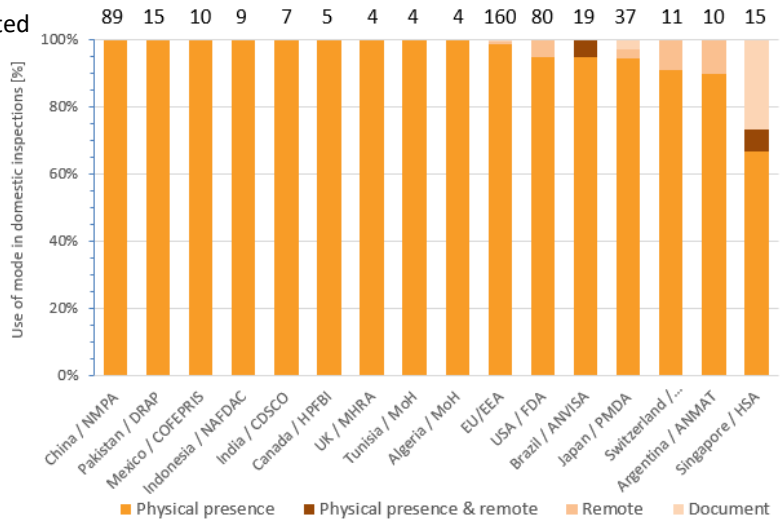
2022

Domestic

No of inspections reported

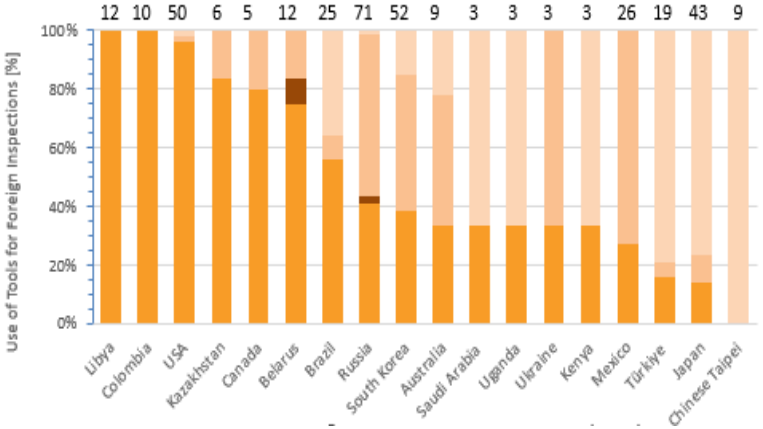
2023

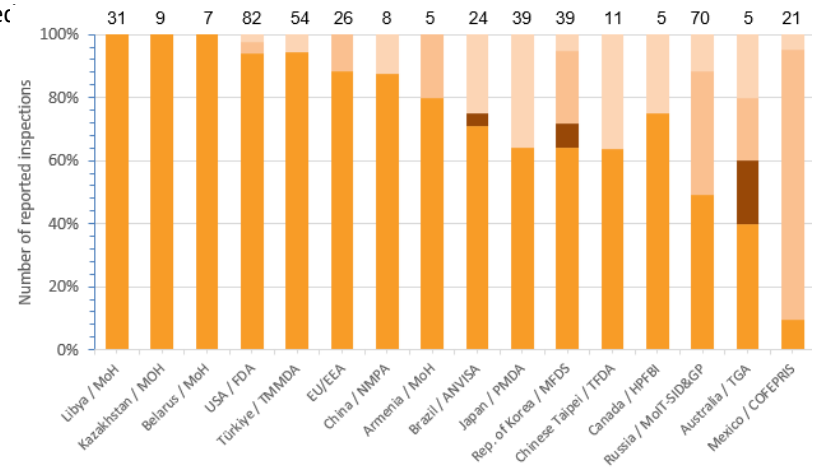




Foreign

No of inspections reported

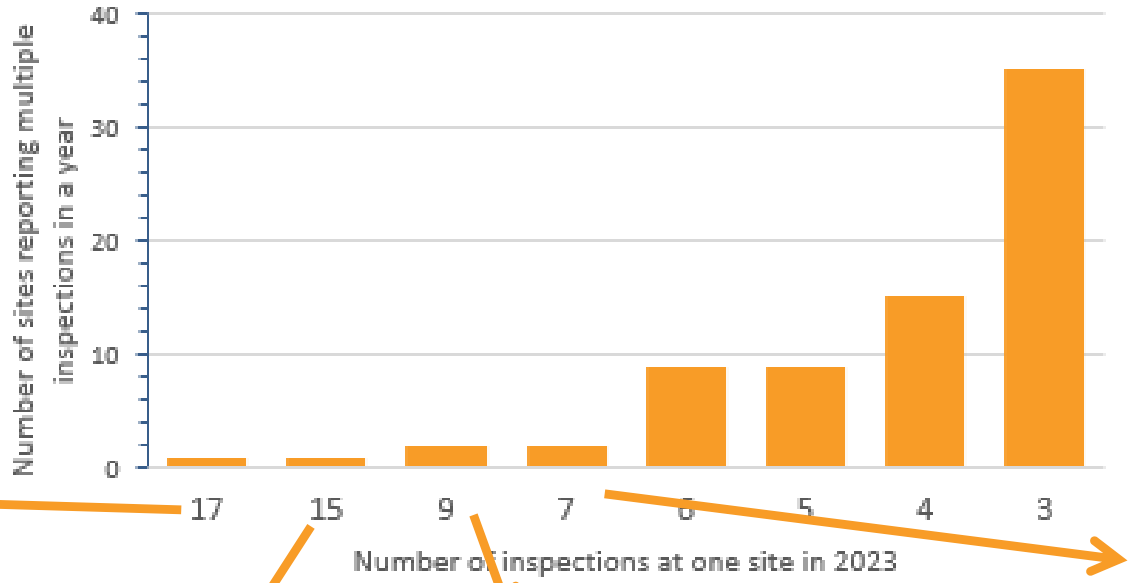




Some inspectorates (e.g., Australia, Mexico, Rep. of Korea, Russia) still see remote inspections beneficial and a valid alternative

The 2022 graphic show only inspectorates performing three and more inspections
The 2023 graphic show only inspectorates performing four an more inspections

Multiple inspections at a manufacturing site - all hosted domestic inspections too



Site in Belgium
- Belgium / FAMHP (4)
- Brazil / ANVISA (3)
- USA / FDA (2)
- EMA/Germany / BfArM
- Vietnam / MoH
- Chinese Taipei / TFDA
- Russia / MoIT-SID&GP
- Egypt / MoH
- Rep. of Korea / MFDS
- Chinese Taipei / TFDA
- Vietnam / MoH

Site in Denmark
- Denmark / DKMA (2)
- Türkiye / TMMDA (3)
- Japan / PMDA (5)
- Brazil / ANVISA
- Chinese Taipei / TFDA
- USA / FDA
- Rep. of Korea / MFDS
- Chinese Taipei / TFDA

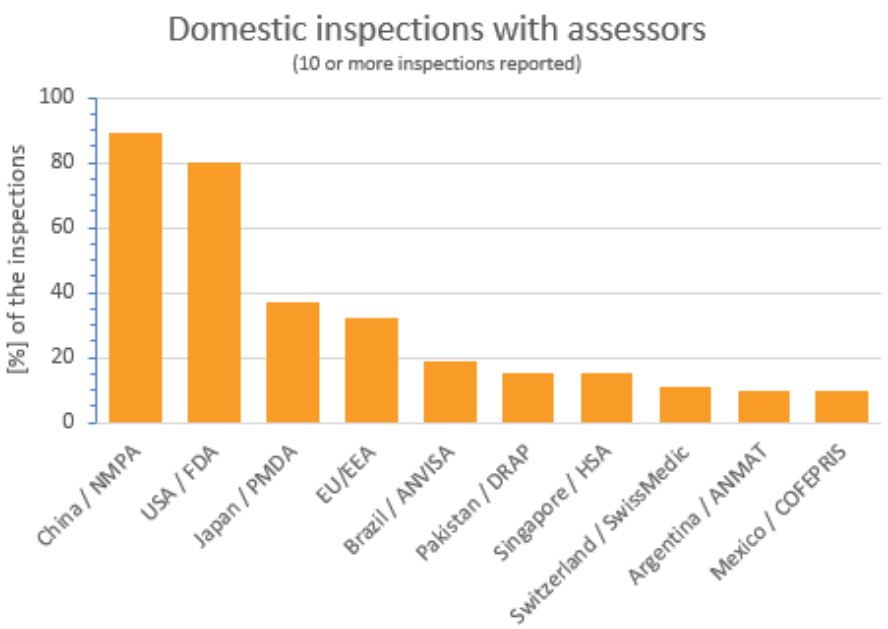
Site in China
- China / NMPA (6)
- Japan / PMDA
- Germany / BfArM
- Australia / TGA

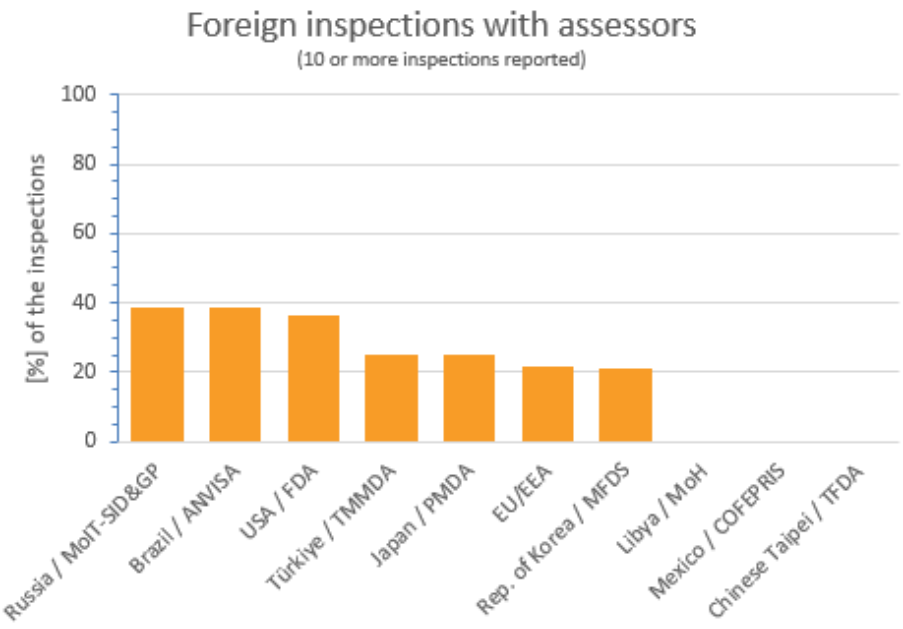
Site in US
- USA / FDA (4)
- Libya / MoH
- Japan / PMDA
- Chinese Taipei / TFDA
- Indonesia / NAFDAC
- Rep. of Korea / MFDS

Site in China
- China / NMPA(2)
- Australia / TGA
- USA / FDA
- Rep. of Korea / MFDS
- EMA
- Brazil / ANVISA

Site in US
- USA / FDA
- Russia / MoIT-SID&GP (2)
- Rep. of Korea / MFDS (2)
- Türkiye / TMMDA
- Libya / MoH

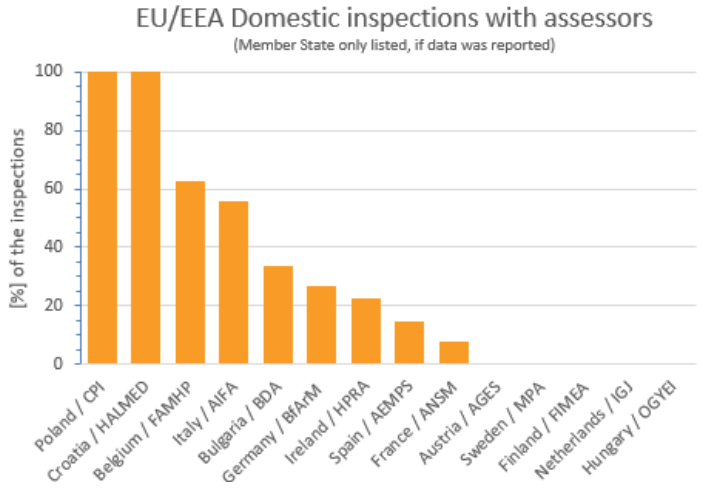
Inspections with assessors - over all

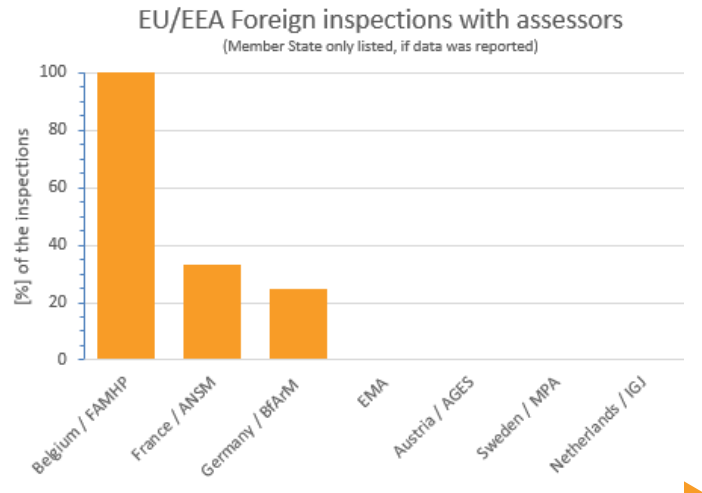




Certification audits: 10% had assessors included (3 out of 33; 30 unknown)

