



European Federation of Pharmaceutical
Industries and Associations

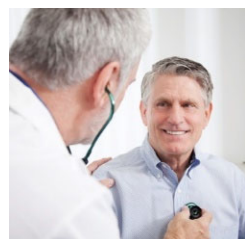


Annual Regulatory GMP/GDP Inspection Survey 2023 Data

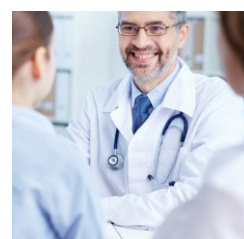
Author: MQEG Inspections topic team

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

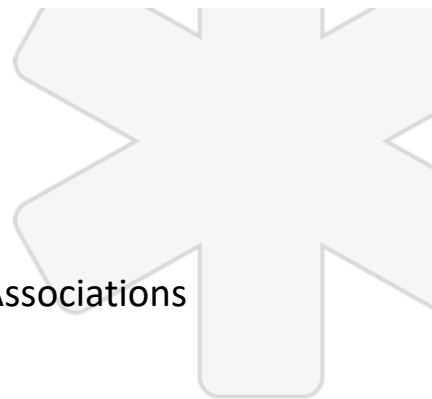
- * Monitor trends and new focus areas
- * Promote reliance optimizing the use of inspection resources
- * Materialise the benefits of PIC/S membership and MRAs

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

INSPECTION SURVEY - 2023 DATA

Outcome of the data

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



At Manufacturing sites¹

- 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

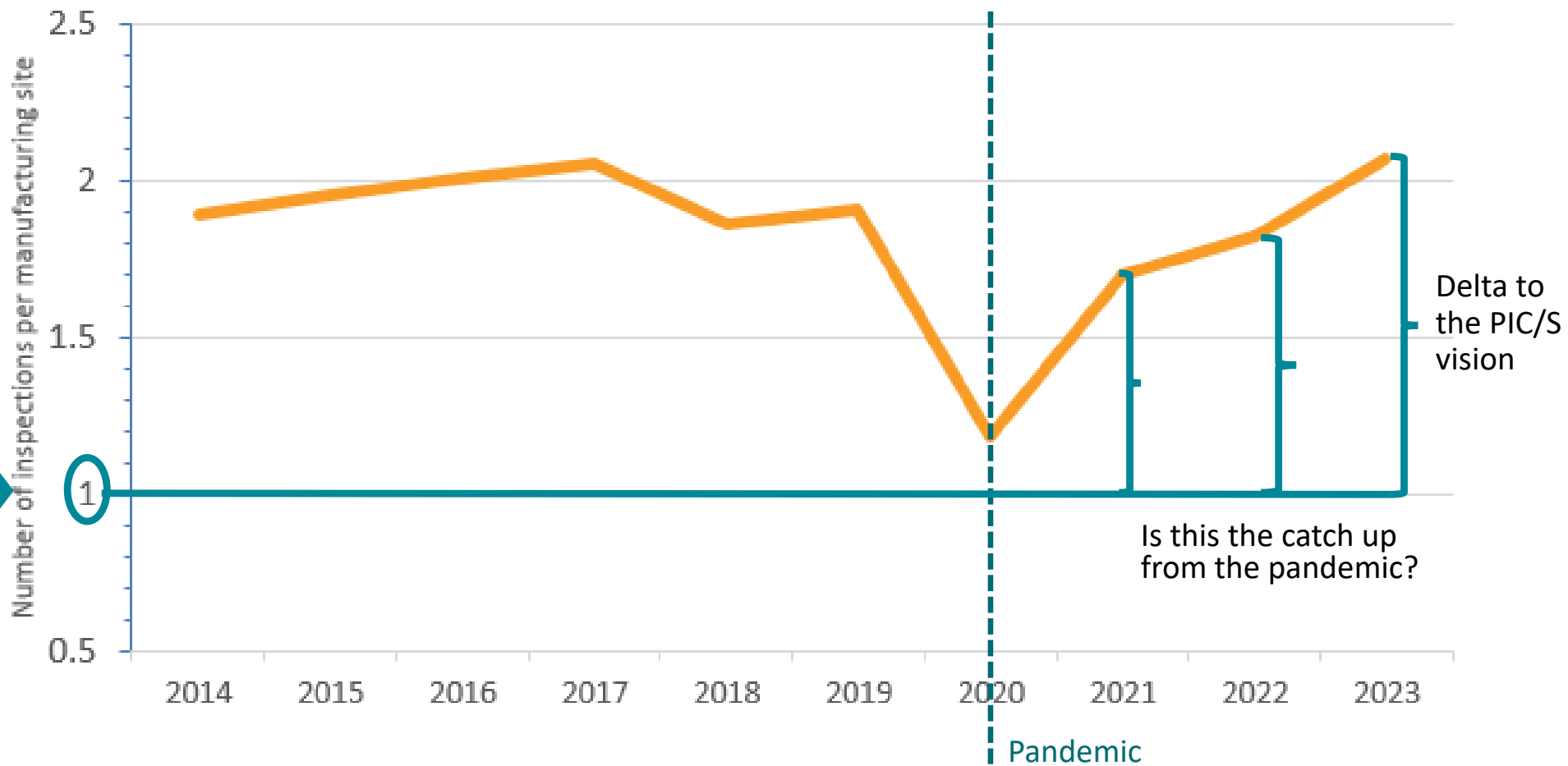
- Constant high numbers of inspections – mostly domestic
- Very limited impact by the pandemic on the number of inspections
- 80% without inspections – assumption: inspections every 5 years

* 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.

INSPECTION SURVEY - 2023 DATA

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

Number of inspections per manufacturing site in a year



PIC/S vision

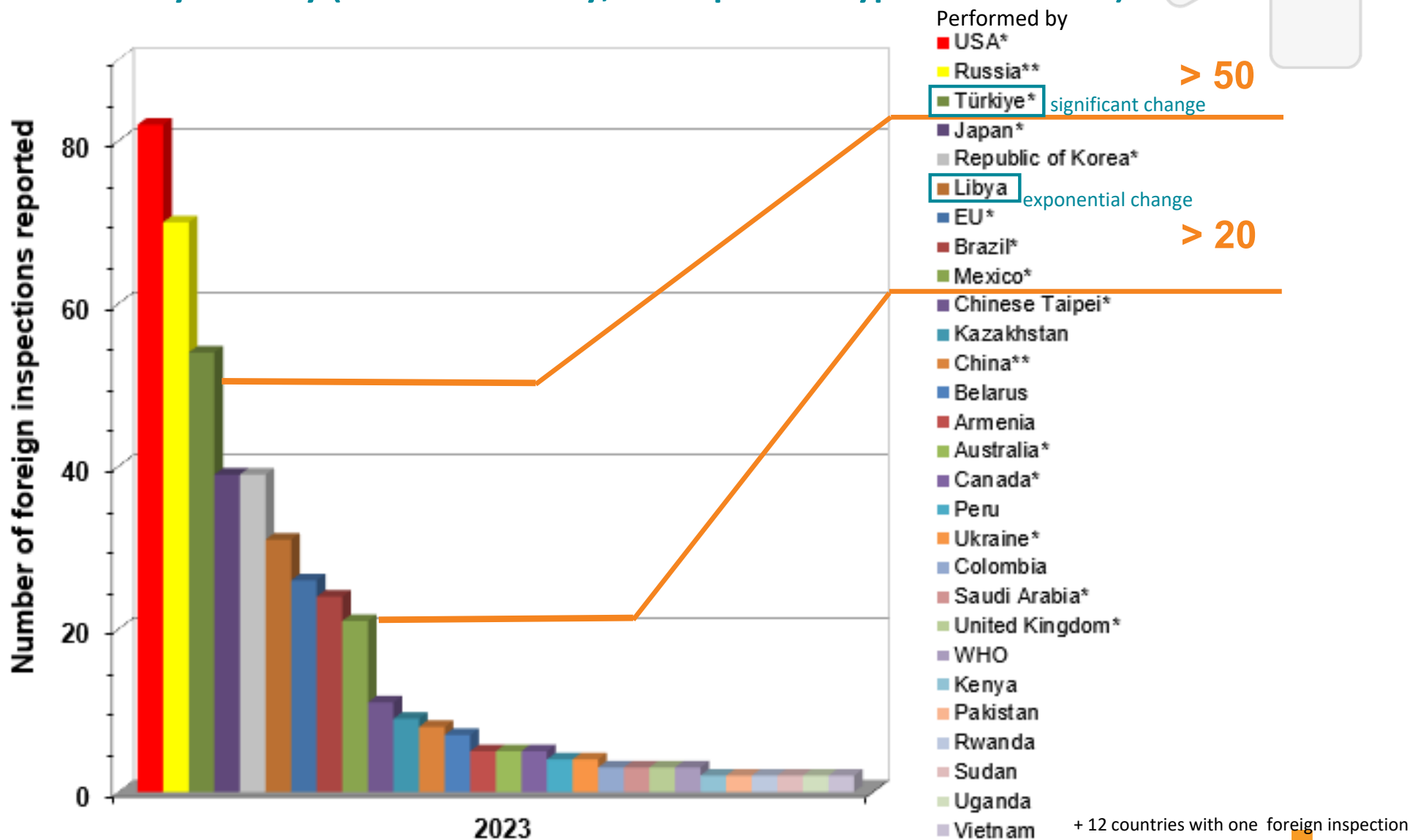
Delta to the PIC/S vision

Is this the catch up from the pandemic?

Pandemic

INSPECTION SURVEY - 2023 DATA

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








INSPECTION SURVEY RESULTS 2023

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)

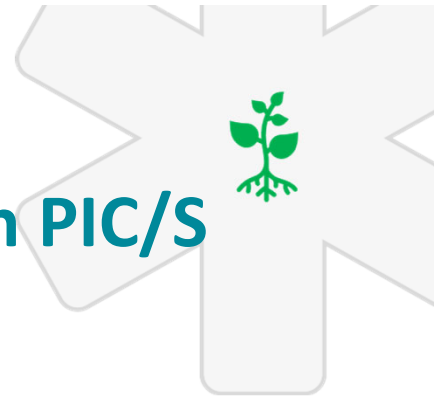
* We observe an increasing average of inspector days*

* 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

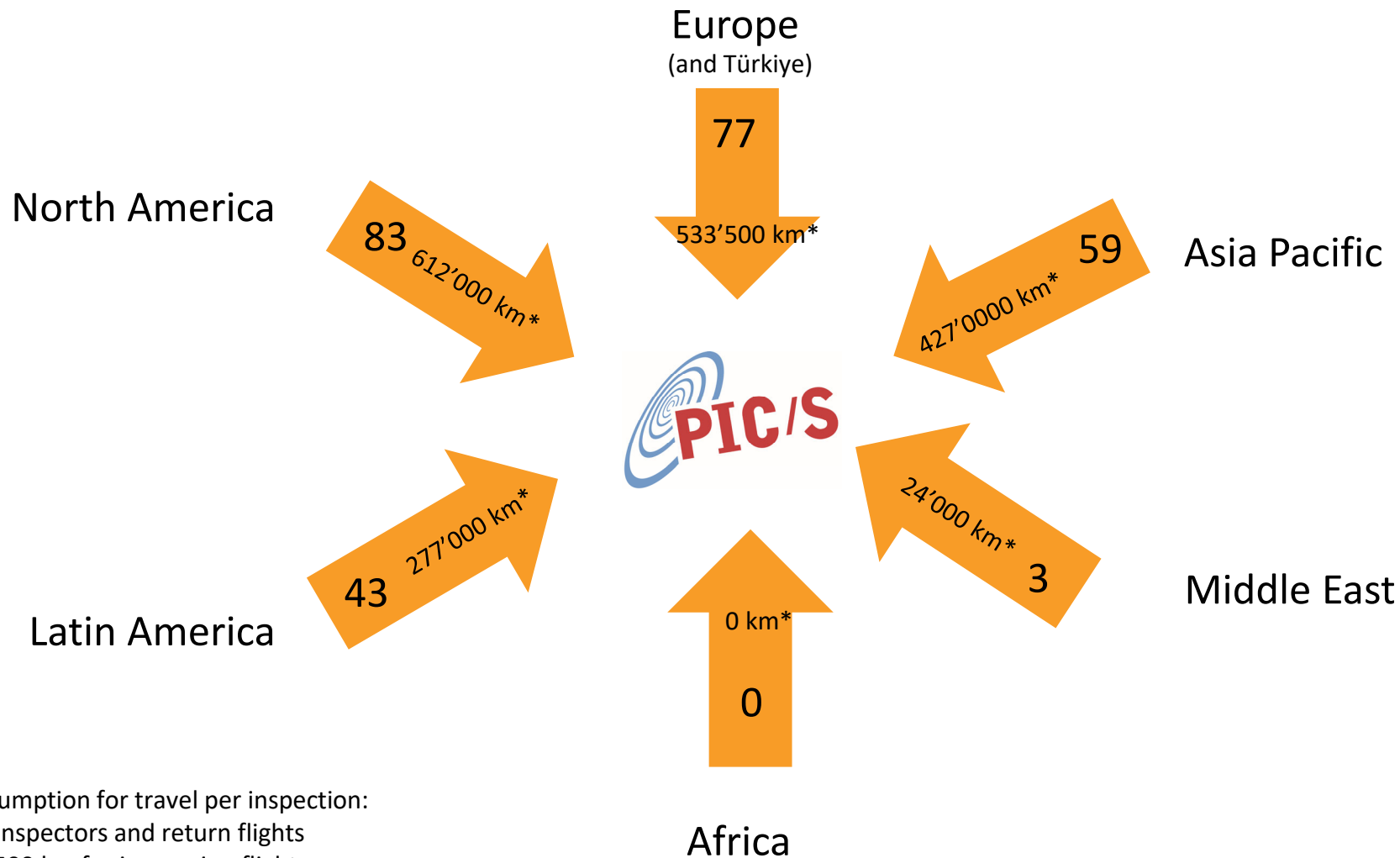
*Assumption: having additional inspectors for training purposes



OPPORTUNITIES FOR PIC/S PARTICIPATING AUTHORITIES

Reducing environmental footprint by reliance on PIC/S

 $\approx 1'900'000 \text{ km/y}^* \approx 26'000'000 \text{ kg CO}_2$



Assumption for travel per inspection:

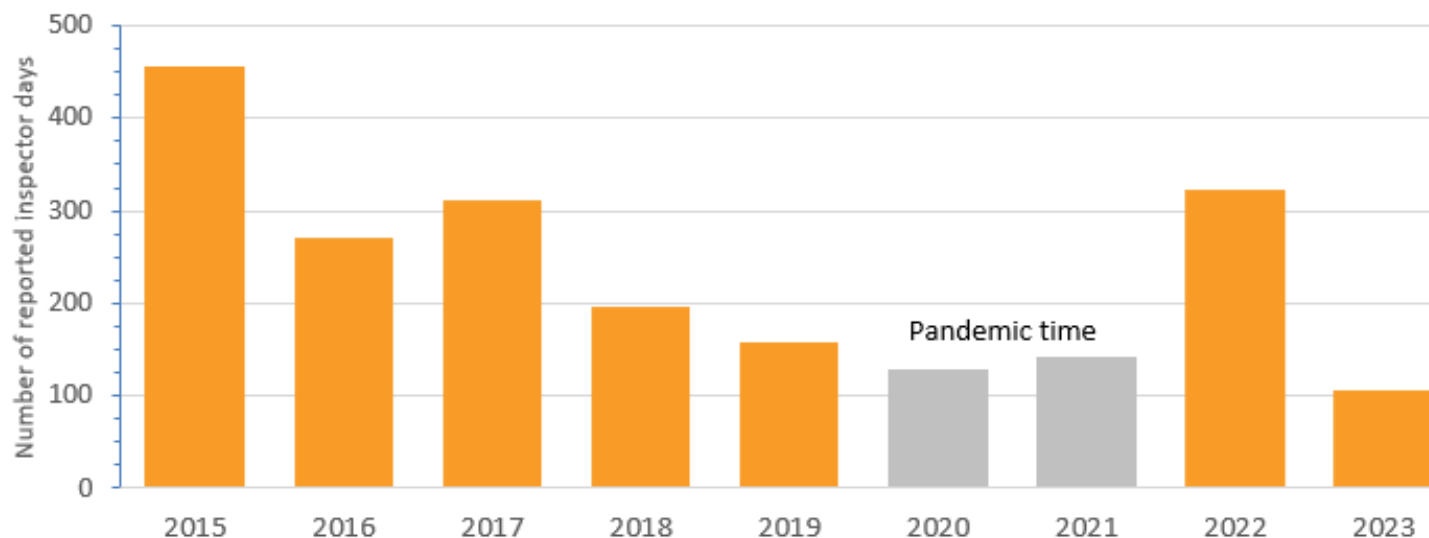
- 2 inspectors and return flights
- 500 km for in a region flights
- 8'000 km for interregional flight

INSPECTION SURVEY - 2023 DATA

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

Reported inspector days spent from an EU/EEA-MS
where the supervisory authority is a PIC/S member inspectorate



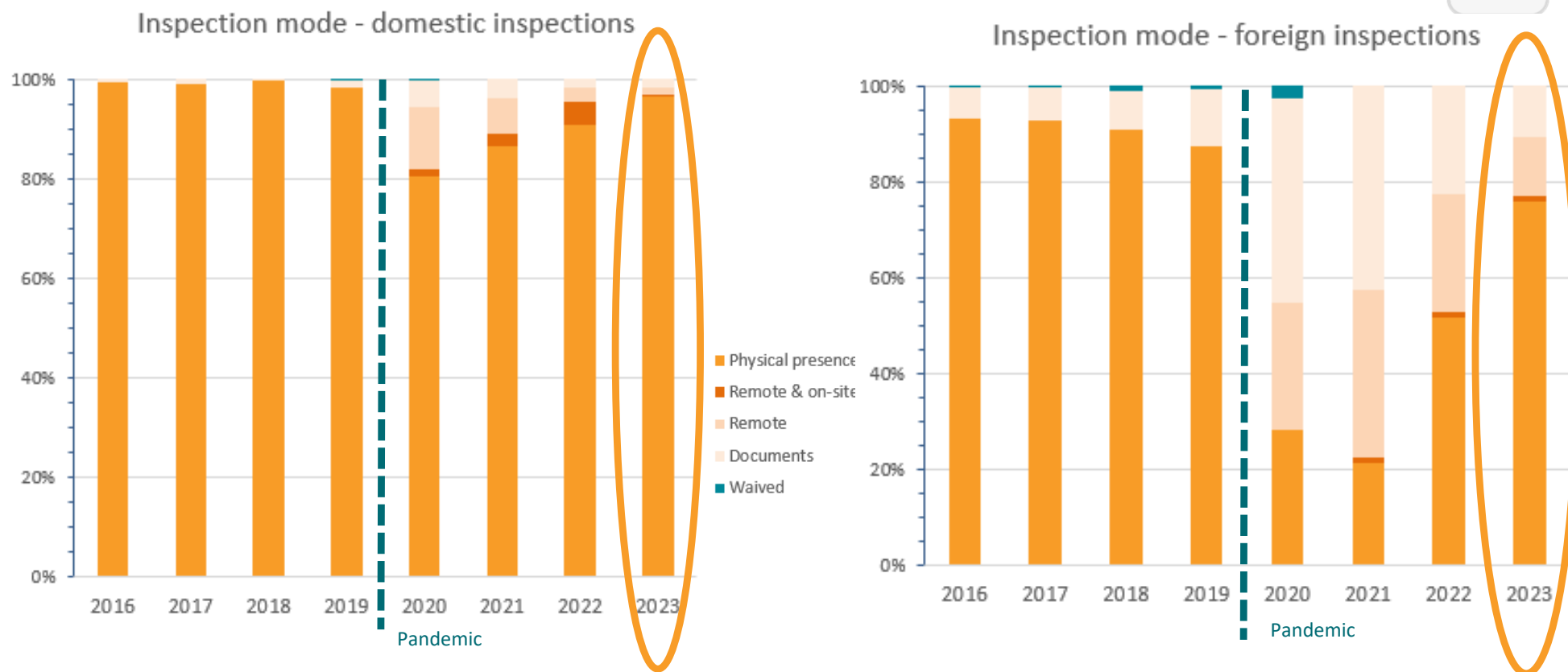
INSPECTION SURVEY RESULTS 2023

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



INSPECTION SURVEY RESULTS 2023

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

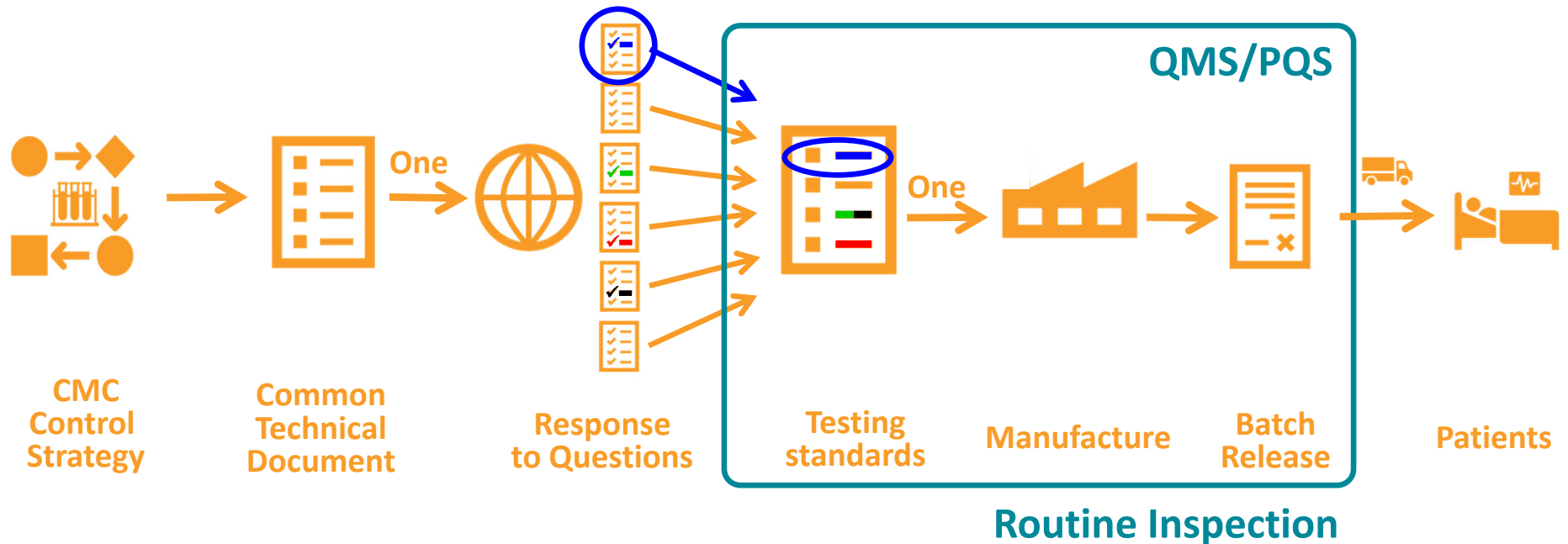
- * **Presence of regulatory assessors in**
 - * Foreign inspection worldwide
 - * Routine average 51% (US-FDA 48%)
 - * PAI average 76% (US-FDA 25%*)