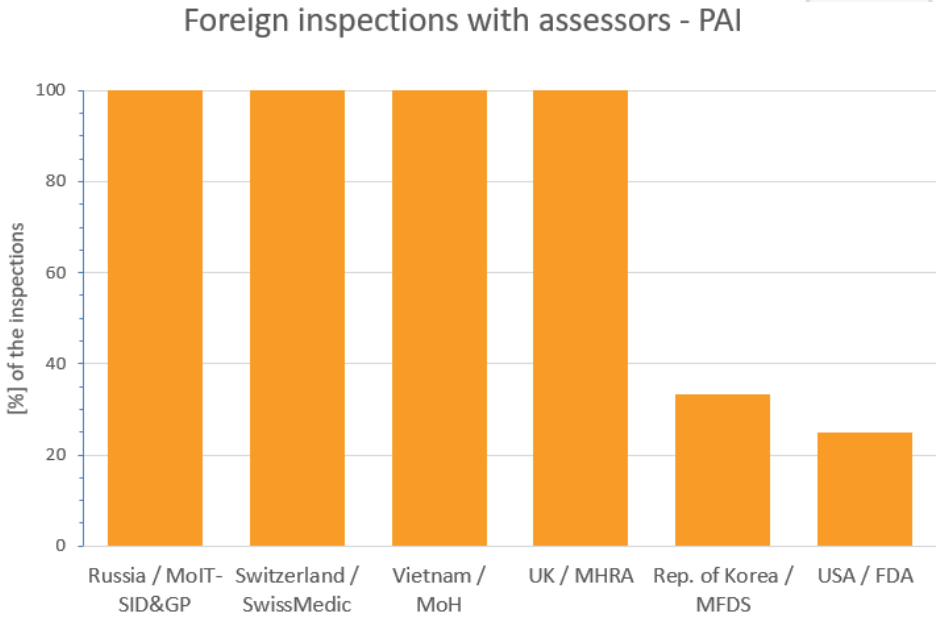
EU/EEA

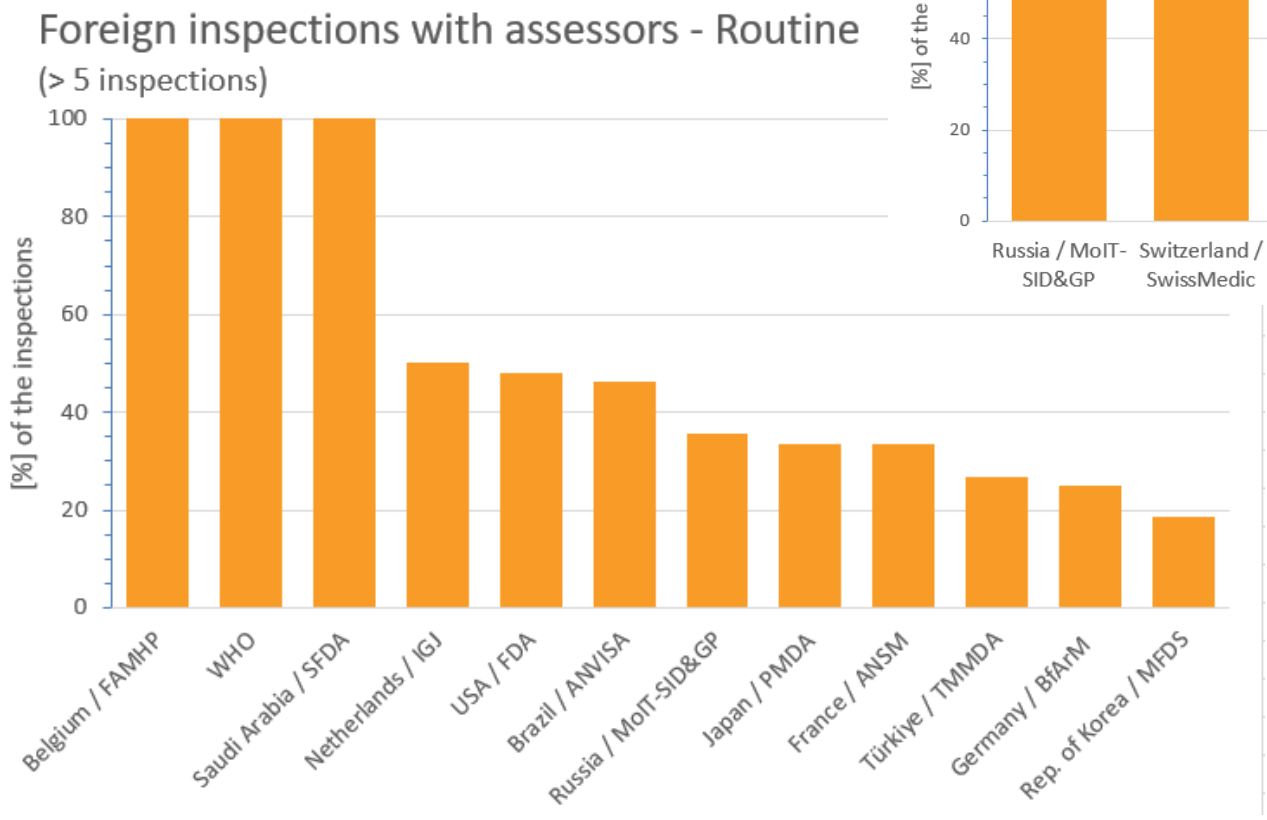




Answers giving 'unknown' are excluded

Inspections with assessors - PAI / Routine inspections

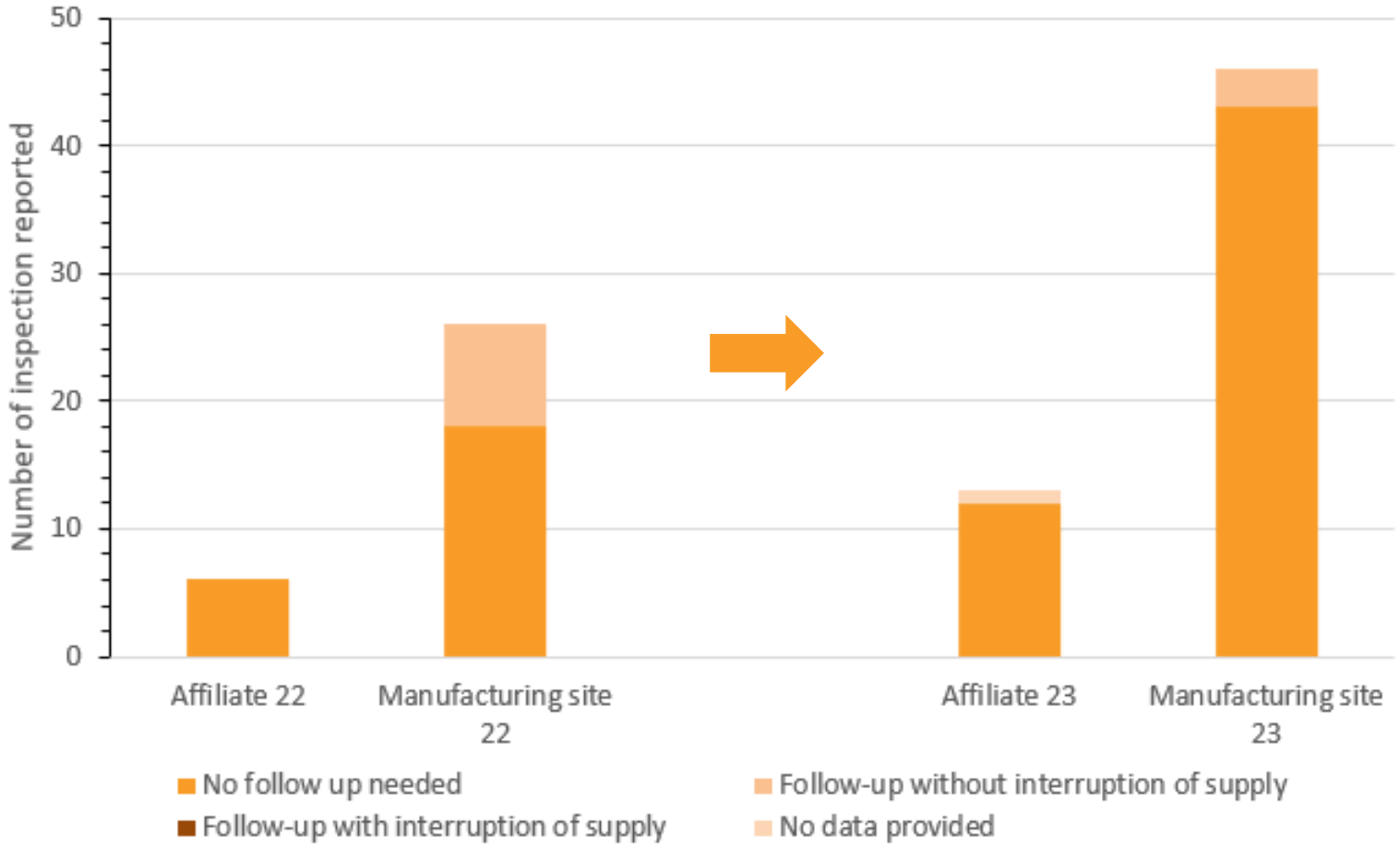




Answers giving 'unknown' are excluded

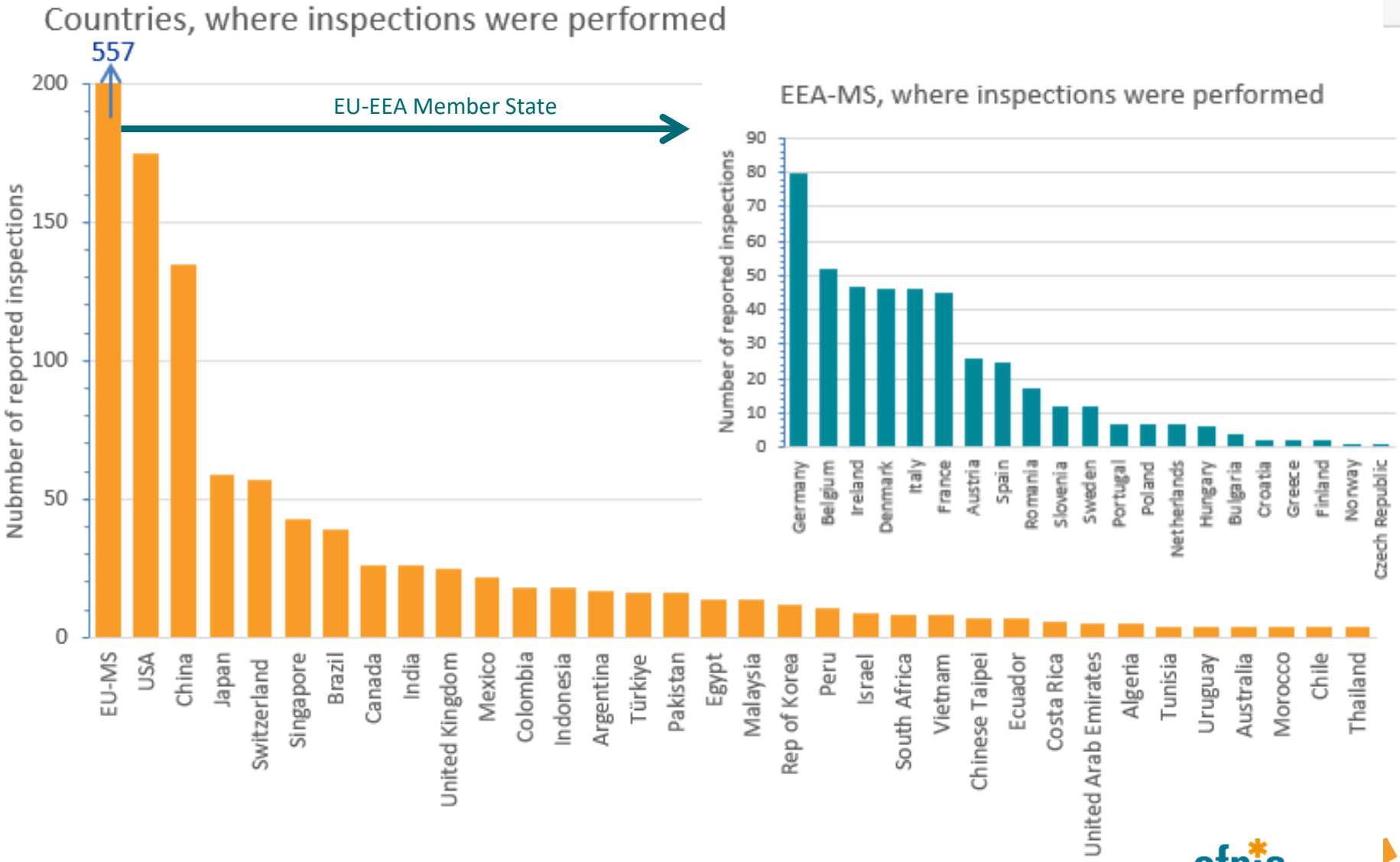
INSPECTIONS AT MANUFACTURING SITES

For cause inspections do not result in interrupted supply

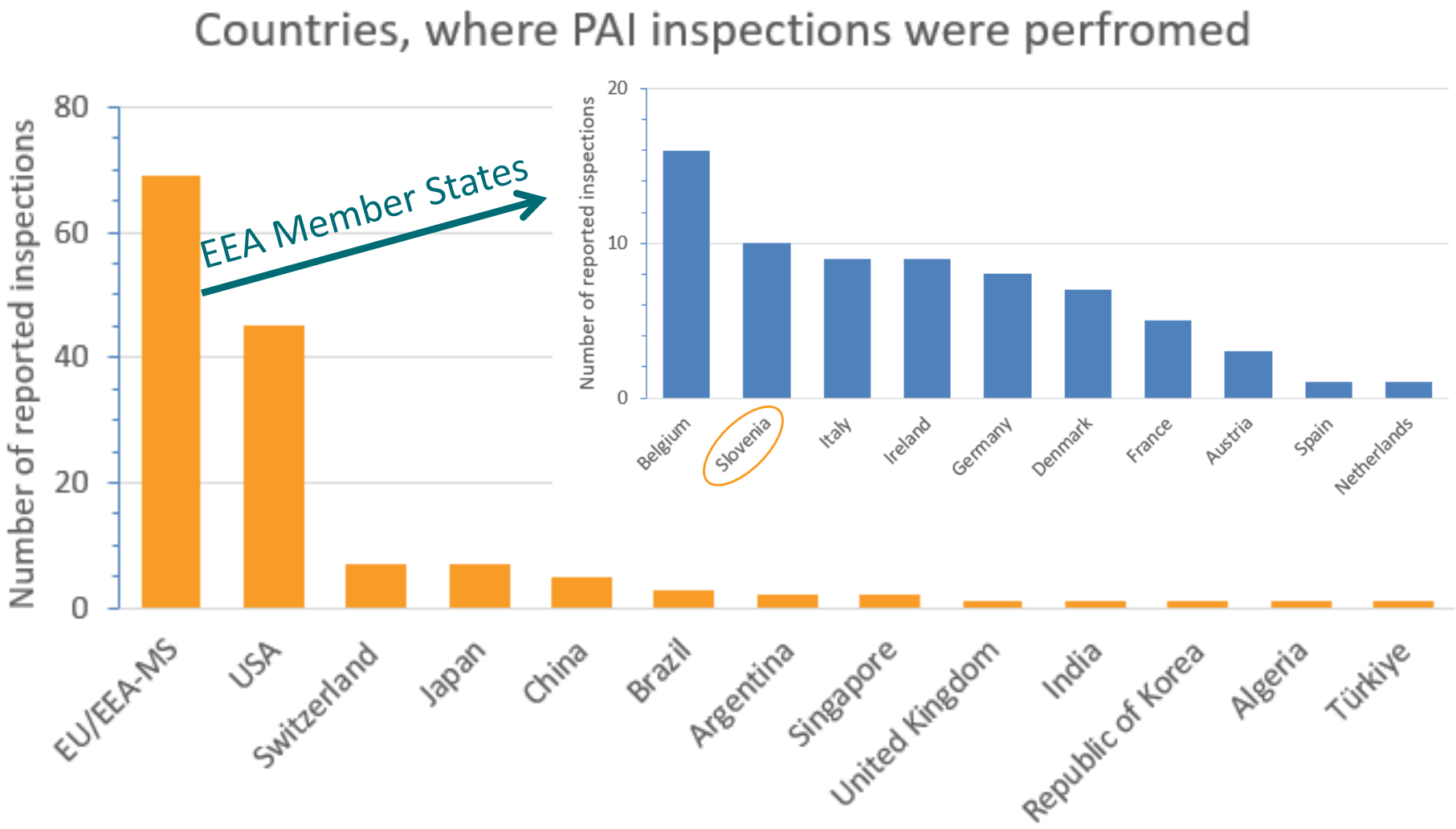


* **The number nearly doubled 2022 to 2023**

Number of inspection per country highlight's locations of manufacturing sites



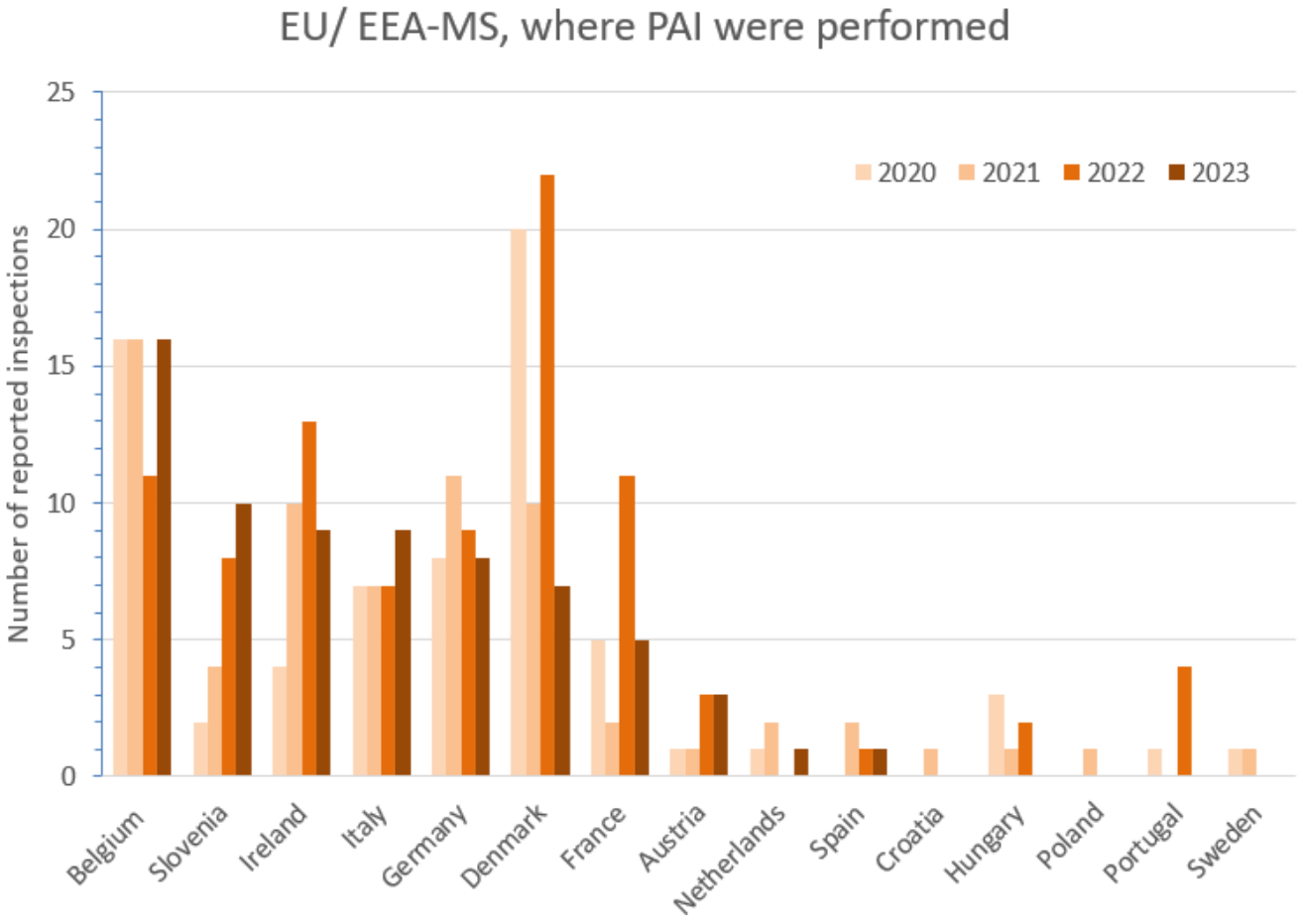
Locations of manufacturing facilities reporting PAI demonstrating where innovative products are manufactured