 - * 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

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

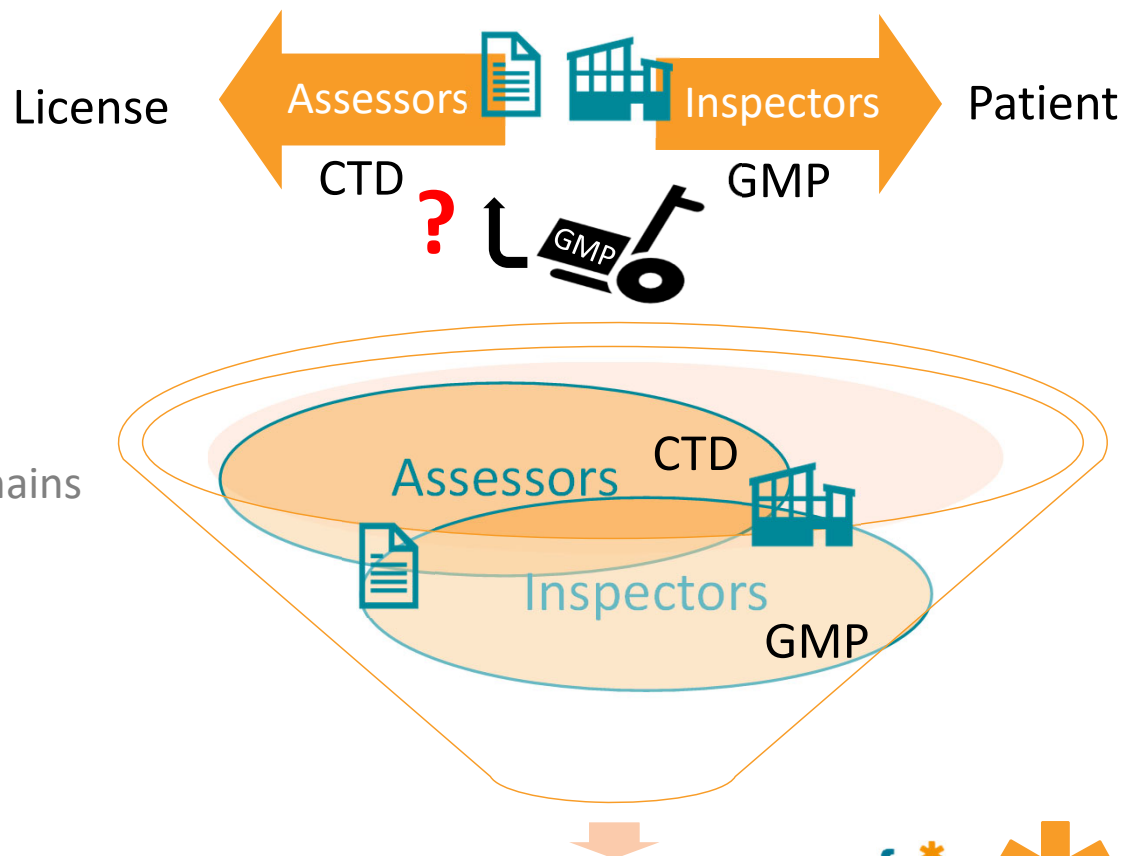
- * GMP aspects are covered by the inspectorate in routine and PAI
- * Early collaboration of assessors and inspectors can facilitate understanding

* 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

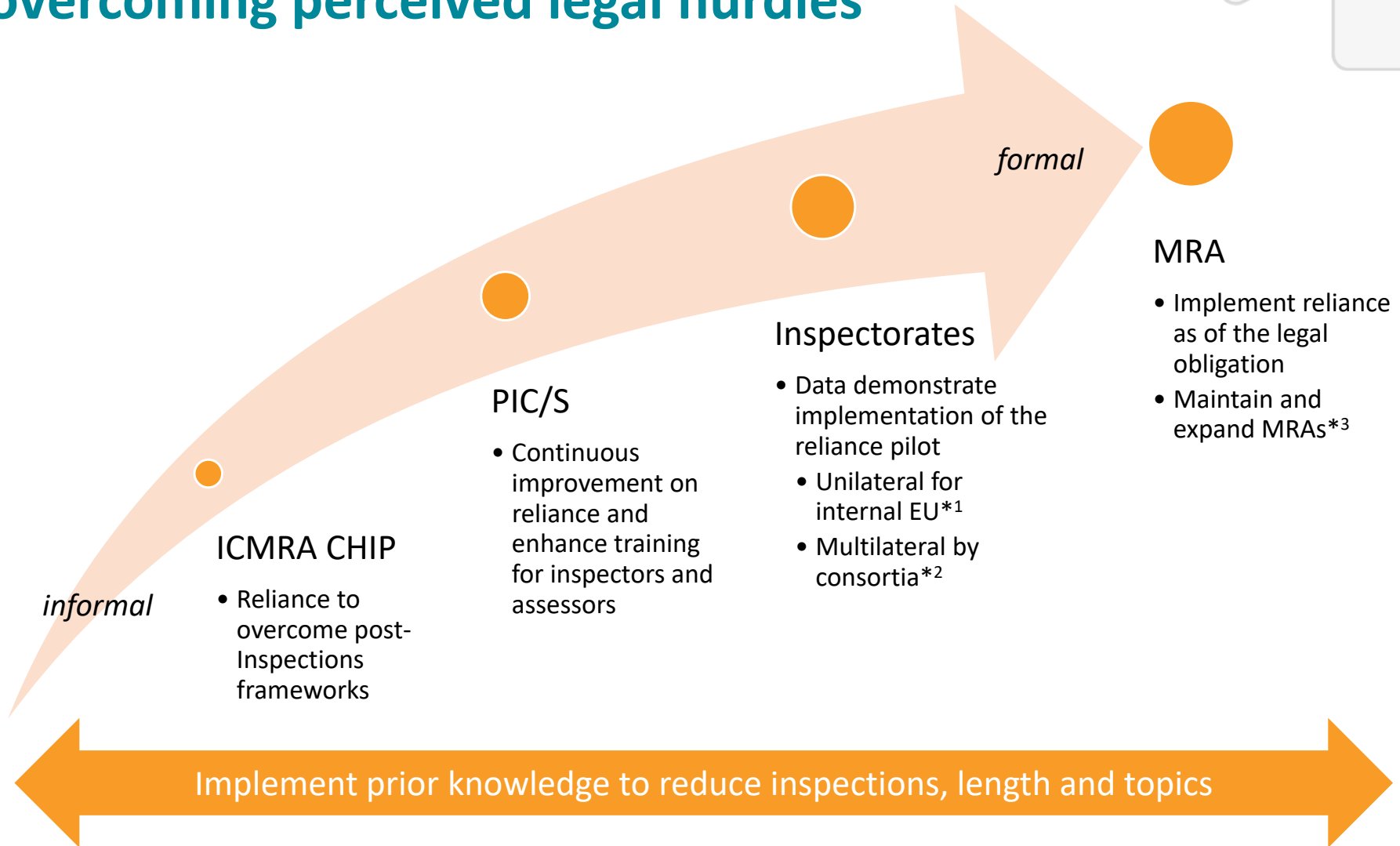
- * ICMRA member countries to rely on the CHIP inspection report – *join as observer if needed*

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



RELIANCE APPROACHES

Pathways to reliance on domestic inspections overcoming perceived legal hurdles



*1 Re-issuing GMP-certificates can be considered

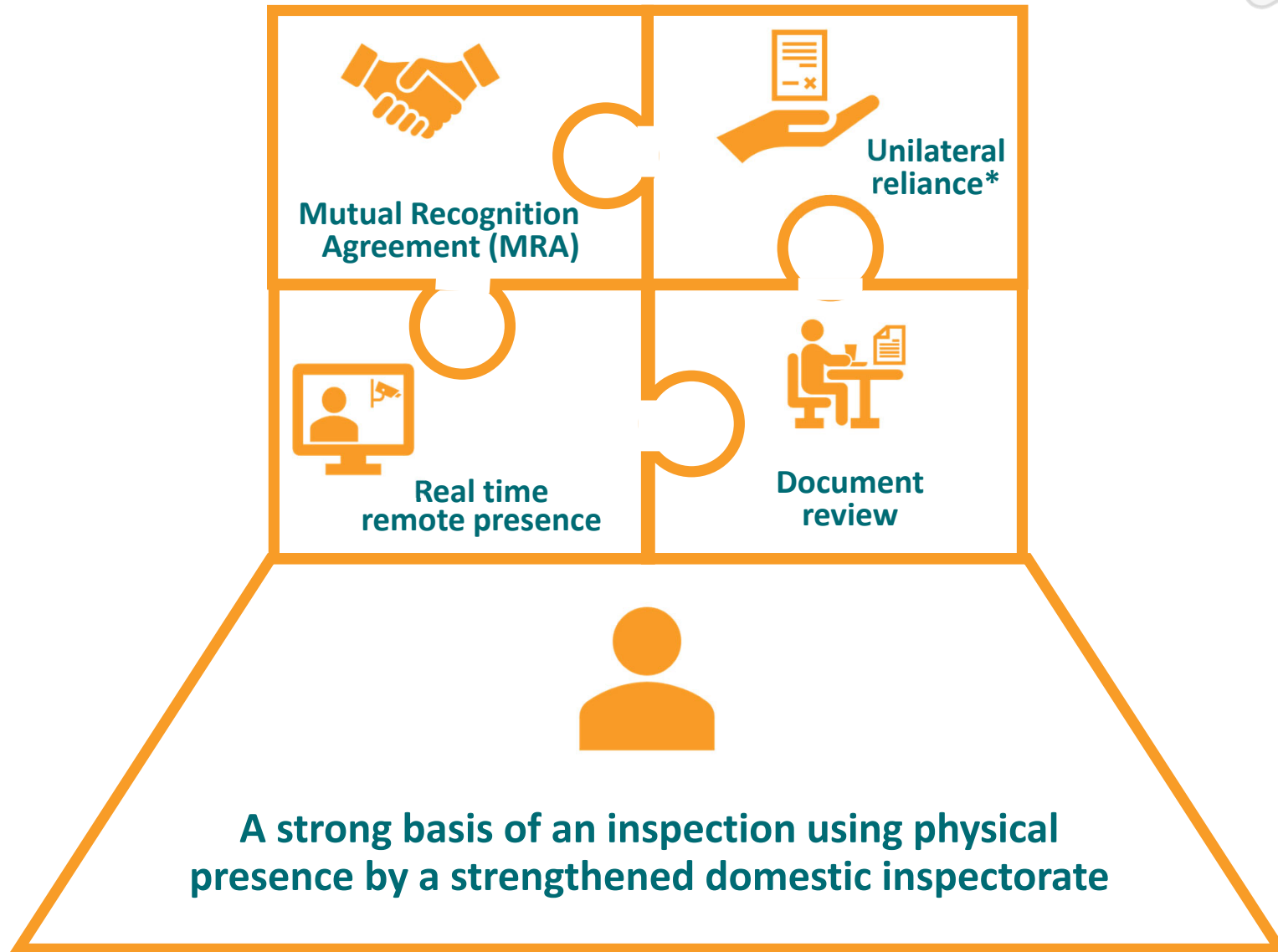
*2 e.g., Australia-Canada-Singapore-Switzerland-United Kingdom (Access)

*3 MRA EU/US, see also new MRAs among ASEAN and Korea / Singapore



SCIENCE AND RISK-BASED INSPECTION APPROACH

Collaboration, Reliance, Recognition



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 $\approx 80\%$ 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](#)



- **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](#)



- 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](#)



- **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.



- EMA, WHO, TGA, US-FDA, EDQM, Council of 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

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- * 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)

EFPIA INSPECTION SURVEY

Additional data





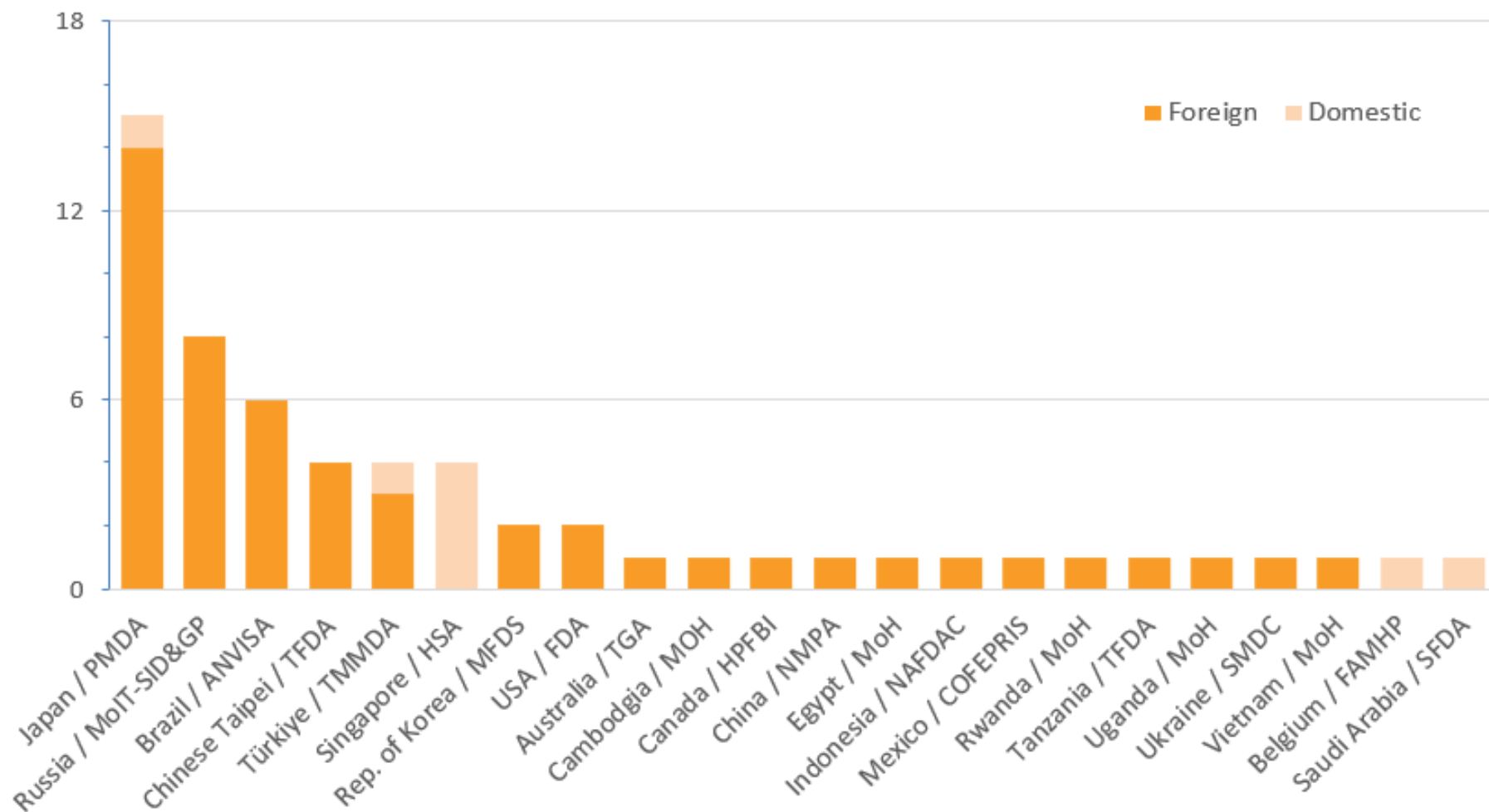
Documents inspections



EFPIA INSPECTION SURVEY - DATA

Inspectorates performing document inspections as an independent inspection mode

Inspectorates reported to perform document inspections





DOCUMENT INSPECTIONS

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

Check with survey results

Site 	<ul style="list-style-type: none">• Site Master File (SMF)*	
Product 	<ul style="list-style-type: none">• Annual Product Quality Review	
Pharmaceutical Quality System 	<ul style="list-style-type: none">• Site Quality Manual	
Additional information 	<ul style="list-style-type: none">• 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

EFPIA ANNUAL INSPECTION SURVEY - 2023 DATA

GMP-INSPECTION RELIANCE, PIC/S GUIDELINE PI 048-1, 01 JUNE 2018, CHAPTER 5.3.1



[back to overview](#)



DOCUMENT INSPECTIONS

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

- * **Common documents required 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.