PAI: Pre-Approval Inspection

EU/EEA competitiveness where new innovative products are manufactured

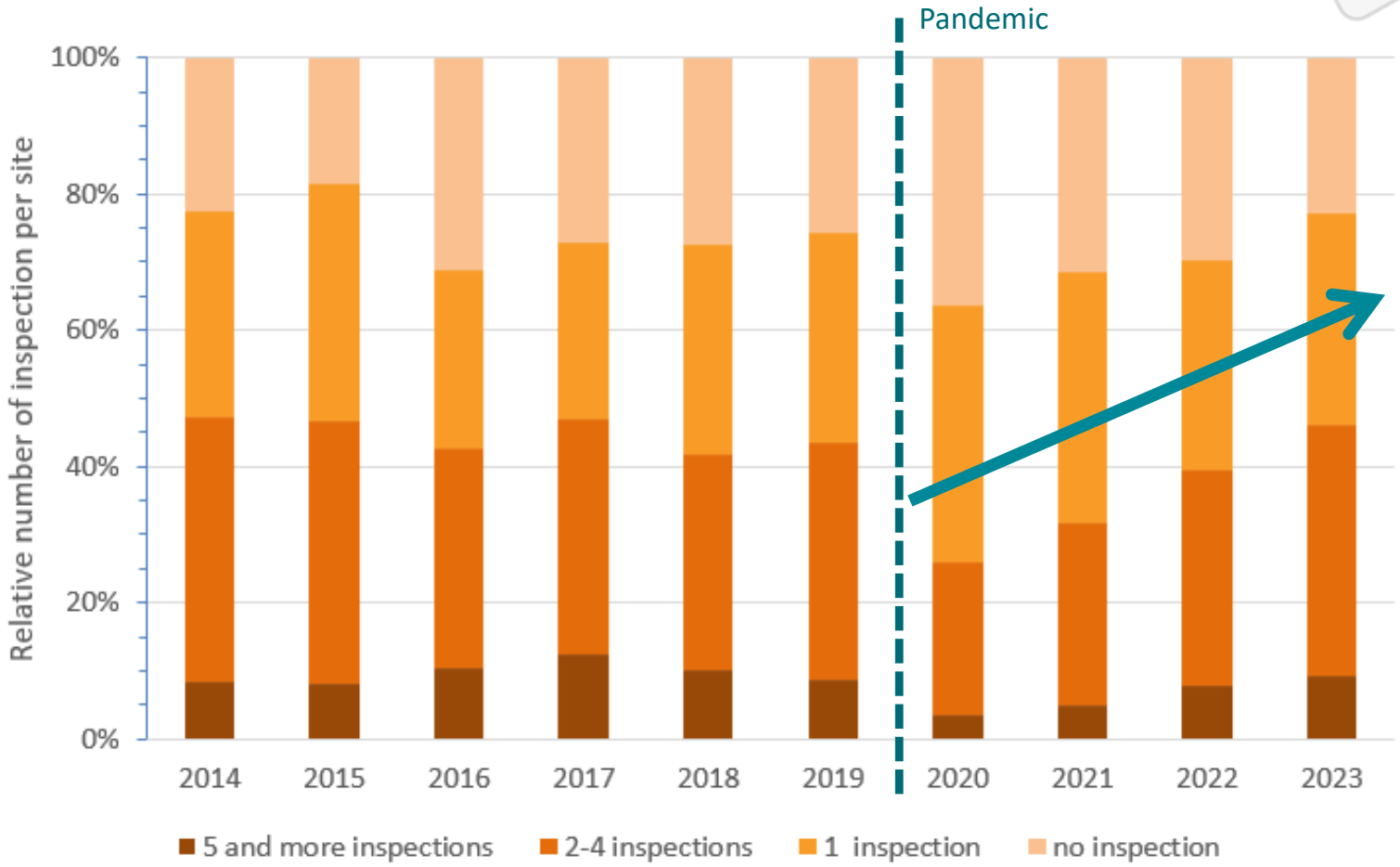
- **MS where new, innovative products are manufactured include**
  - Austria
  - Belgium
  - Denmark
  - France
  - Germany
  - Ireland
  - Italy
  - Slovenia *<growing>*



PAI: Pre-Approval Inspection

INSPECTIONS AT MANUFACTURING SITES

Number of inspections reported per site



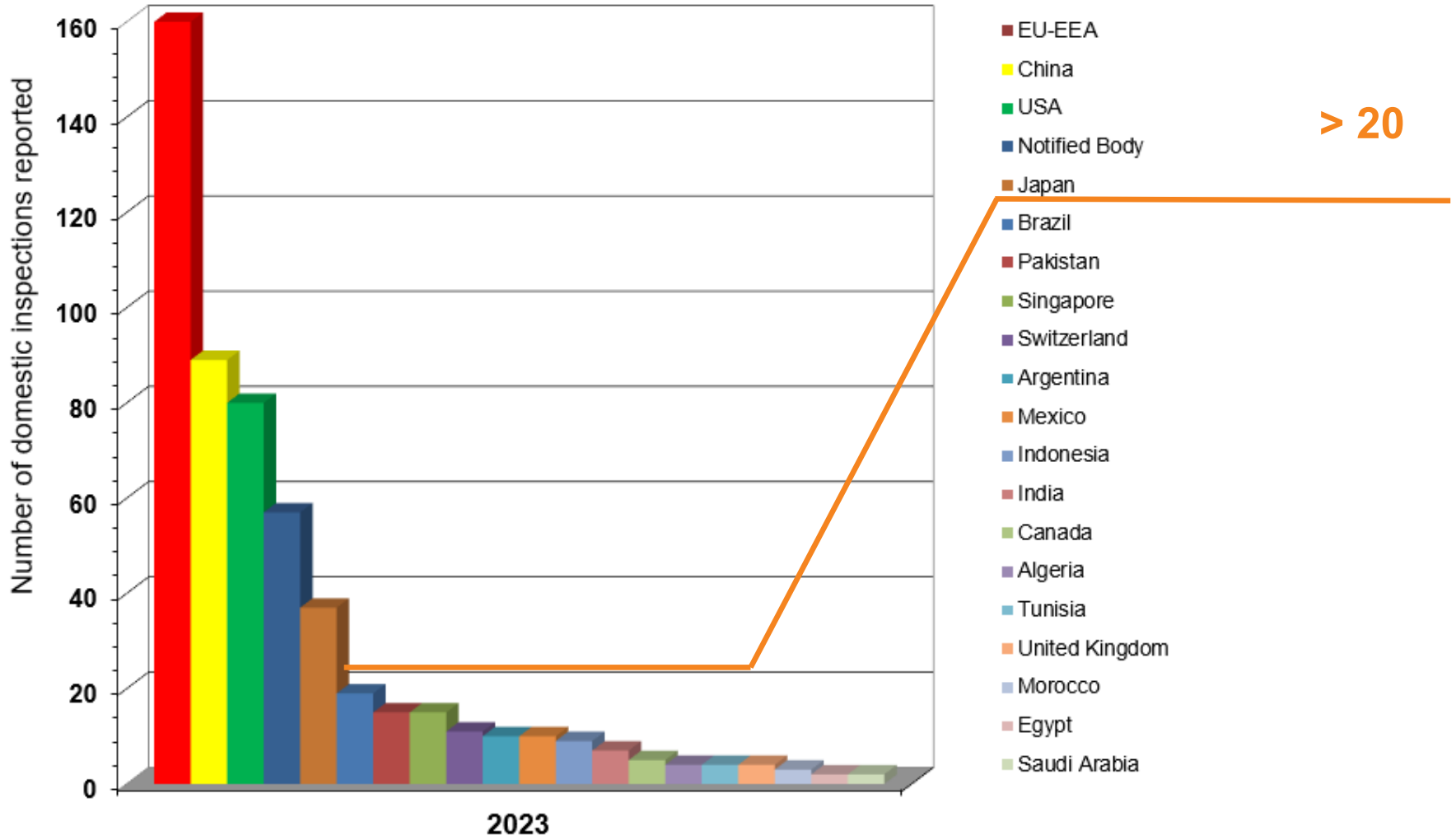
Facts

- Increasing trend towards more inspections at the same manufacturing site
  - Currently at the level of 2014-2019
- Proportion of sites without an inspection is back to the level before the pandemic

Domestic Inspection Activity

Number of domestic inspections

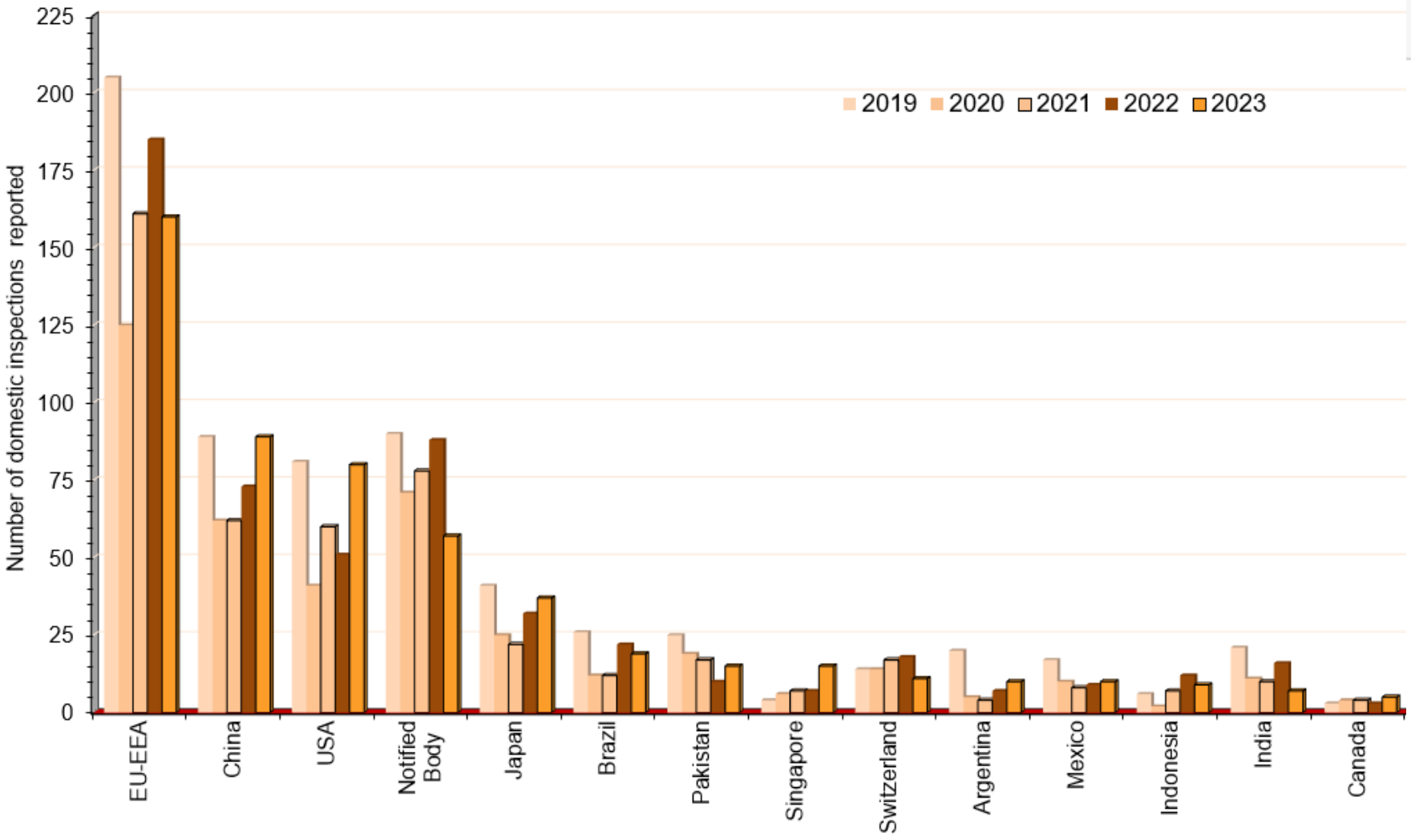
ordered by country (>1 inspections; EU/EEA as one entity; all modes)



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

DOMESTIC INSPECTIONS AT MANUFACTURING SITES

Number of reported domestic inspections

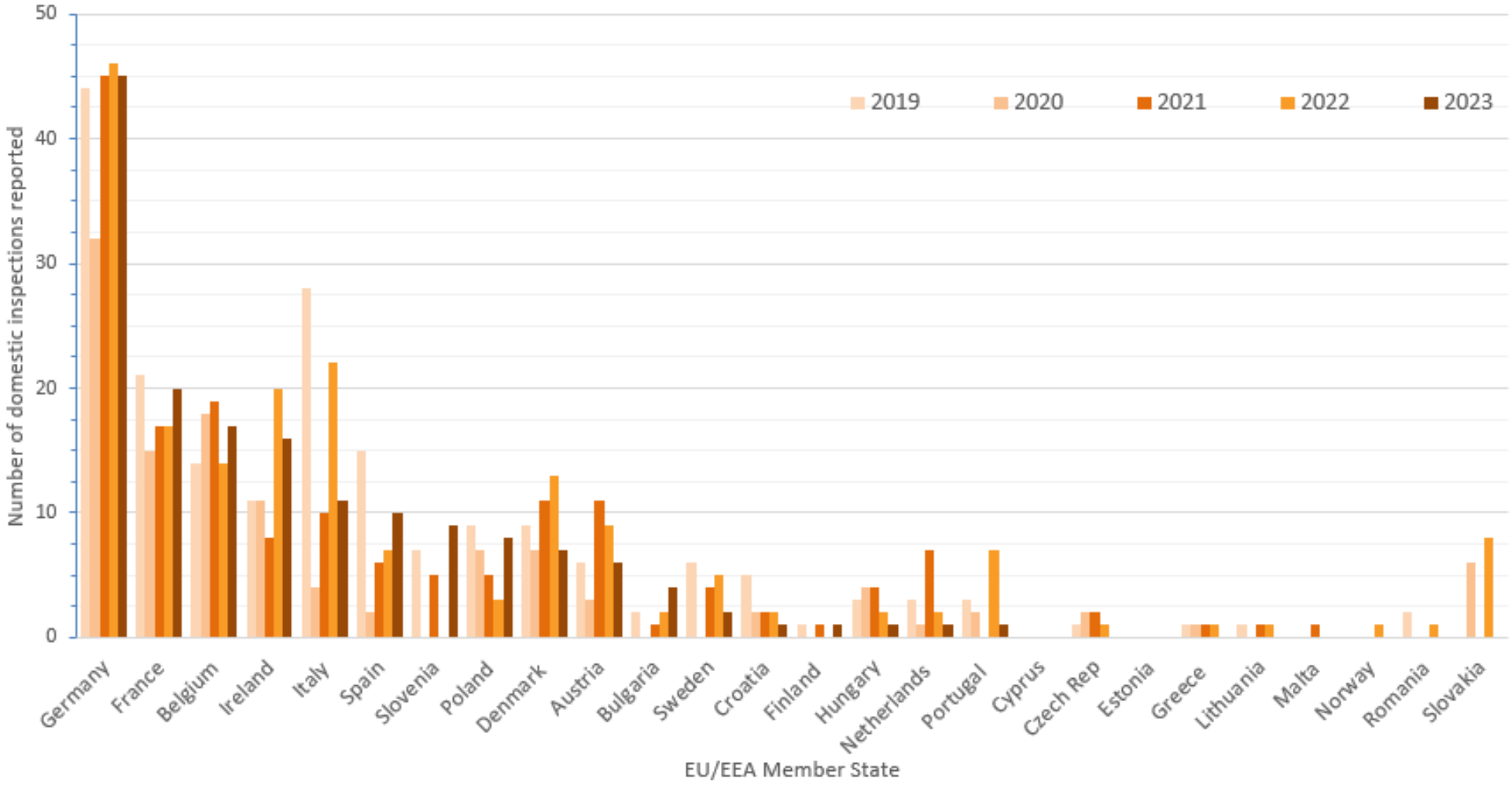


Only listed if more than 7 domestic inspections reported

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

DOMESTIC INSPECTIONS AT MANUFACTURING SITES

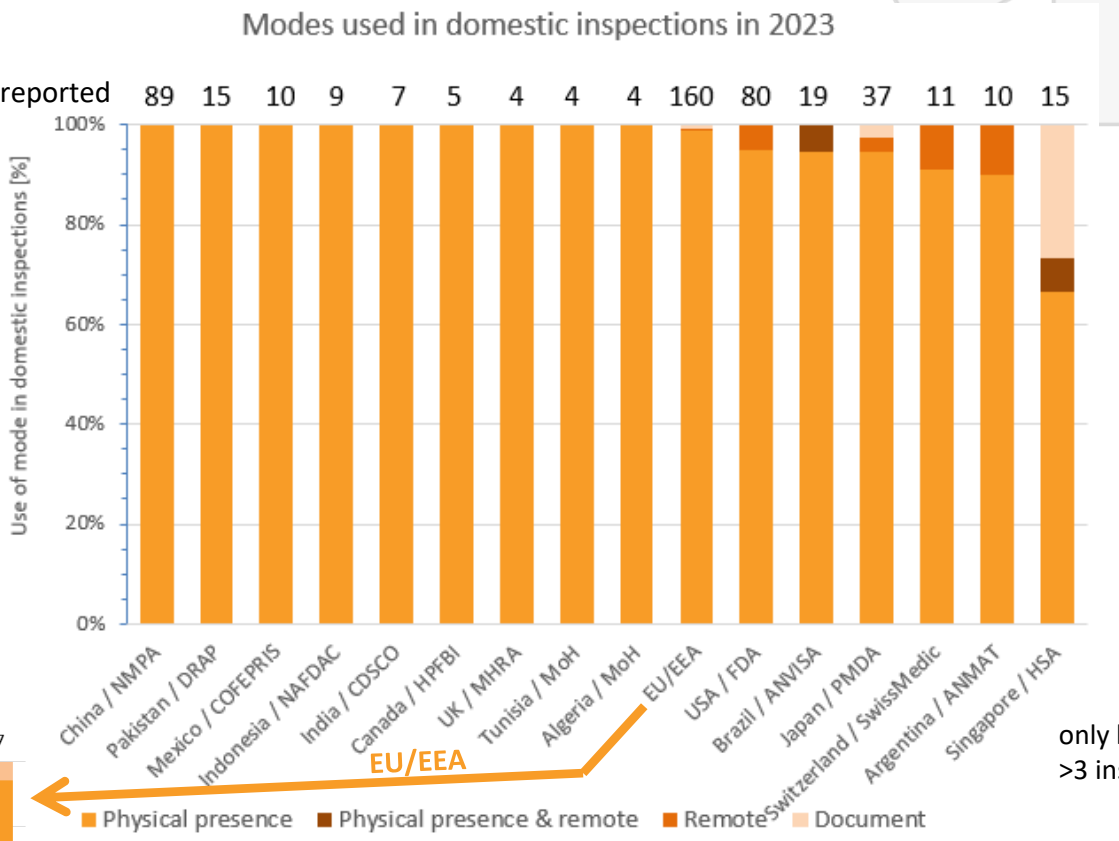
Number of reported domestic inspections by authorities in EU/EEA Member States



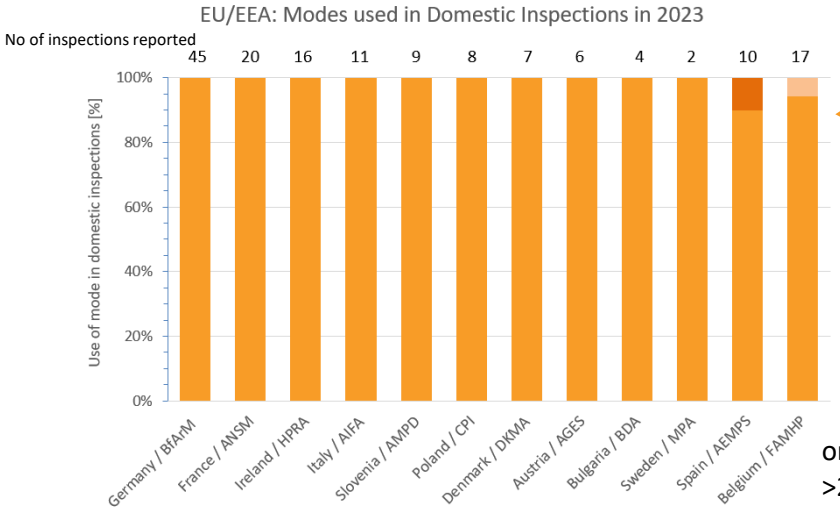
DOMESTIC INSPECTIONS AT MANUFACTURING SITES

Inspection modes used in domestic inspections

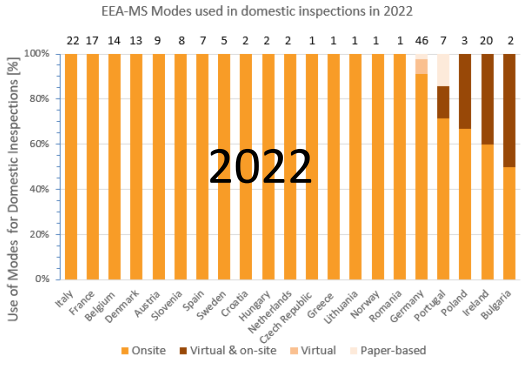
- **Domestic inspections**
  - Physical presence is the preferred mode
  - The combination of physical presence and remote presence is rarely used



only listed if >3 inspections



only listed if >2 inspection

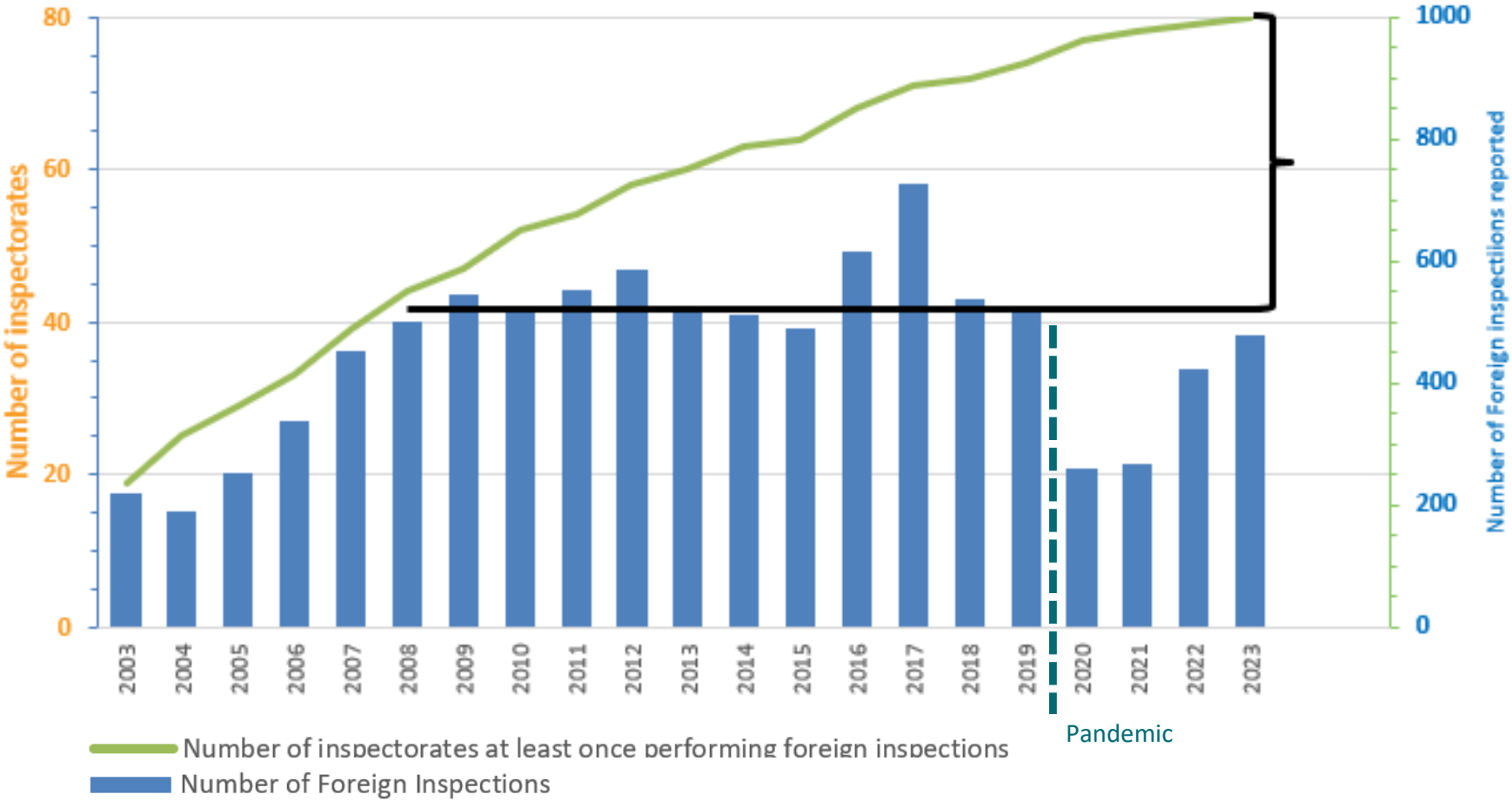


Significant less use of the remote inspection mode in comparison to 2022

Foreign Inspection Activity

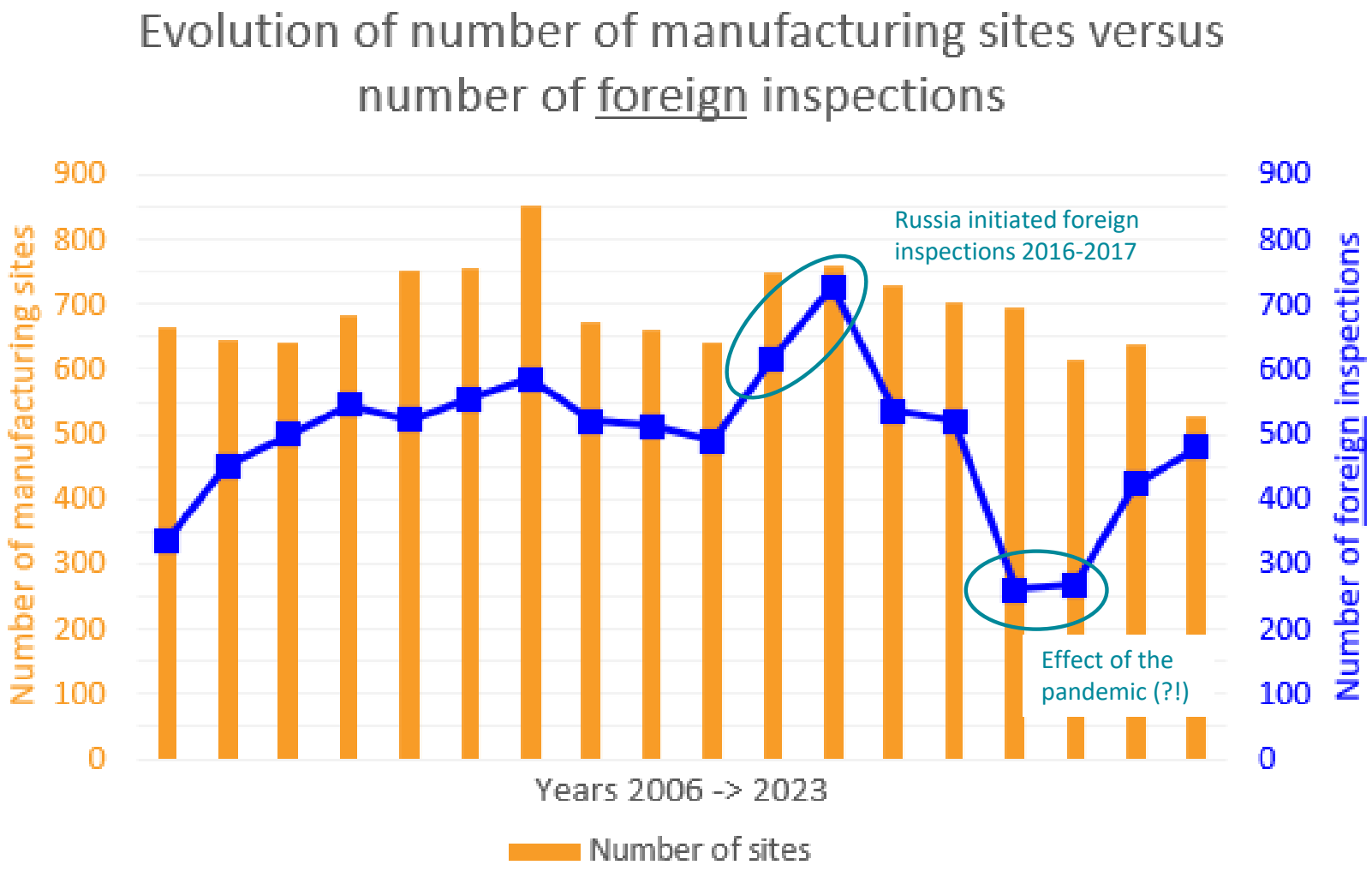
FOREIGN INSPECTIONS AT MANUFACTURING SITES

We broke the trend but back to the previous behaviours



Is this only the backlog or a trend upwards?