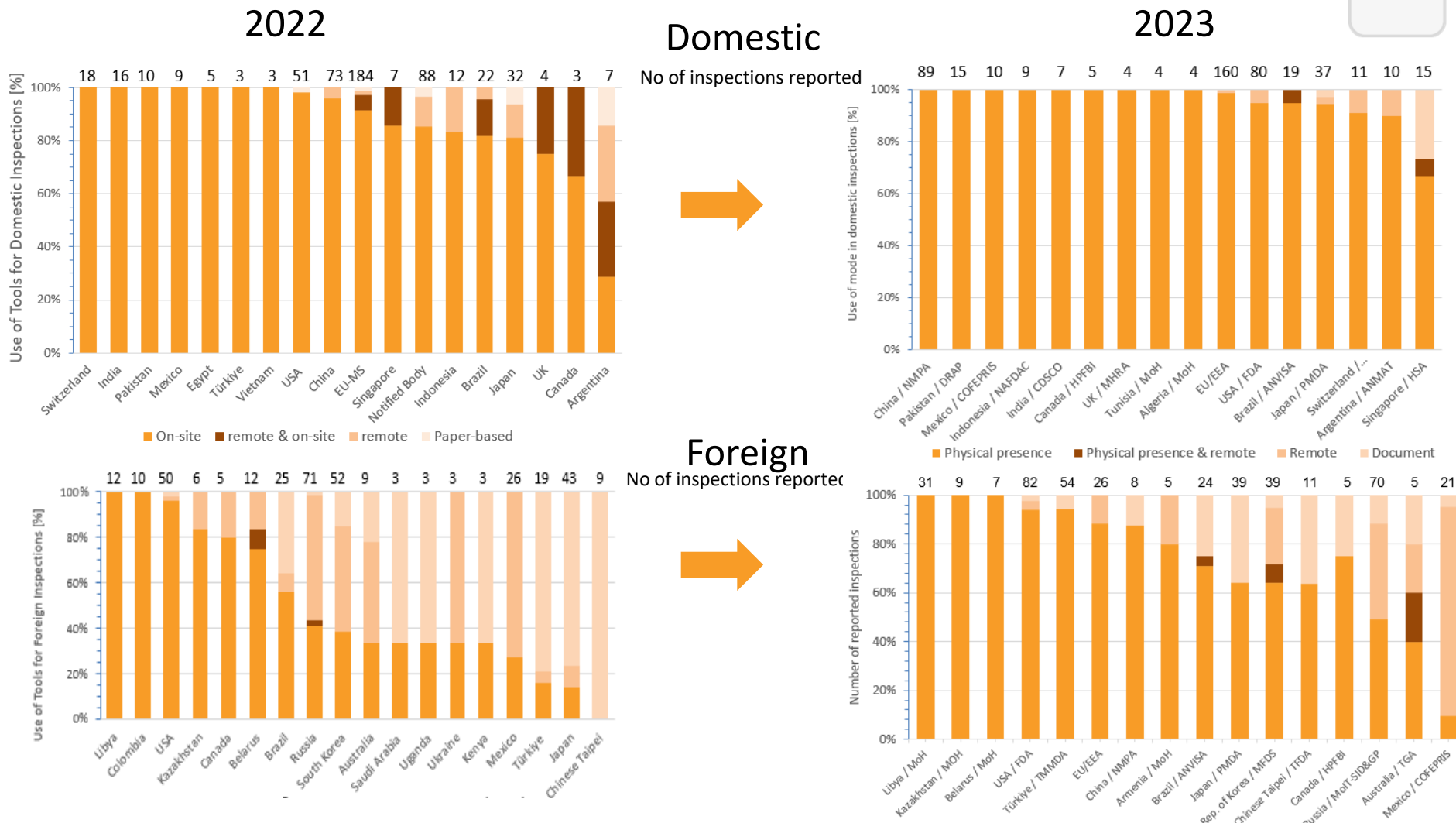


Inspections at Manufacturing Sites



INSPECTION MODES AT MANUFACTURING SITES

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

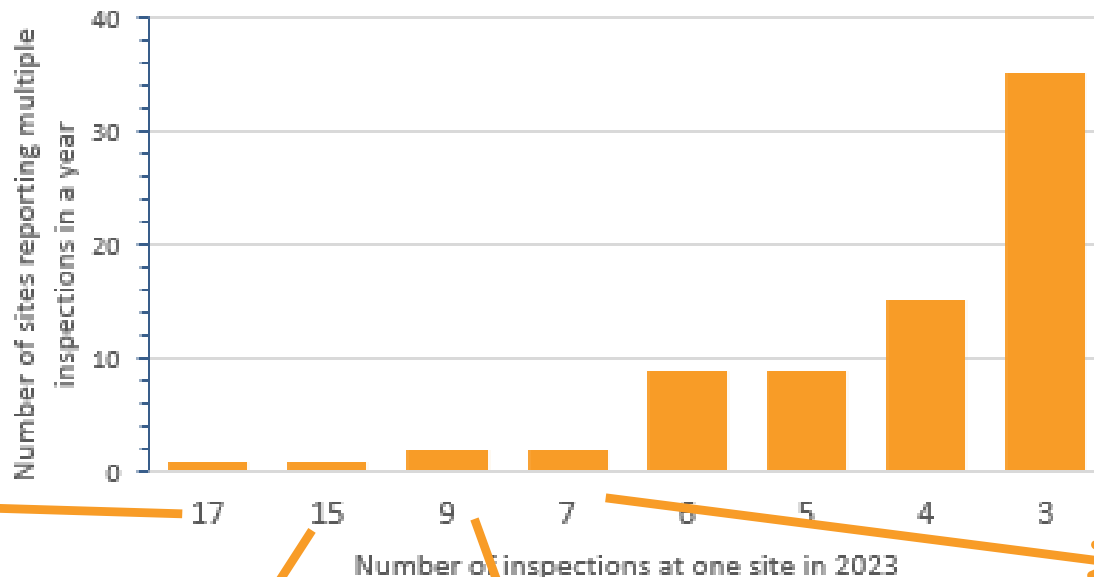


Some inspectorates (e.g., Australia, Mexico, Rep. of Korea, Russia) still see remote inspections beneficial and a valid alternative



INSPECTIONS AT MANUFACTURING SITES

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

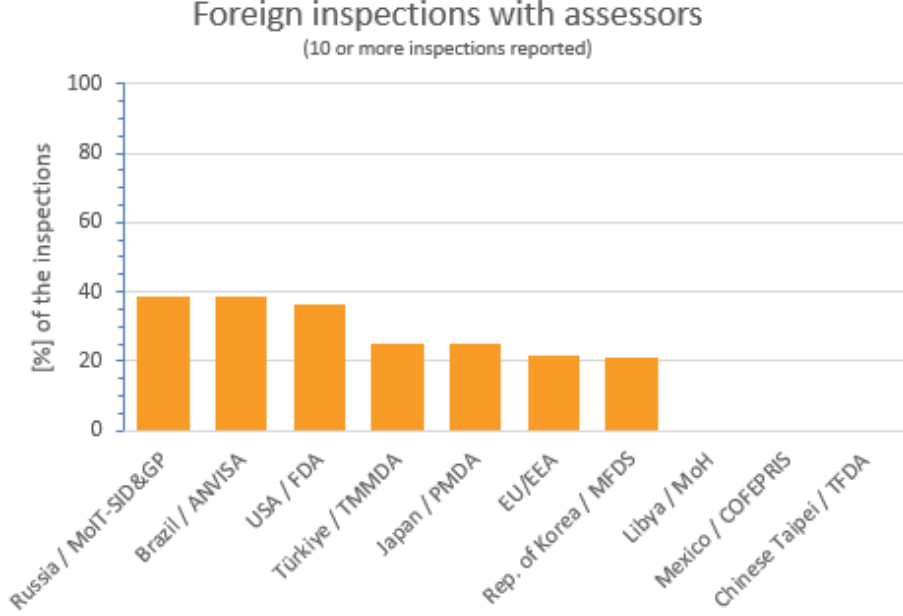
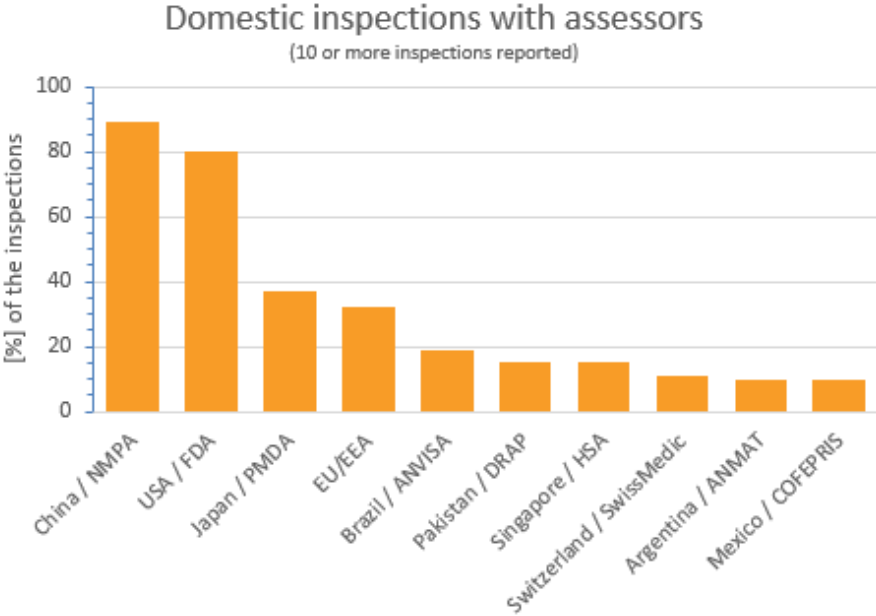
Site in US

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



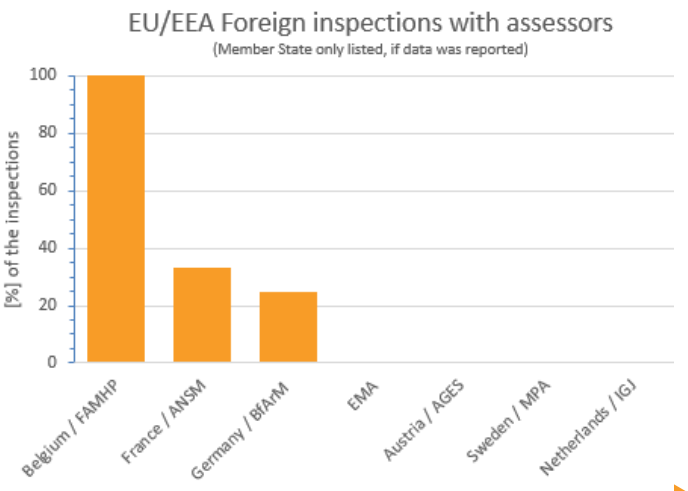
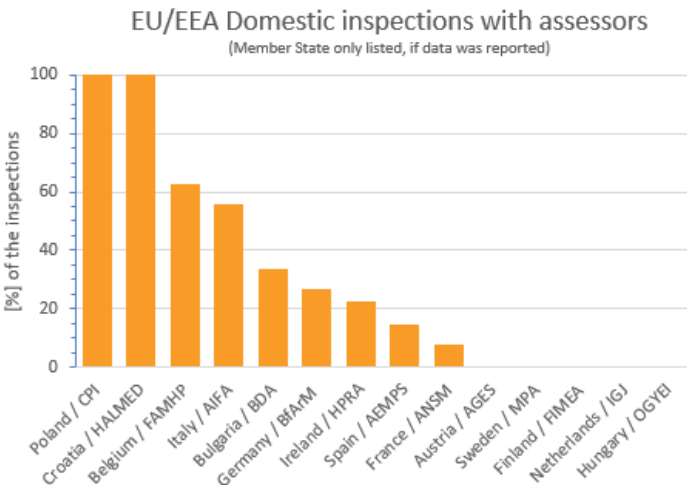
INSPECTIONS AT MANUFACTURING SITES - ASSESSORS