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

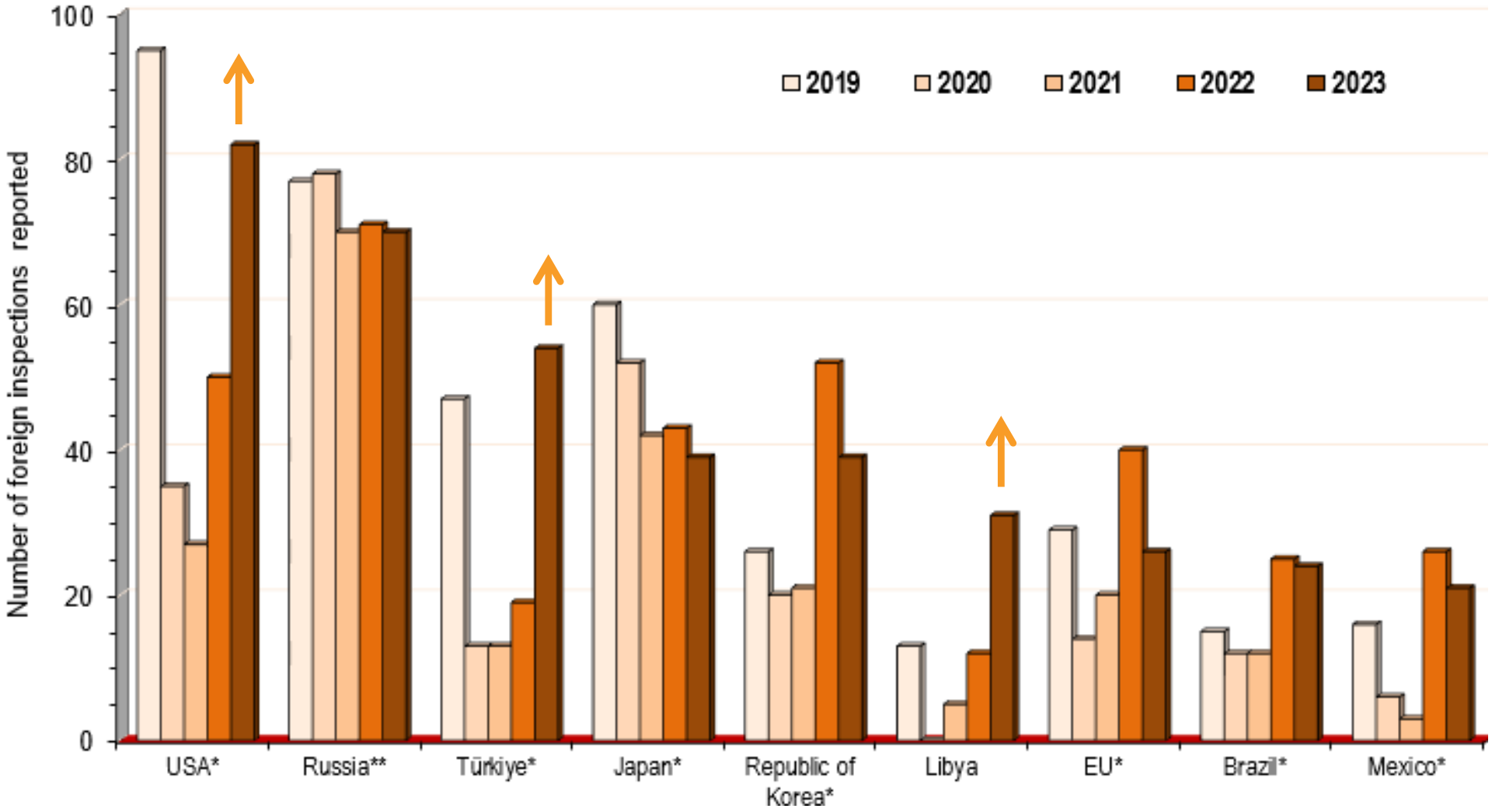


There are no indicators that oversight of the sites was impacted

All inspections included independent of the mode used

FOREIGN INSPECTIONS AT MANUFACTURING SITES

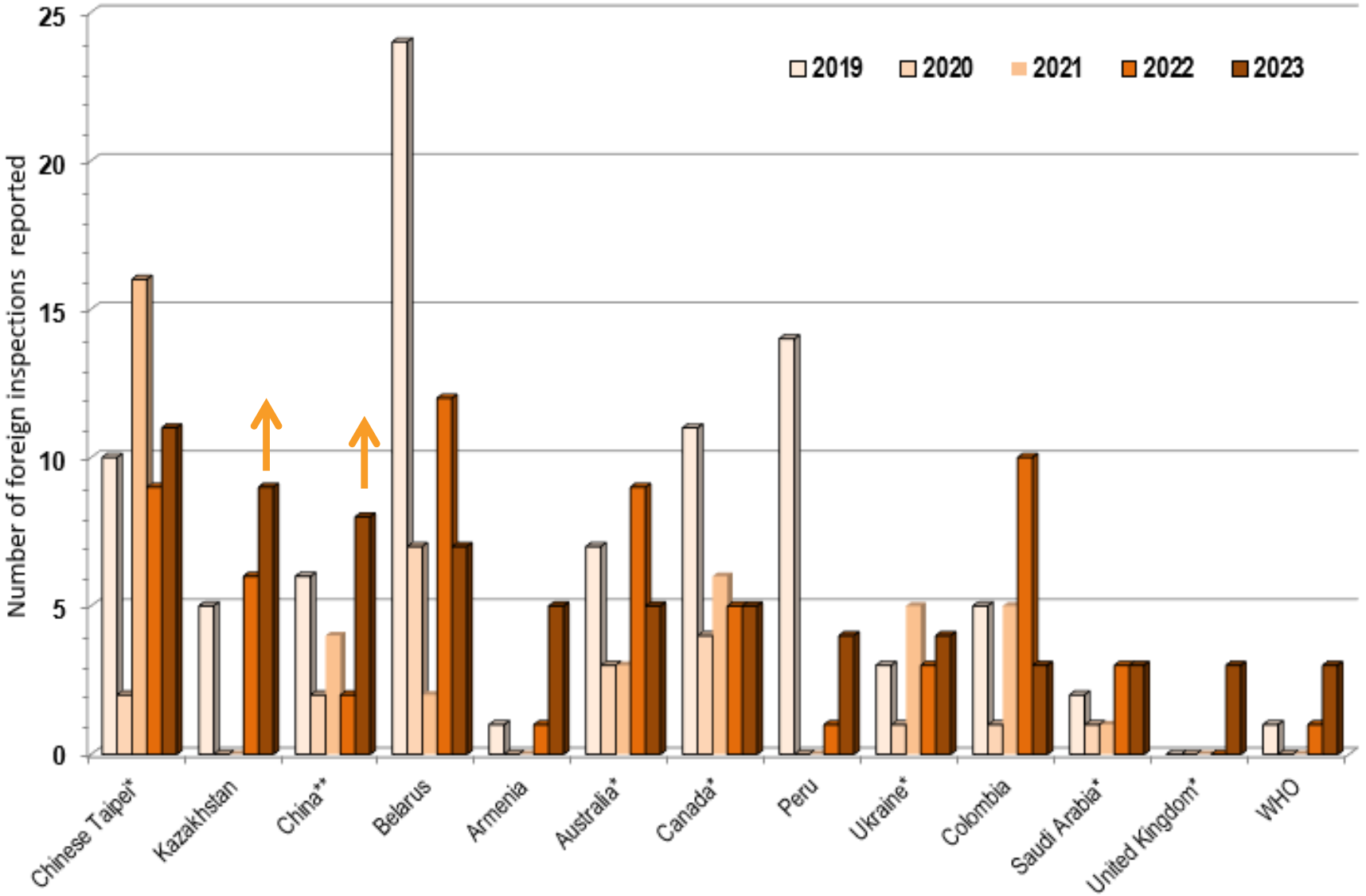
Number of foreign inspections by country 1/2



*Inspectorate is a PIC/S member **PIC/S applicant

FOREIGN INSPECTIONS AT MANUFACTURING SITES

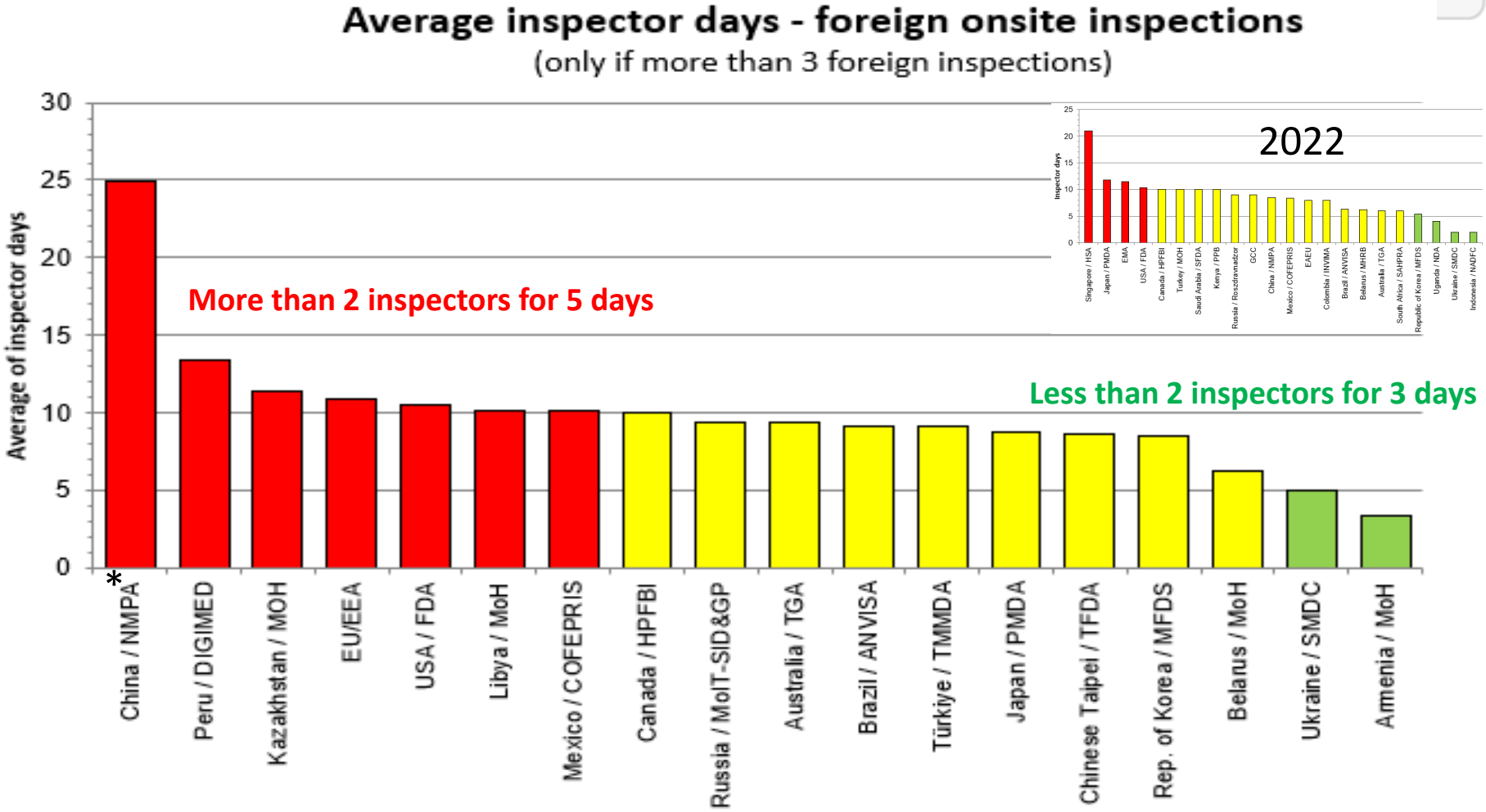
Number of foreign inspections by country 2/2



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

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

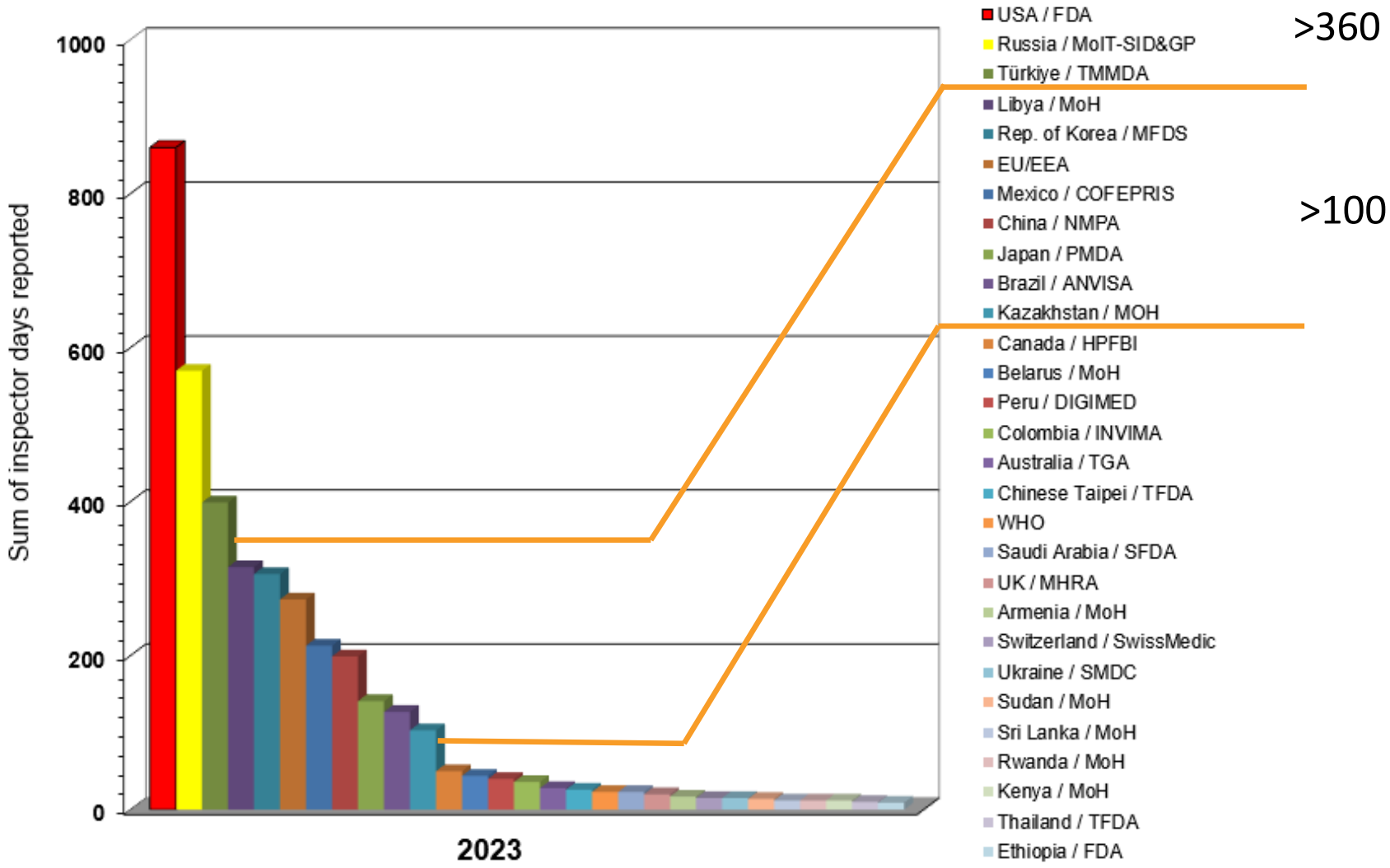
Average inspector days for foreign inspections at a manufacturing site (onsite only)



We observe an increasing average of inspector days
Why? - Additional inspectors for training purposes?

*for China 4.5 inspectors in average – assumption: training of inspectors?

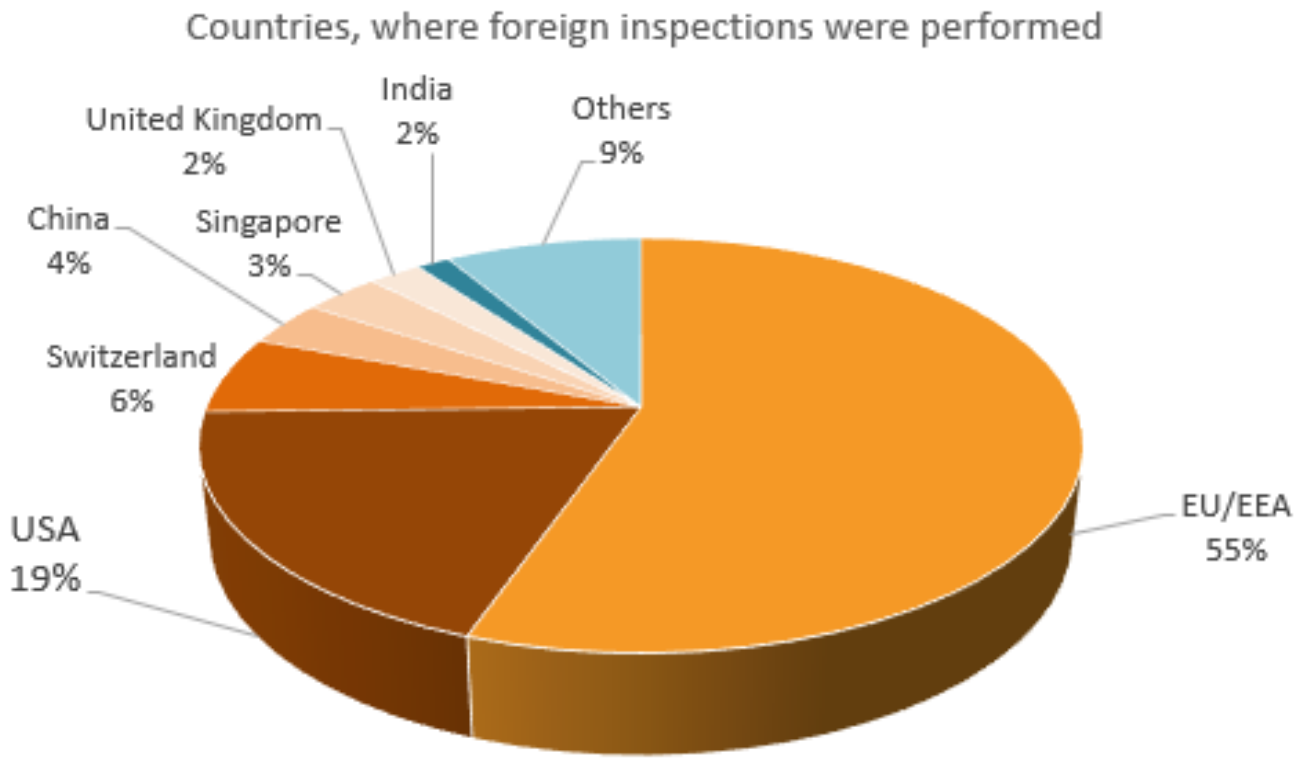
Inspector days spent on foreign inspections at manufacturing sites (onsite only)



Excluded 13 inspectorates with < 10 days

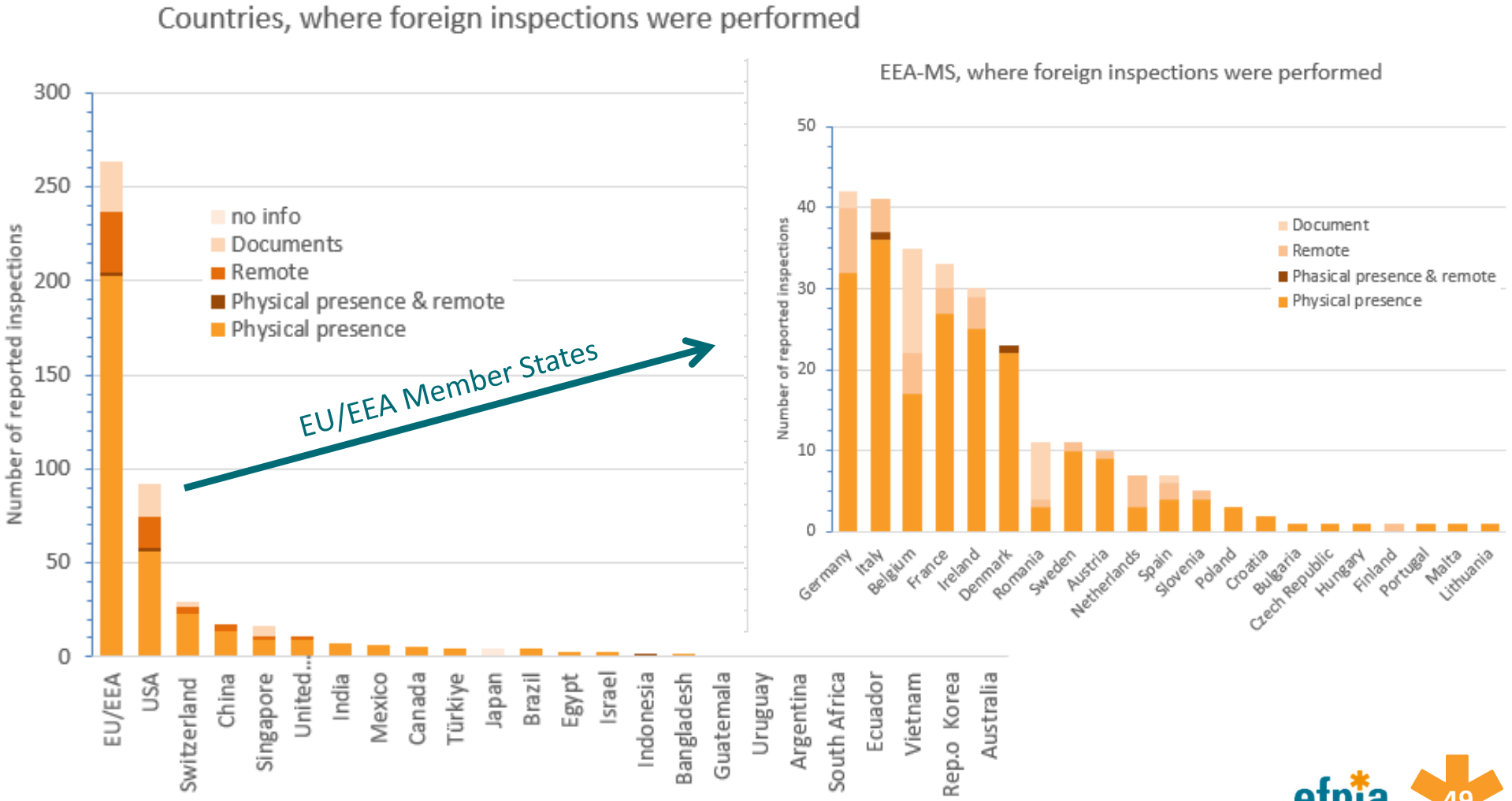
Locations of manufacturing facilities hosting foreign inspections

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

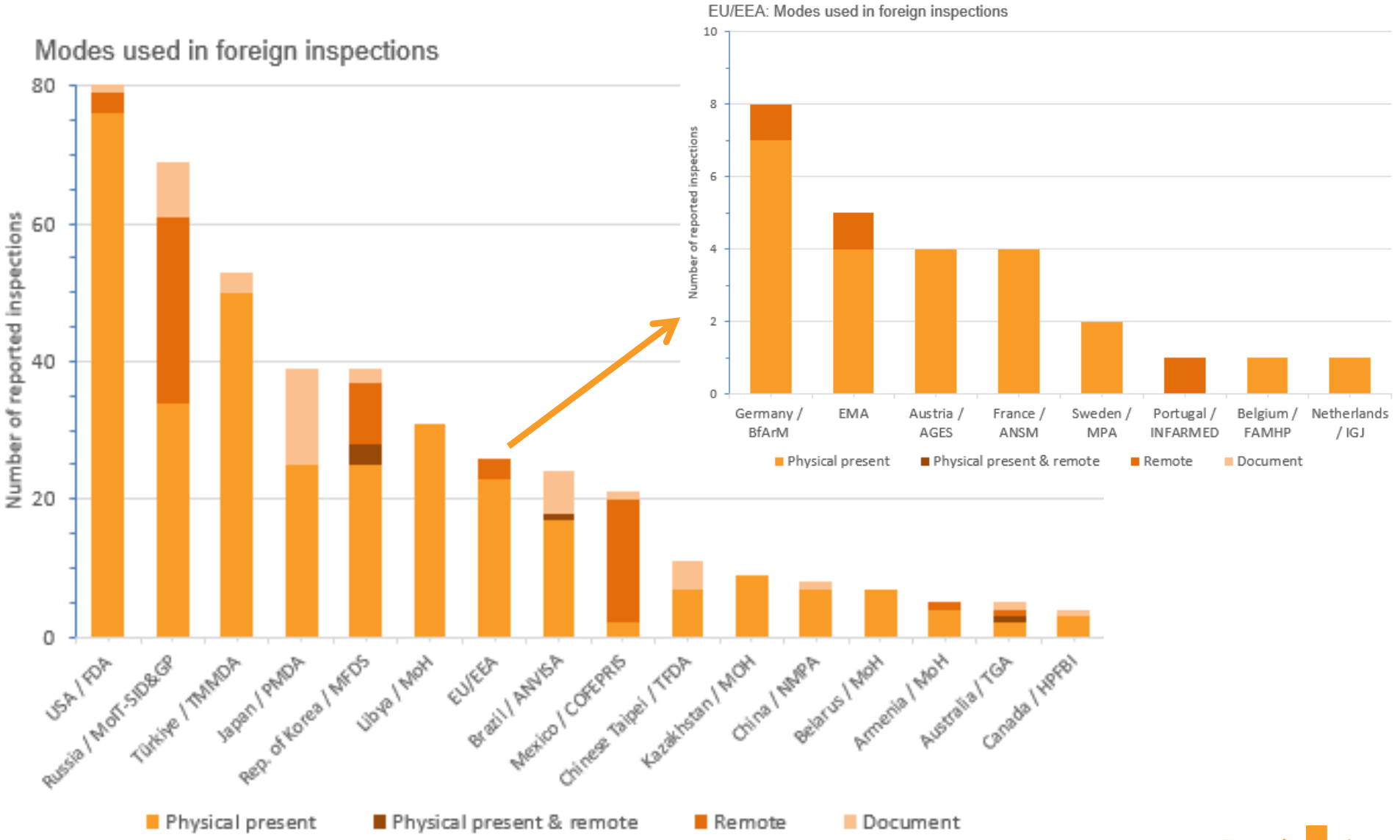


About 80% of the foreign inspections are conducted in EU/EEA, US and Switzerland

Locations of Manufacturing Facilities Hosting Foreign Inspections

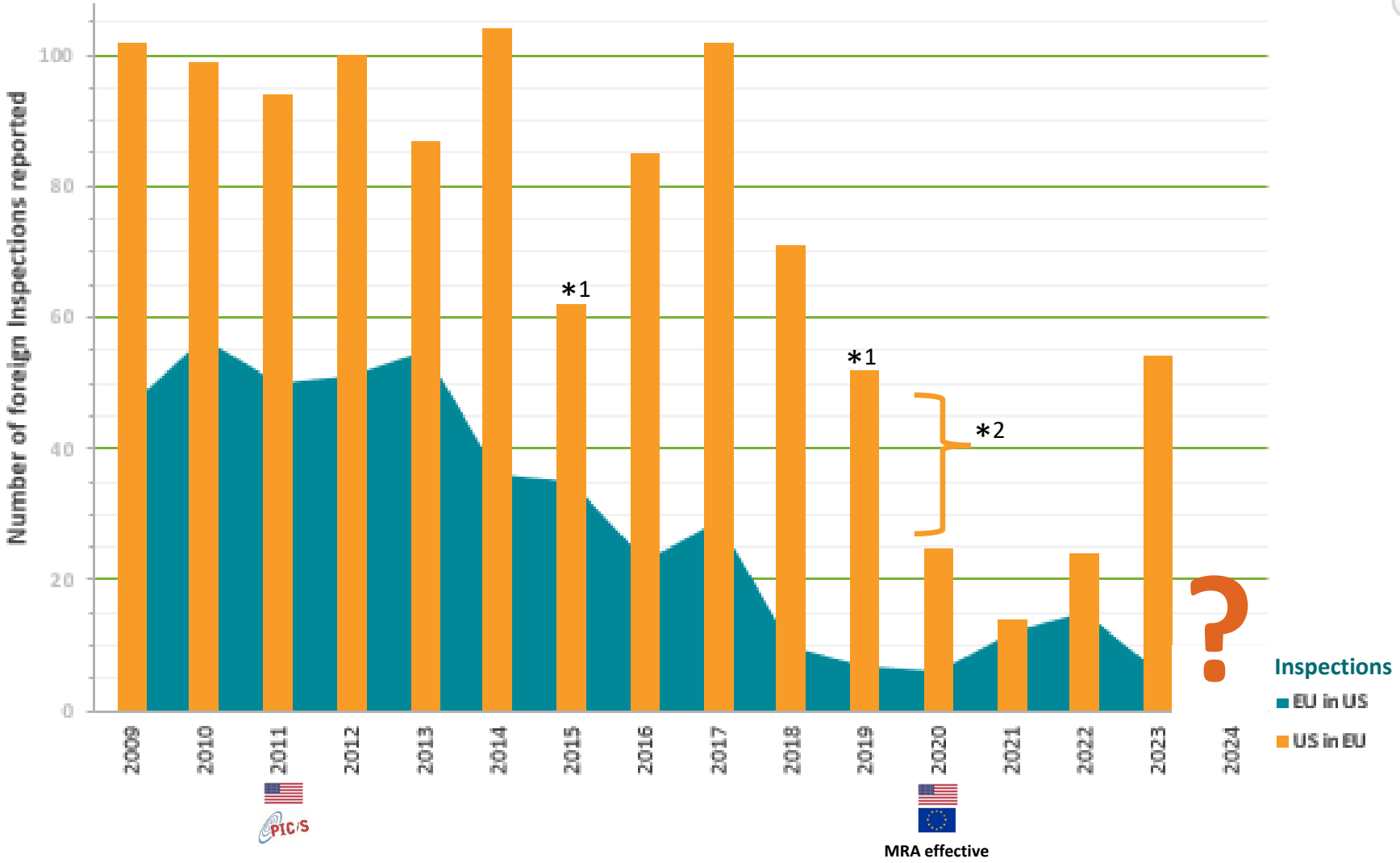


Modes used by inspectorates in foreign inspections



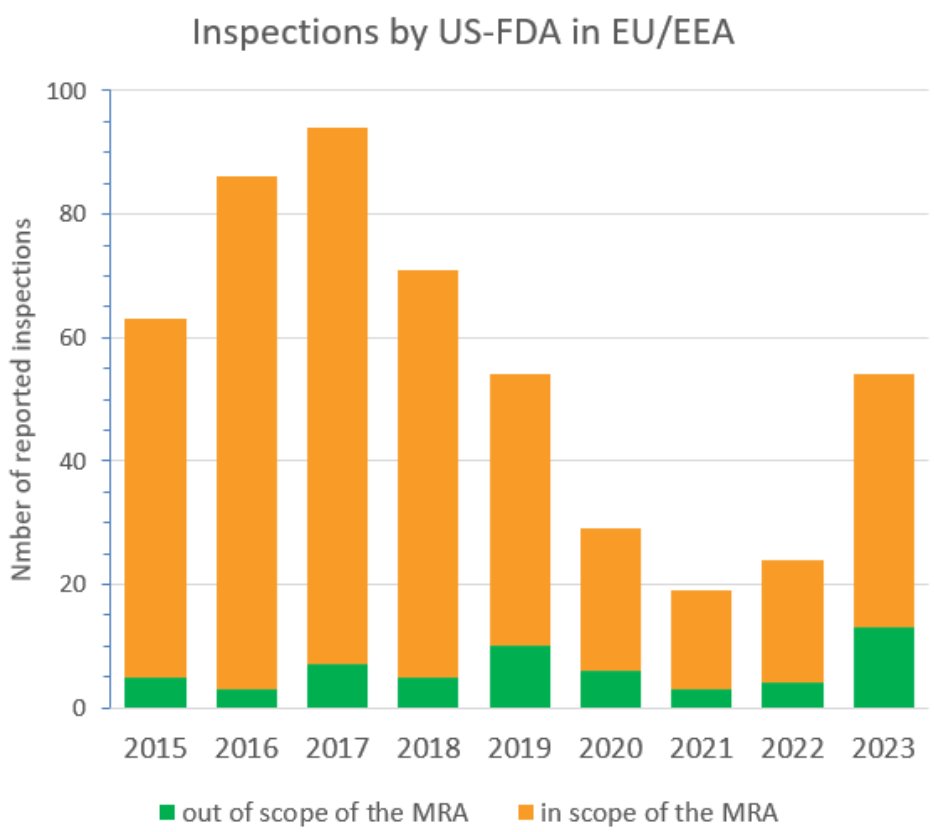
Mutual Recognition Agreements

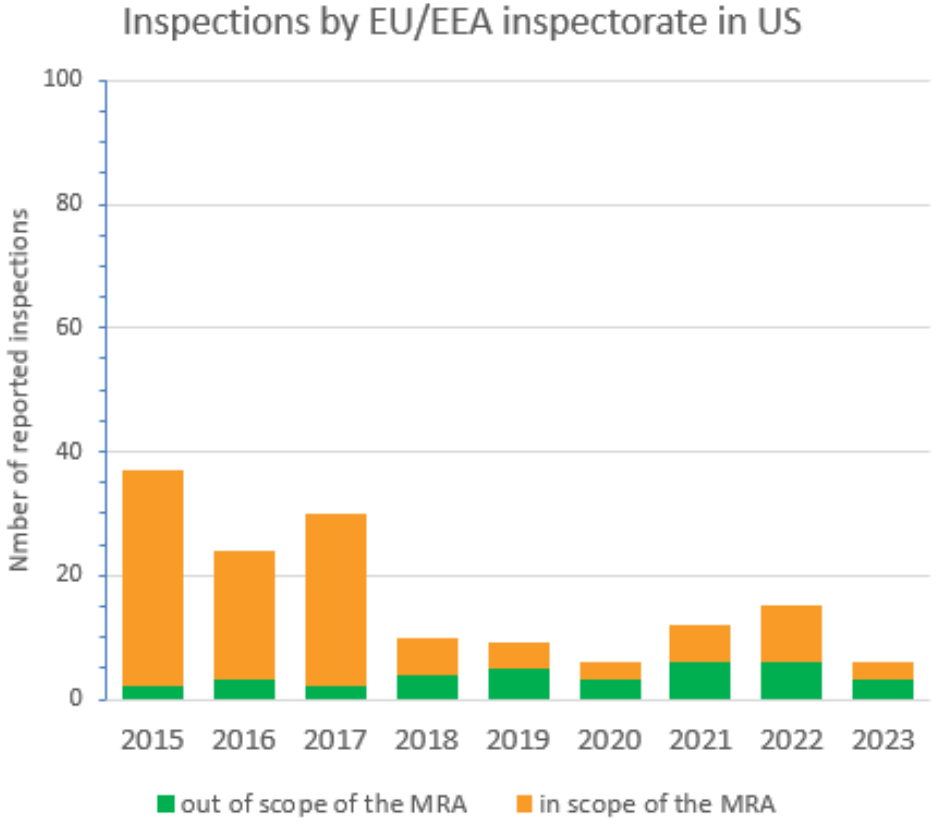
Full EU / US MRA implementation could leverage further benefits