Inspections with assessors - over all



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

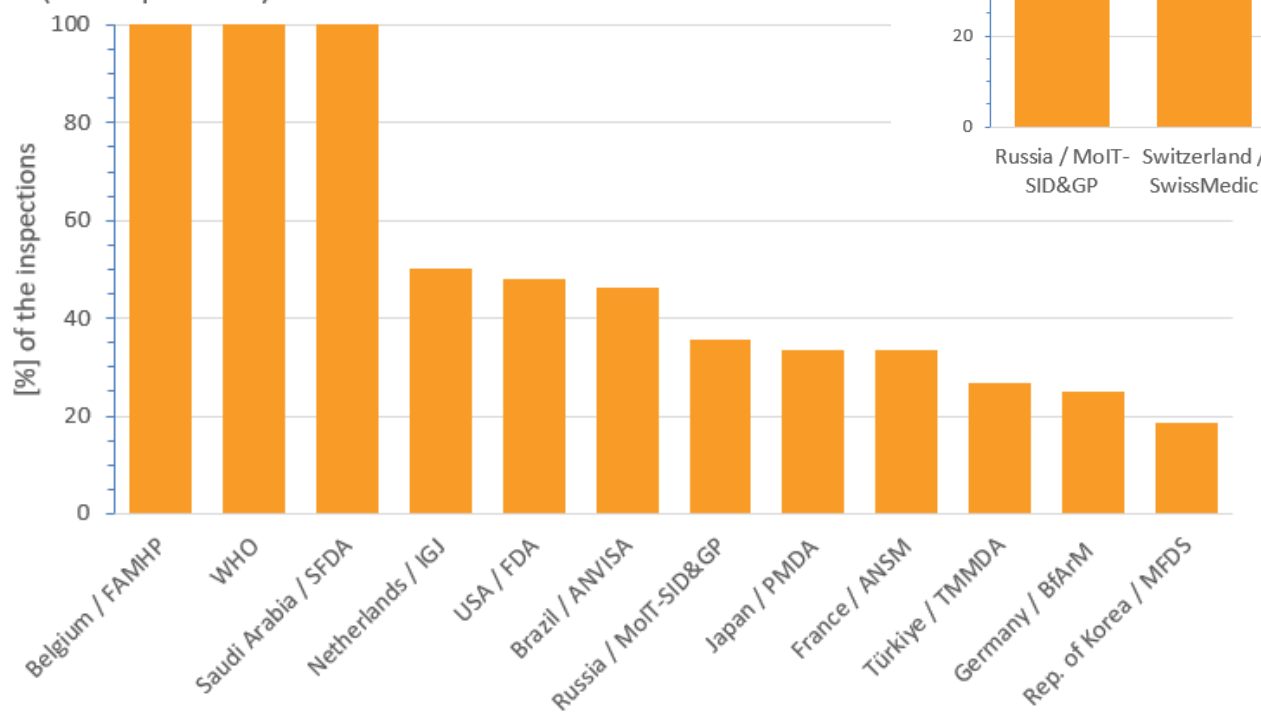
EU/EEA



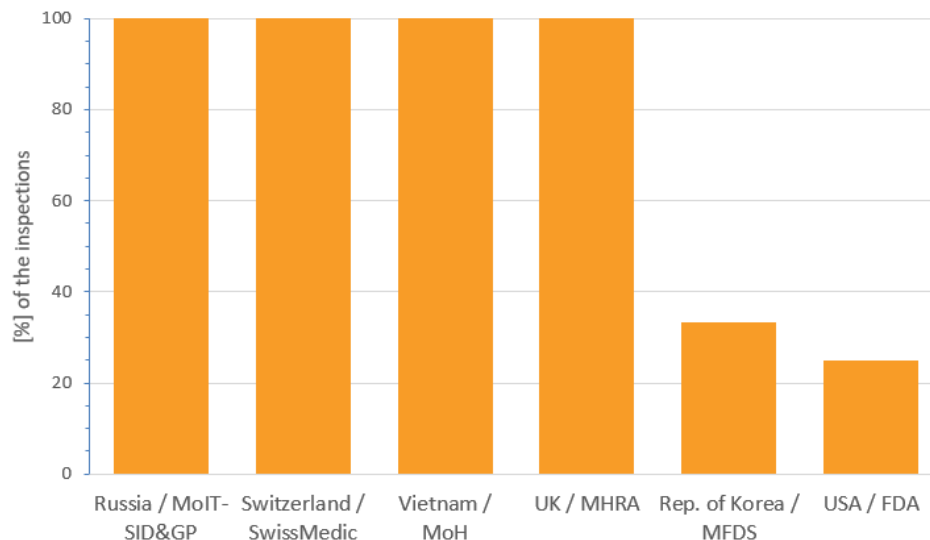
INSPECTIONS AT MANUFACTURING SITES – ASSESSORS

Inspections with assessors - PAI / Routine inspections

Foreign inspections with assessors - Routine (> 5 inspections)



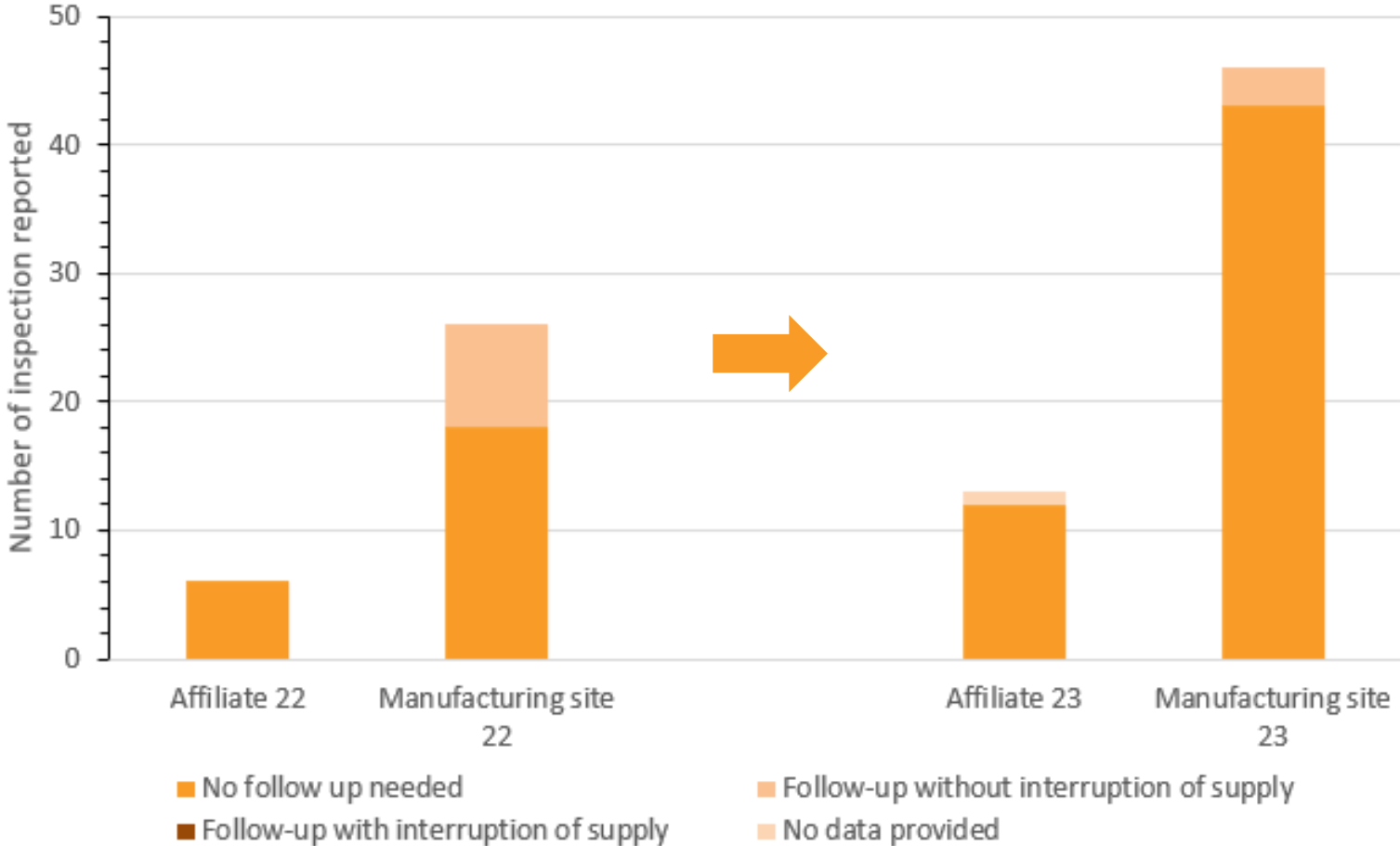
Foreign inspections with assessors - PAI





INSPECTIONS AT MANUFACTURING SITES

For cause inspections do not result in interrupted supply

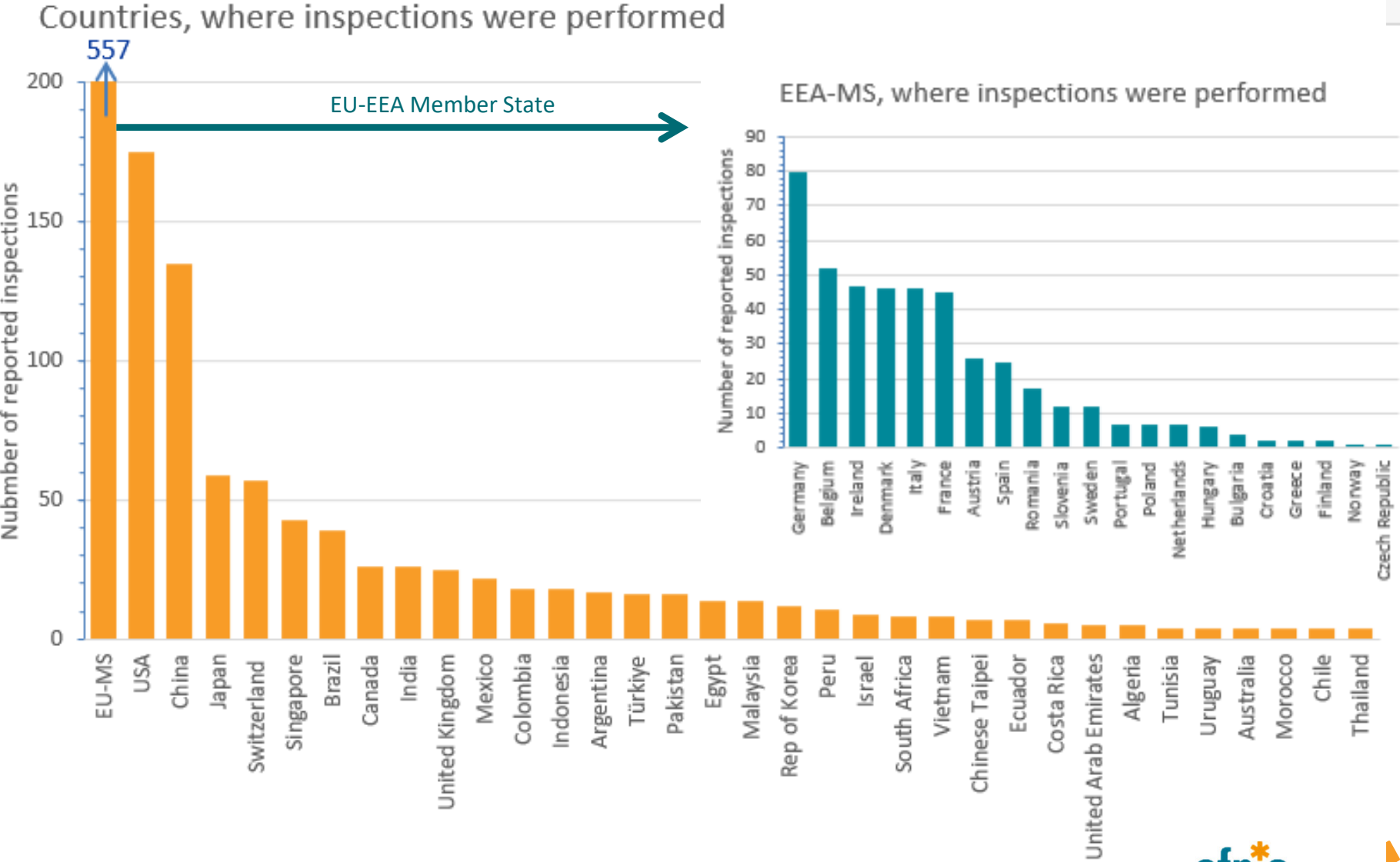


* The number nearly doubled 2022 to 2023



INSPECTIONS AT MANUFACTURING SITES

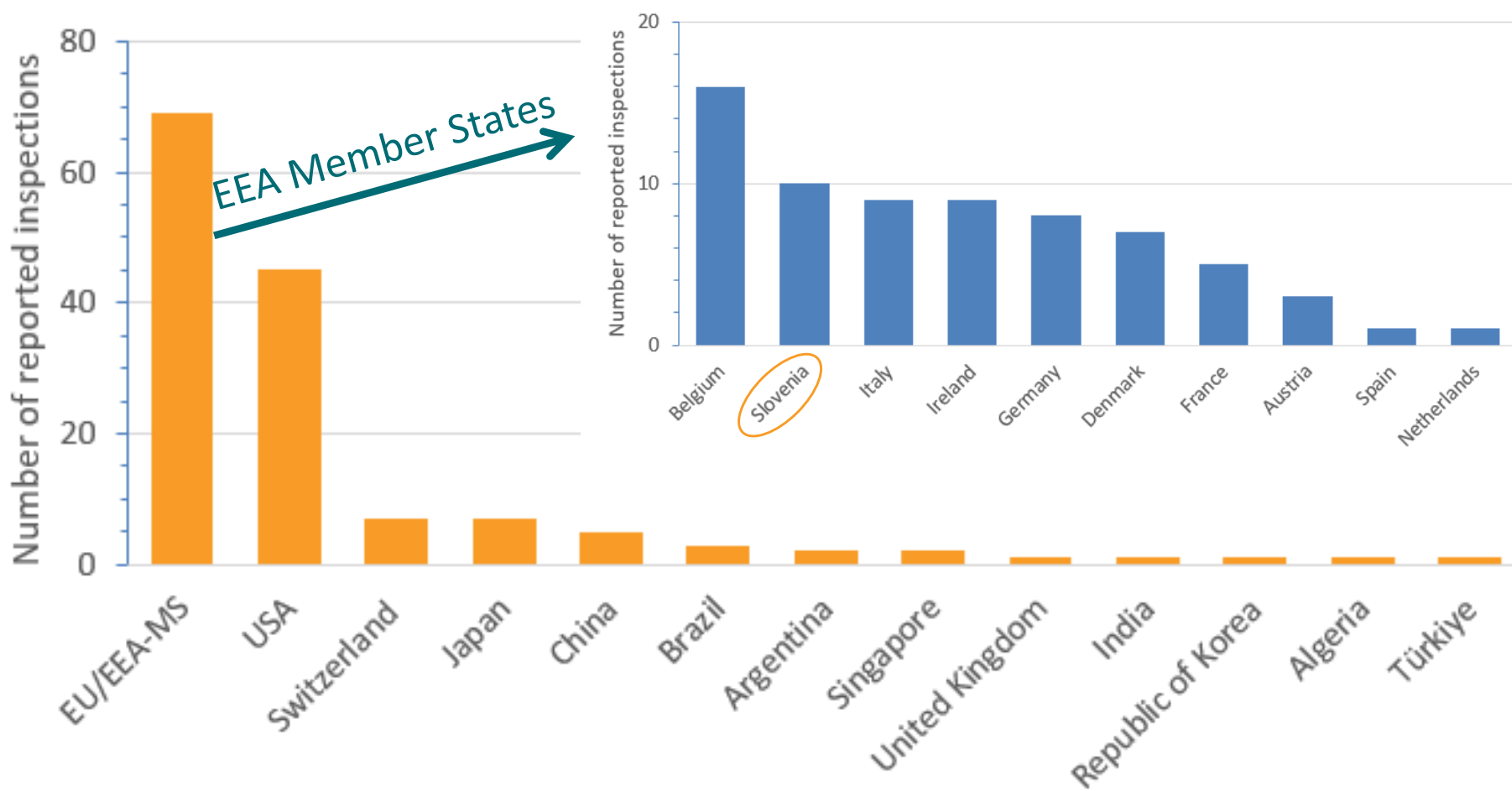
Number of inspection per country highlight's locations of manufacturing sites



INSPECTIONS AT MANUFACTURING SITES - PAI

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

Countries, where PAI inspections were performed





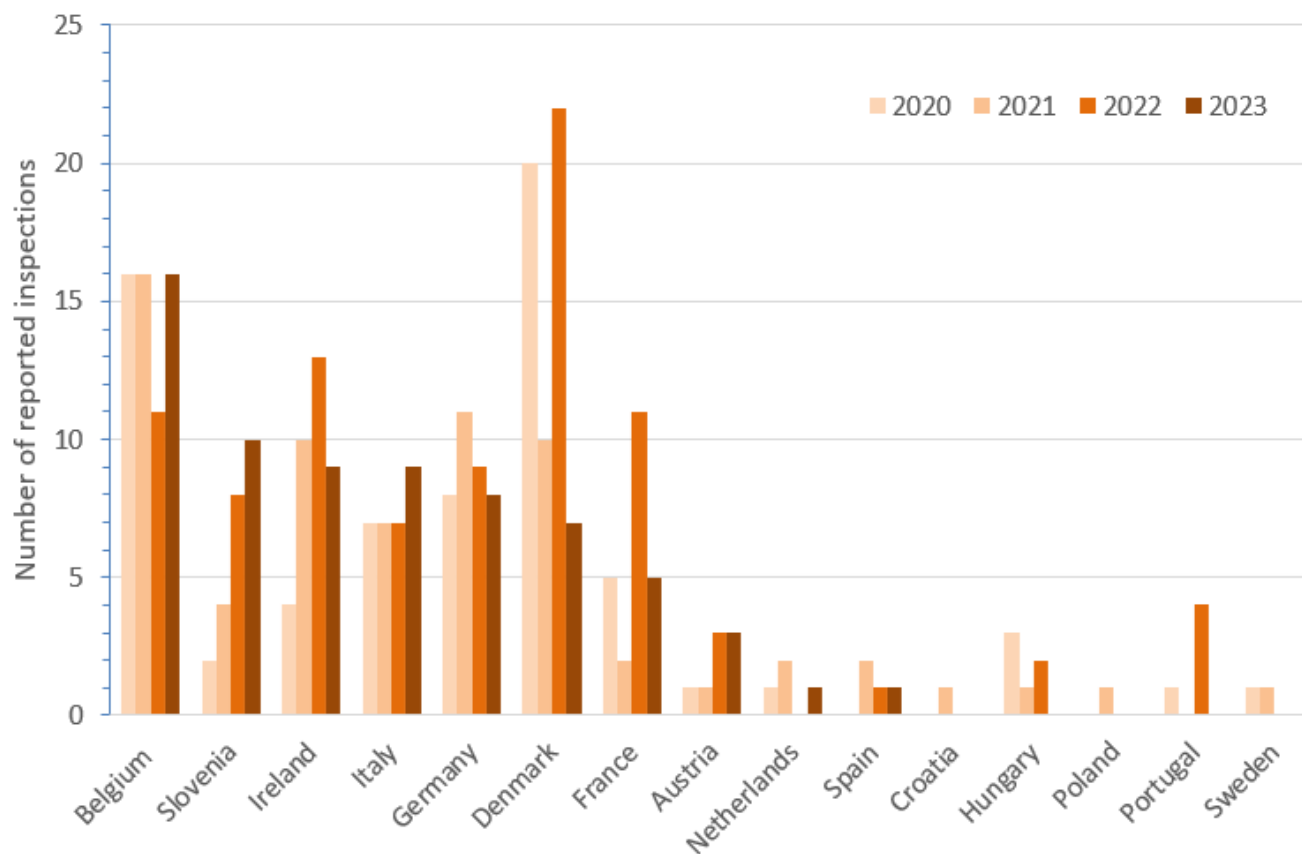
INSPECTIONS AT MANUFACTURING SITES - PAI