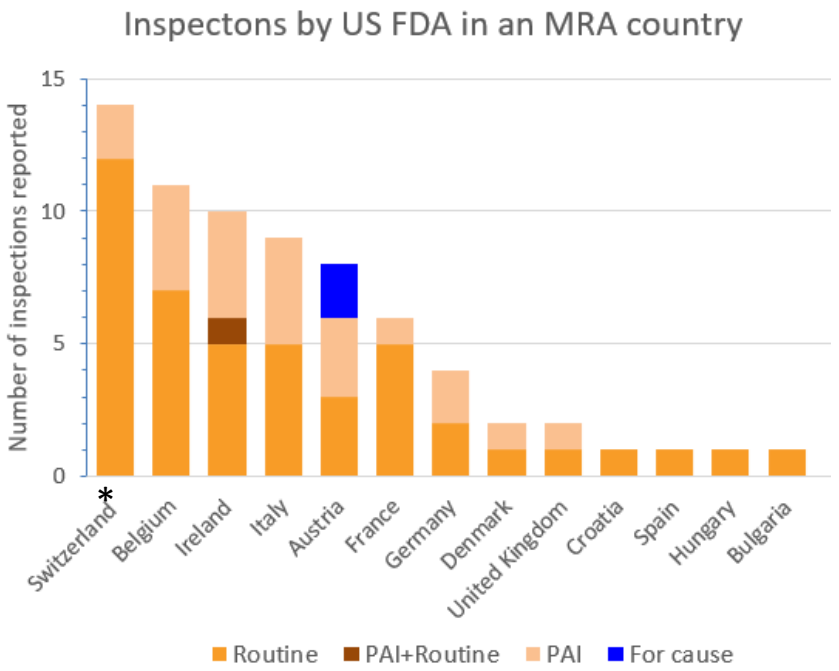
*1 Government shut down in US >20 days
*2 Effect may only result from the general reduction of foreign inspections in 2020 (~50%)
*3 7 out of 15 inspection from the EU in US had been reported to be for vaccines or ATMP

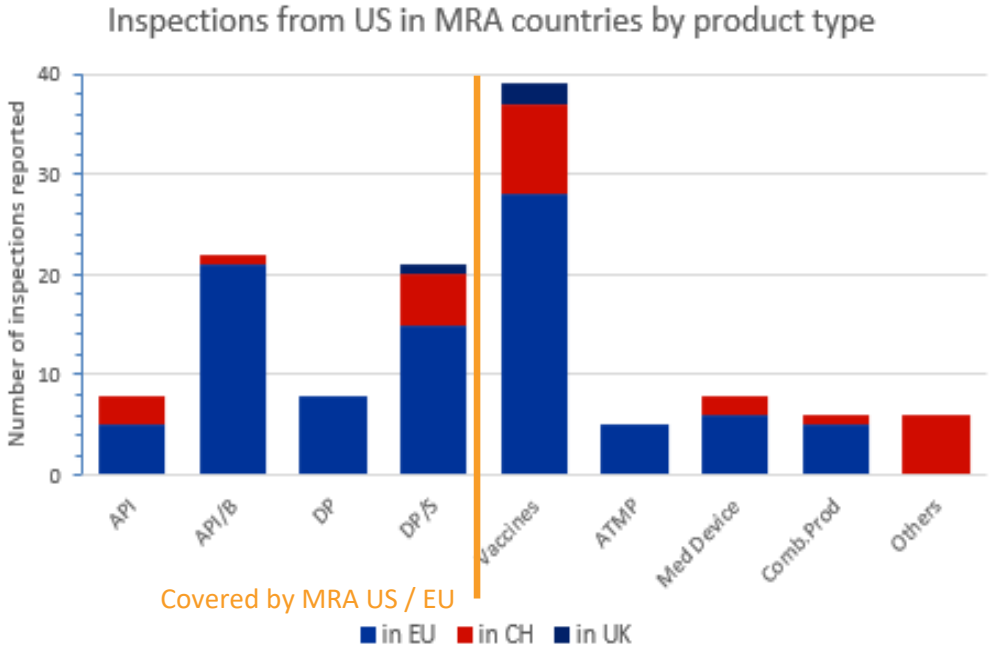
Inspections in each other territory as of scope





Full MRA implementation could leverage further benefits





- **70/162 of reported foreign inspections are performed in an MRA country**
- **39/ 70 cover products under the MRA**
  - 20 routine inspections, 17 PAI, 2 for cause

*MRA US - Switzerland was made effective for routine inspections July 2023

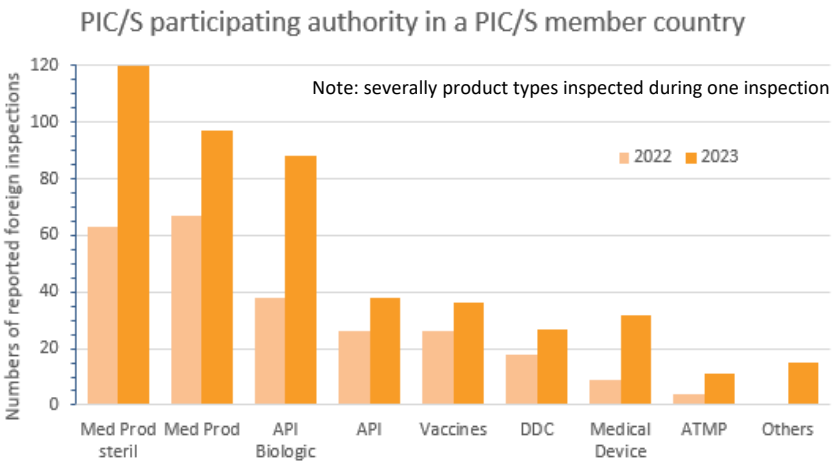
PIC/S

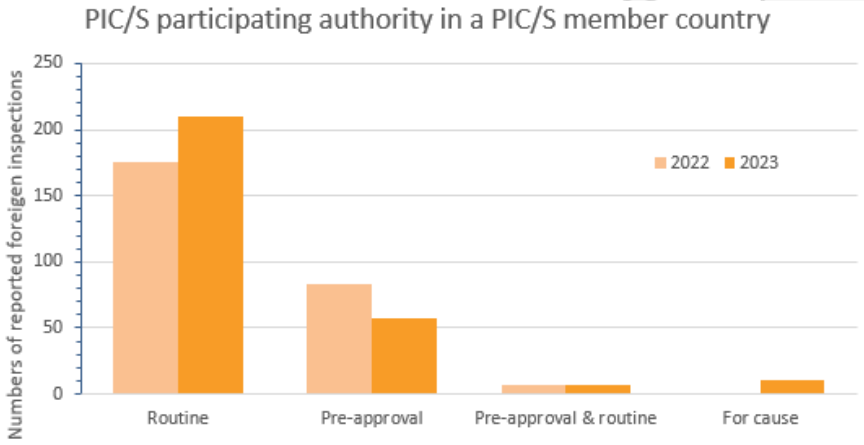
LEVERAGE TOOLS e.g.,

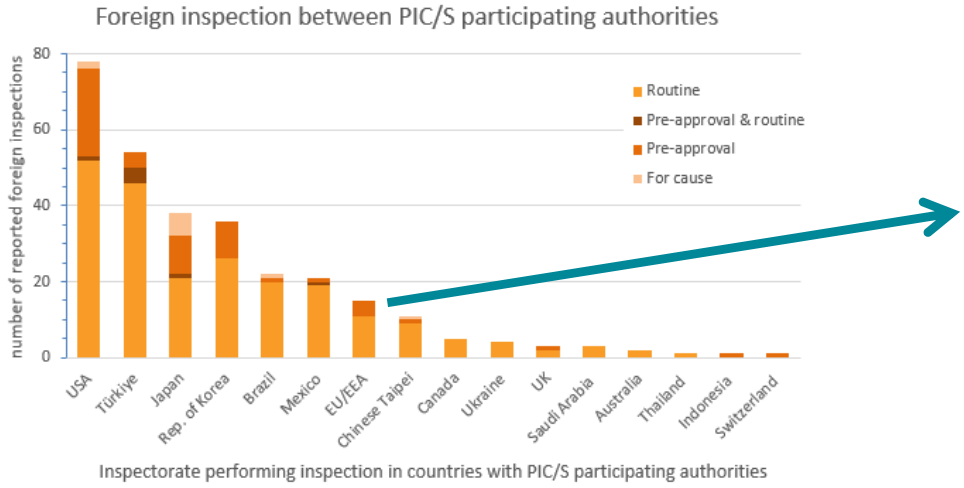
- **Risk-based inspection planning**,
  PIC/S guideline PI 037-1, 1 January 2012
- **GMP-Inspection reliance**,
  PIC/S guideline PI 048-1, 01 June 2018

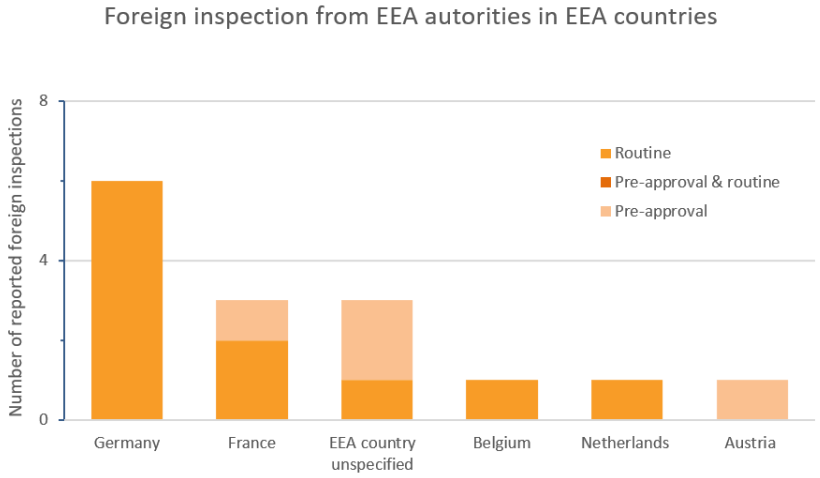
PIC/S Participating Authorities

≈2'500
inspector days used





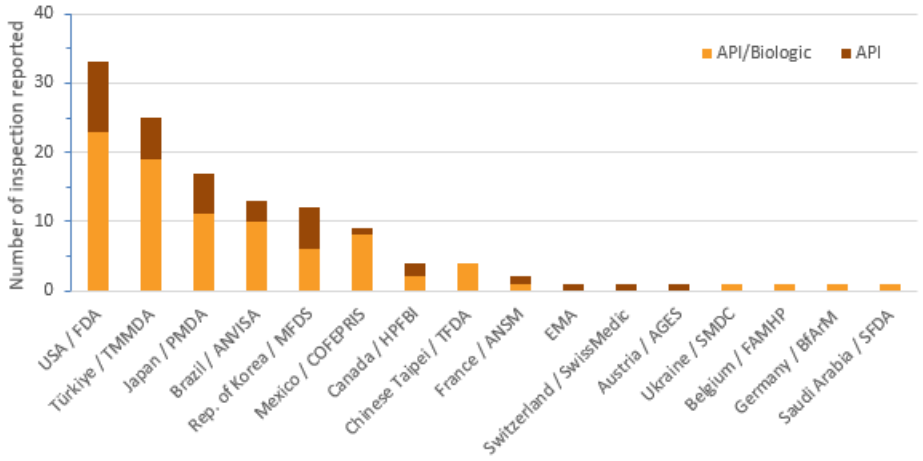




* **295/480 (62%; 63% in 2022) of the reported foreign inspections at manufacturing sites are amongst the PIC/S participating authorities**

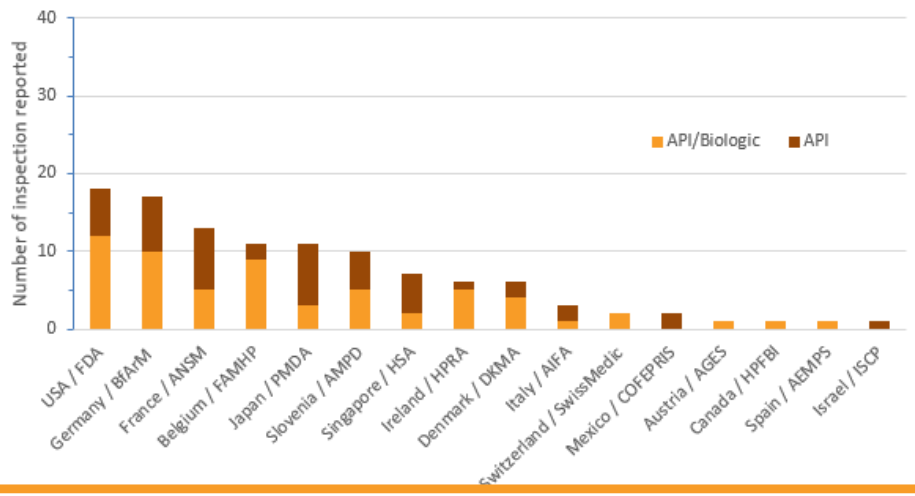
API inspections among PIC/S members

PIC/S inspectorate inspecting in countries with a PIC/S participating authority

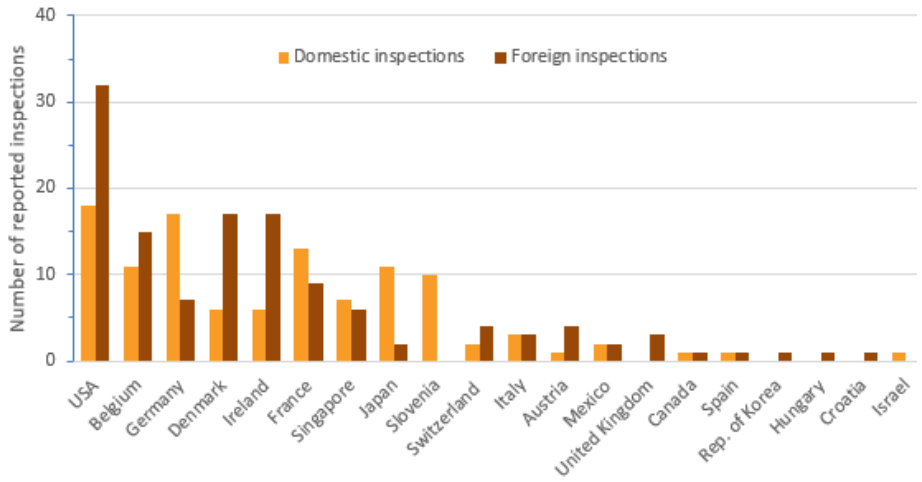


Domestic oversight by inspectorates

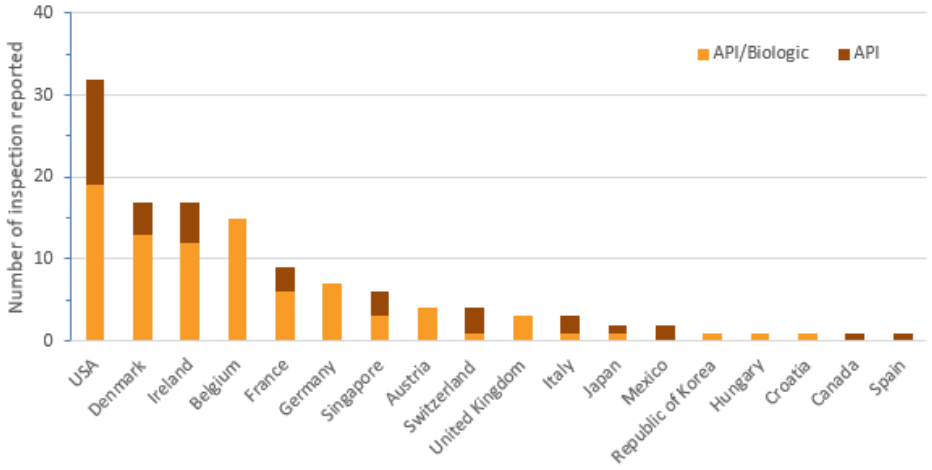
PIC/S member inspectorate perfoming domestic API inspections



Sites receiving inspections



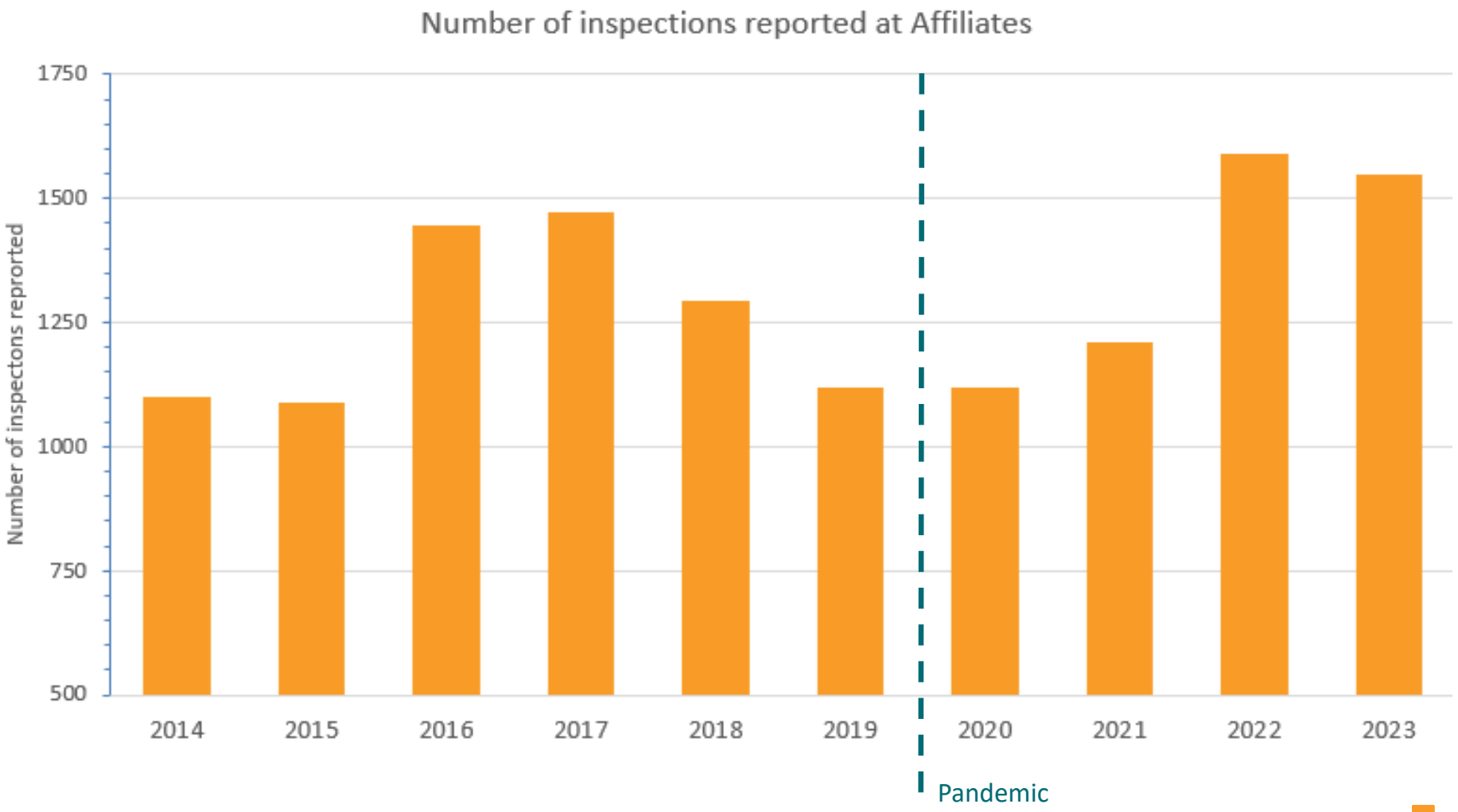
Sites receiving foreign inspections



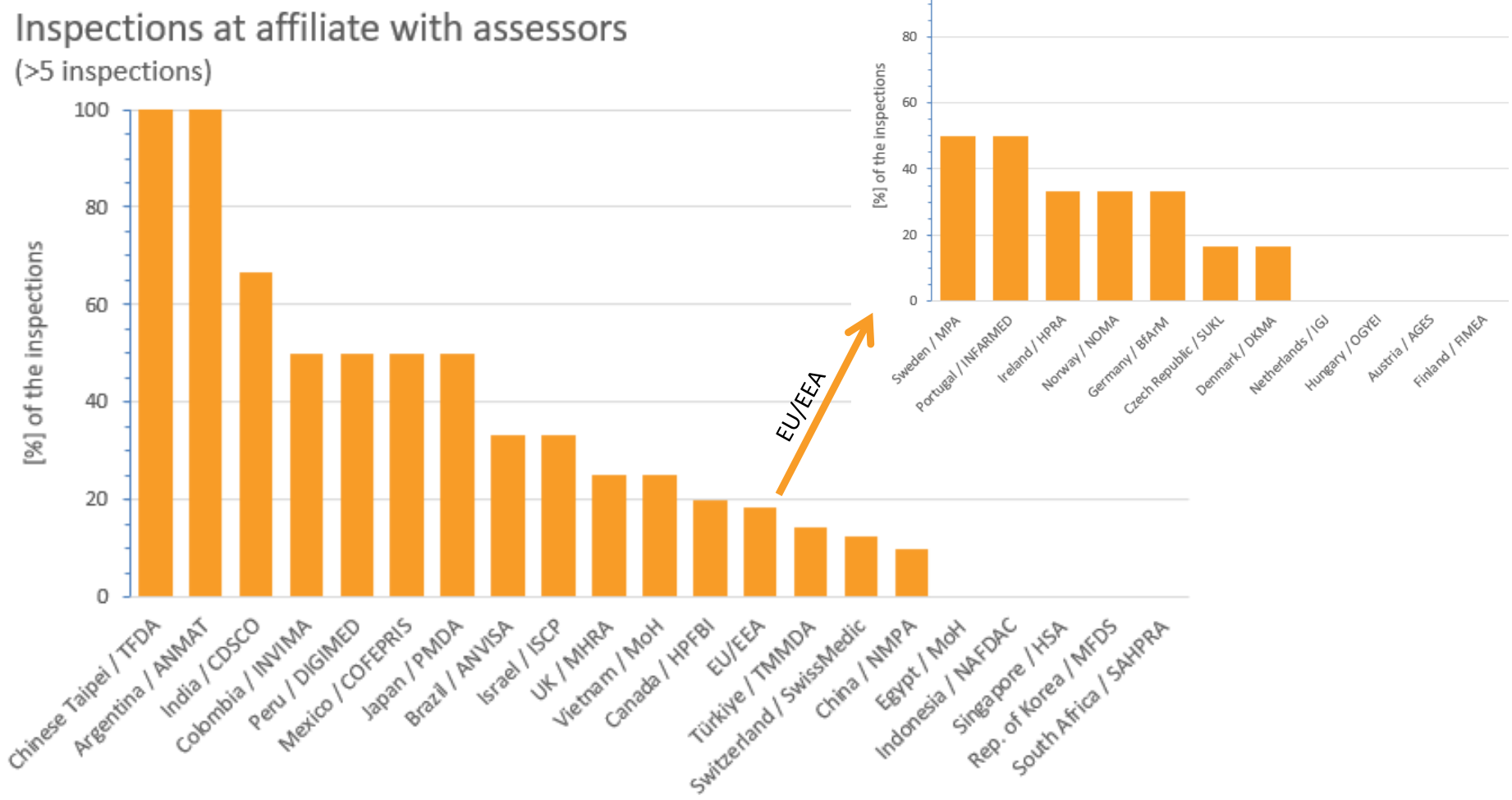
Inspections at Affiliates

INSPECTIONS AT AFFILIATES

High level of inspection at affiliates with very limited influence by the pandemic



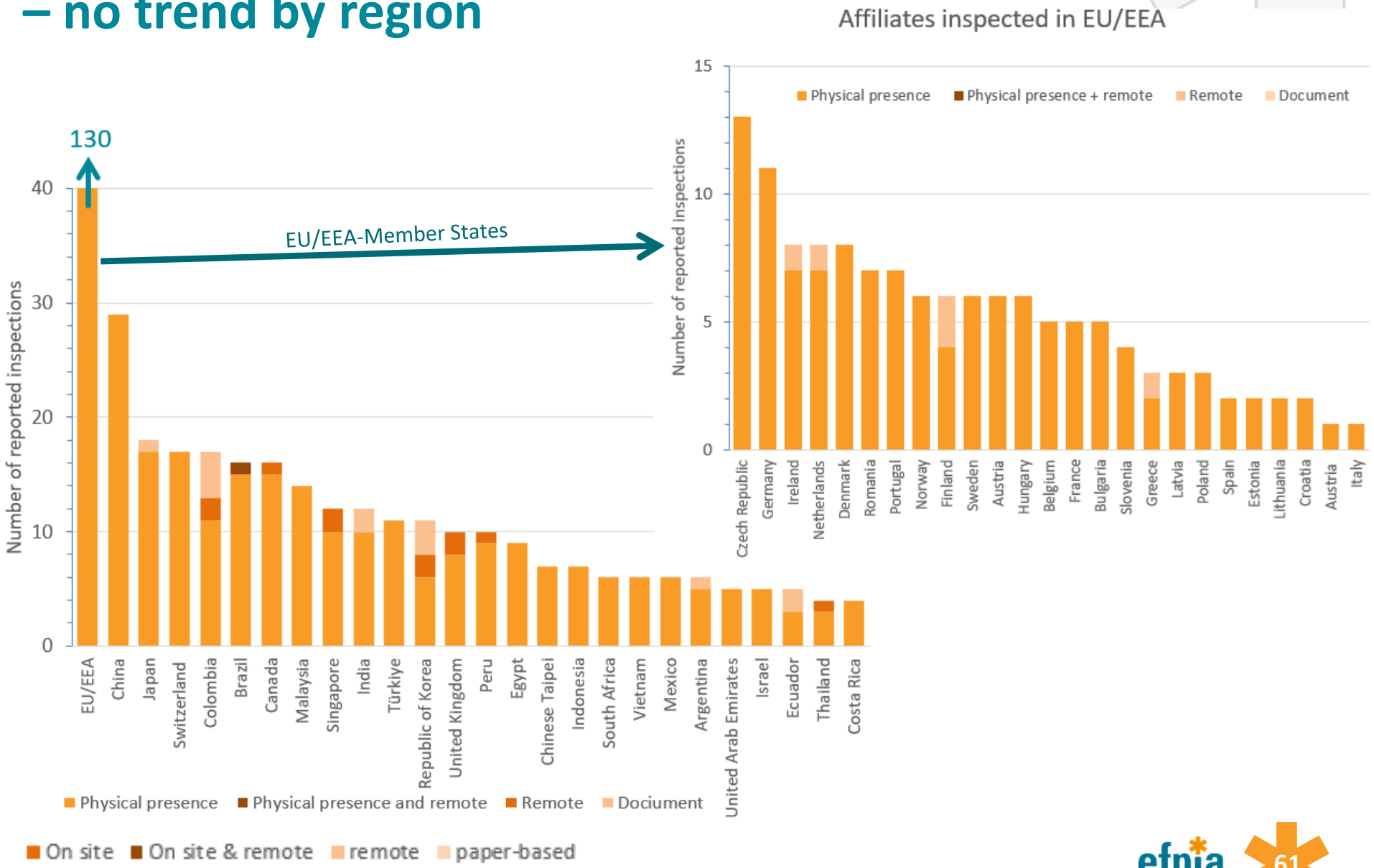
Inspection with assessors over all



For PAI only ‘no’ or ‘unknown’ reported

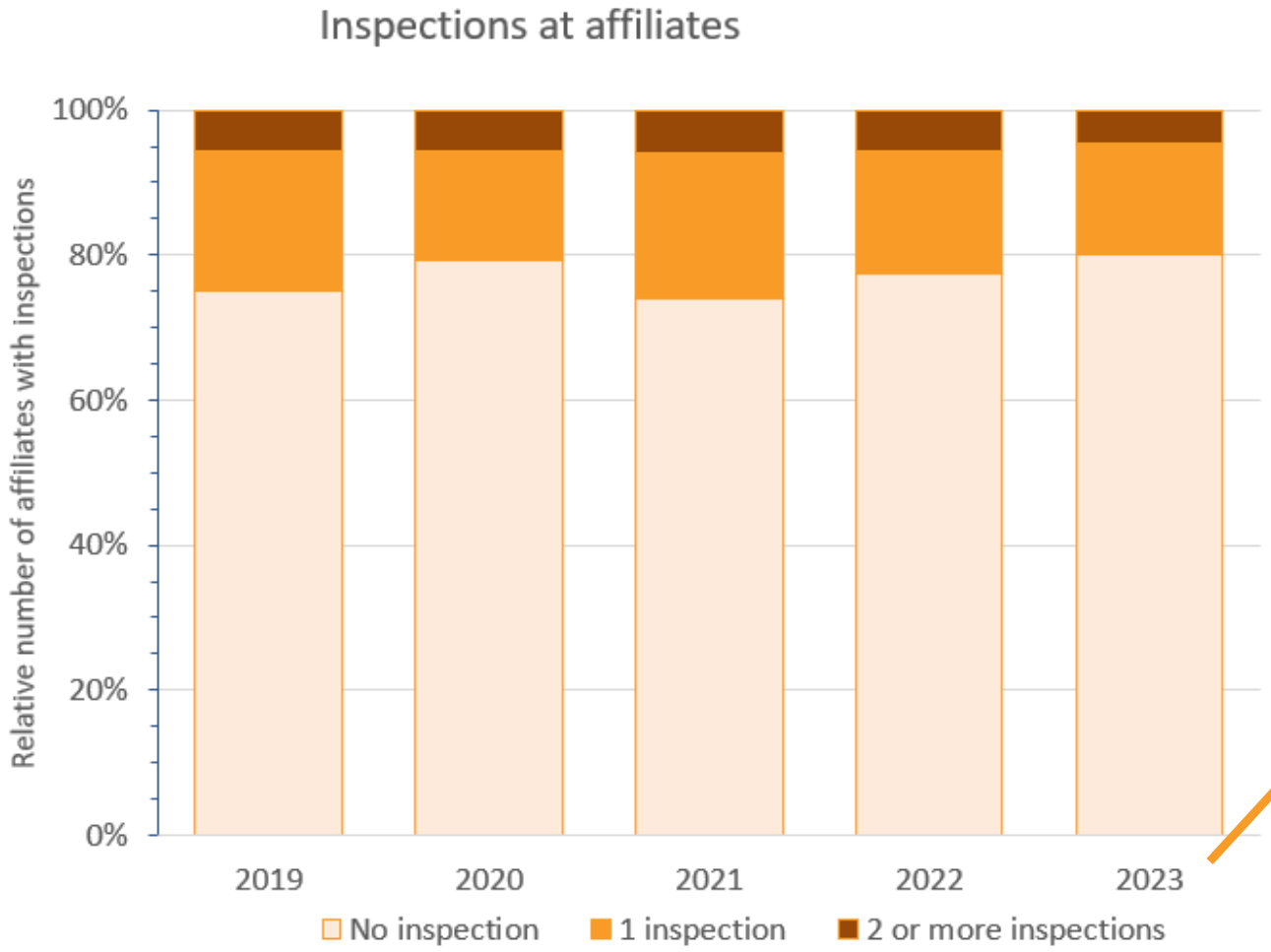
Answers giving ‘unknown’ are excluded

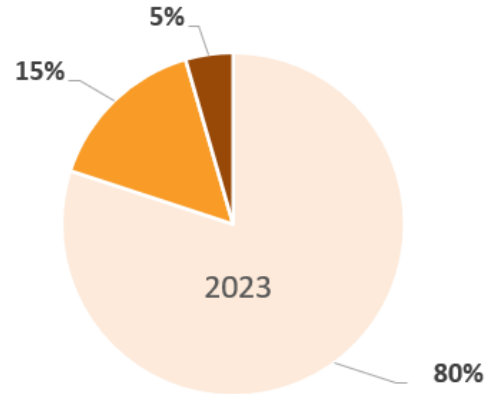
Local affiliates have received inspections – no trend by region



INSPECTIONS AT AFFILIATES

Number of affiliates inspected





- **Facts**
  - Number of oversight constant
  - 80% without inspections – assumption: inspections every 5 years?

efpia

European Federation of Pharmaceutical Industries and Associations

EFPIA Brussels Office
Leopto be updated Plaza Building * Rue du Trône 108
B-1050 Brussels * Belgium
Tel: + 32 (0)2 626 25 55
www.efpia.eu * info@efpia.eu