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>

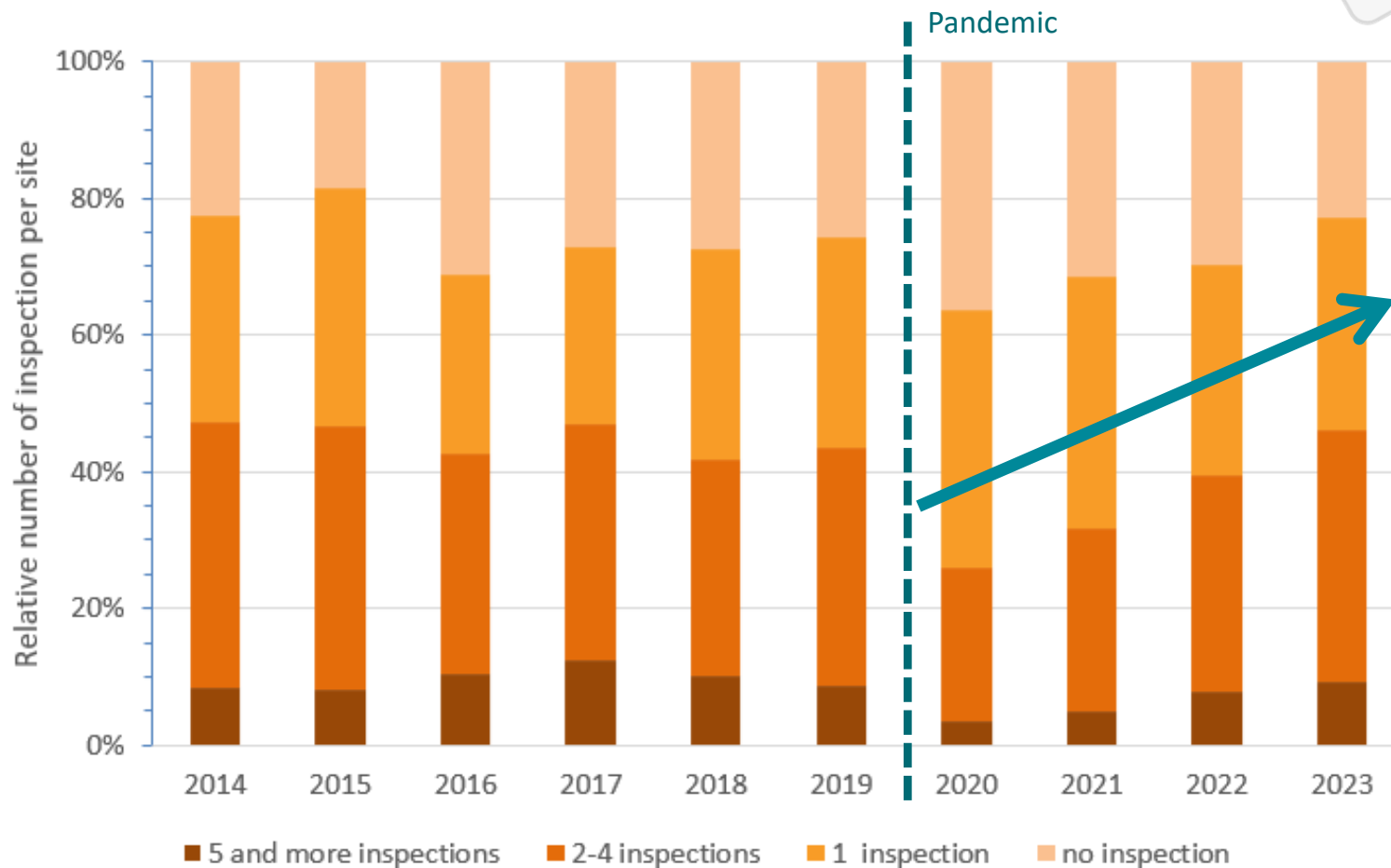
EU/ EEA-MS, where PAI were performed





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



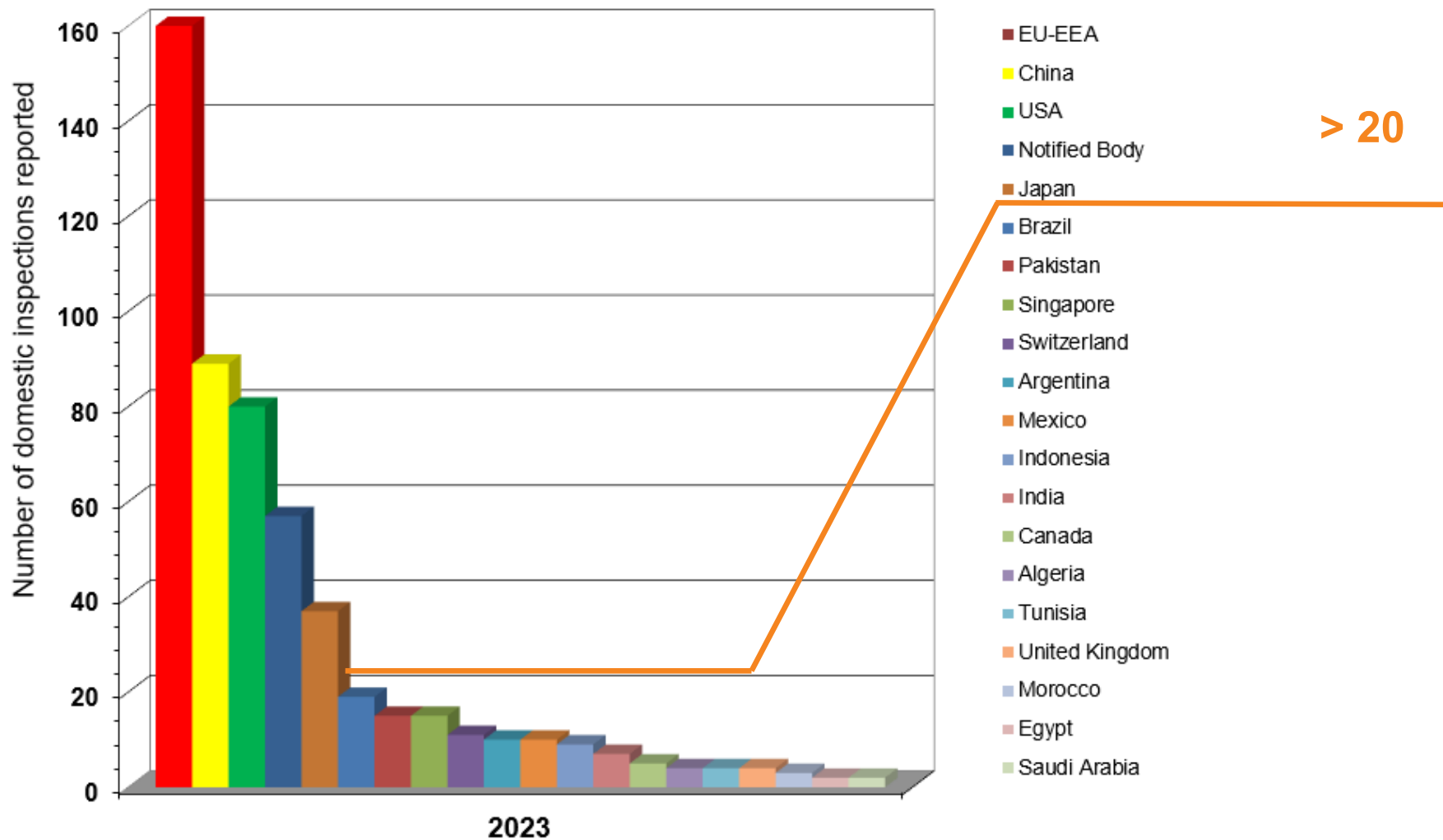
Domestic Inspection Activity



DOMESTIC INSPECTIONS AT MANUFACTURING SITES

Number of domestic inspections

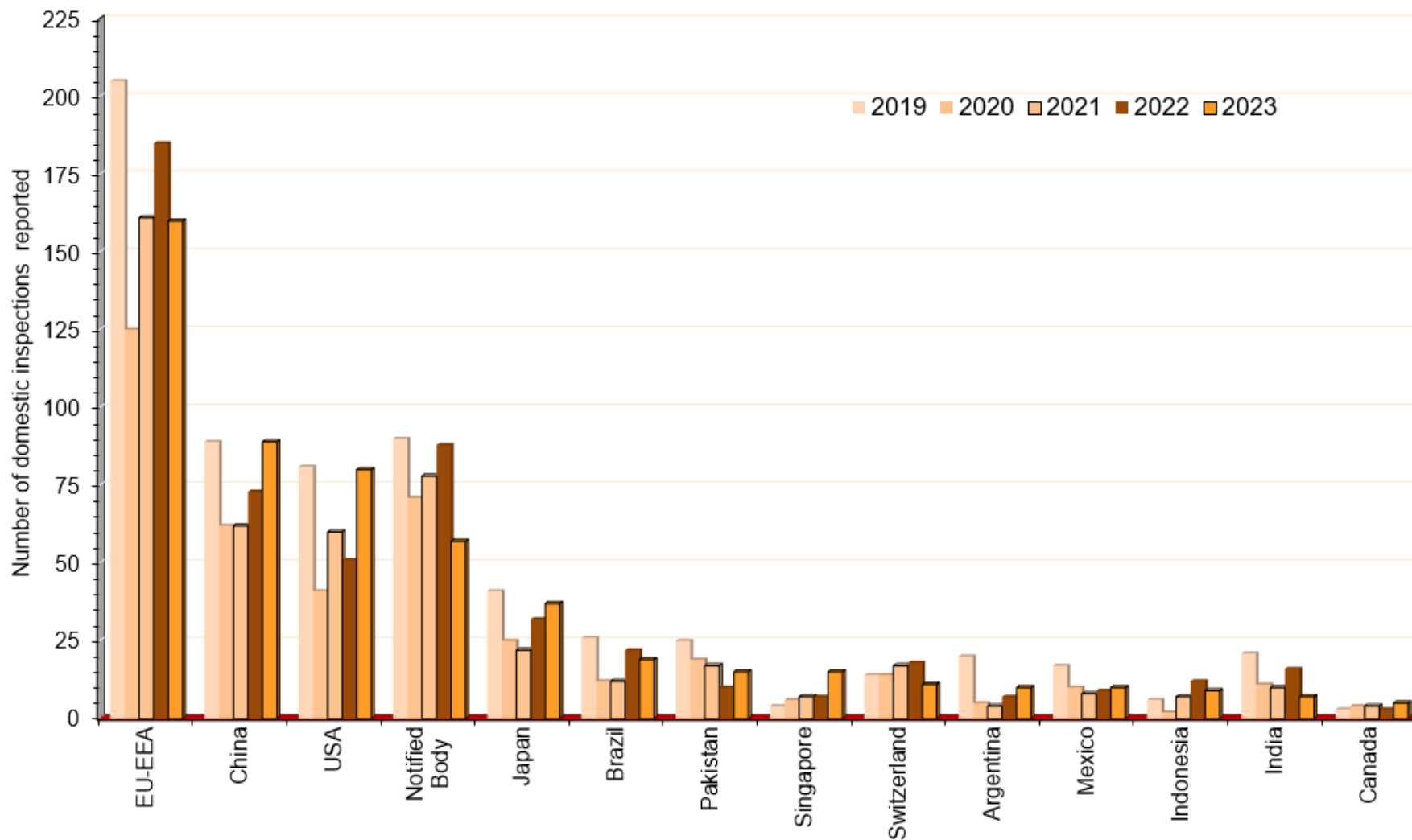
ordered by country (>1 inspections; EU/EEA as one entity; all modes)





DOMESTIC INSPECTIONS AT MANUFACTURING SITES

Number of reported domestic inspections

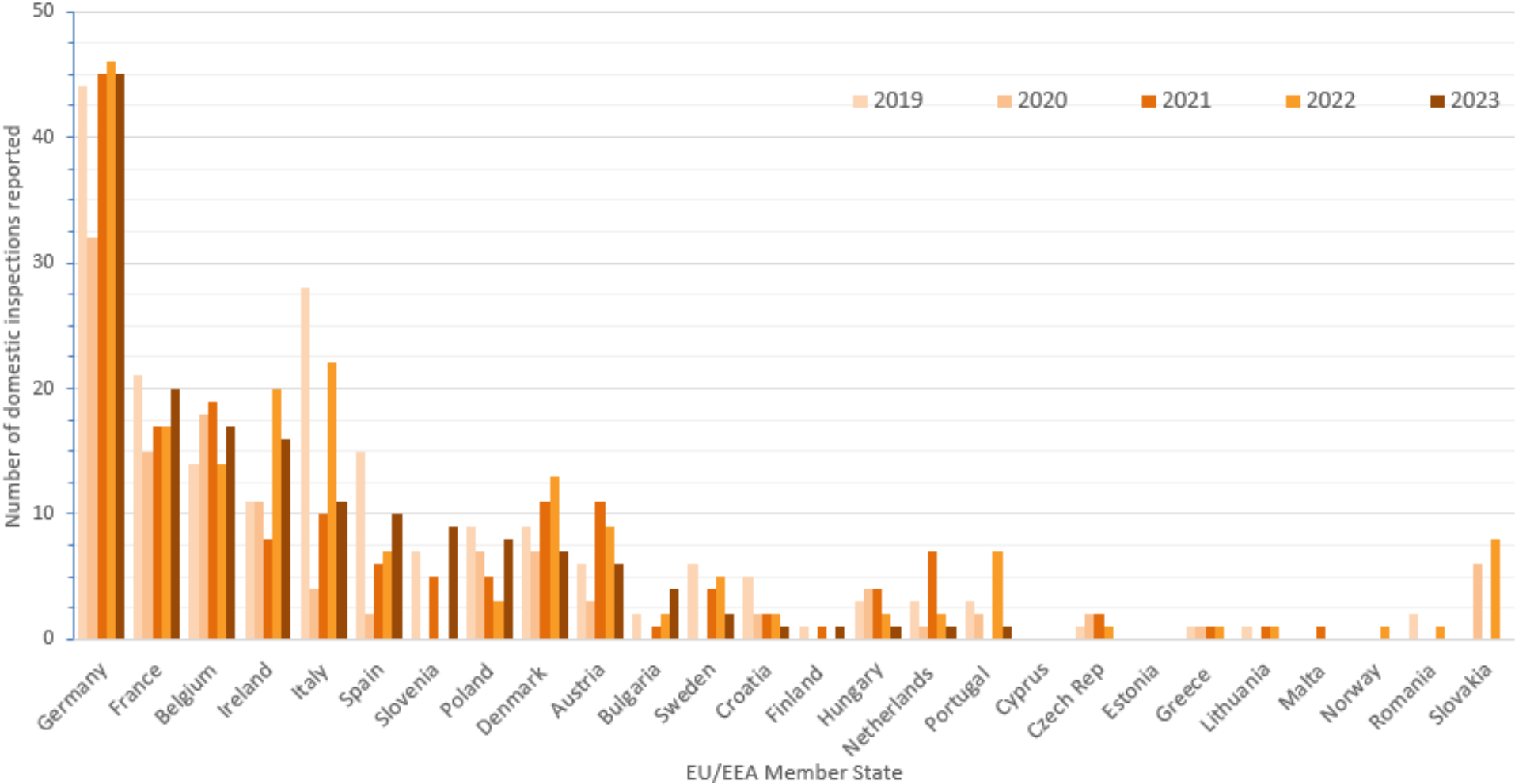


Only listed if more than 7 domestic inspections reported



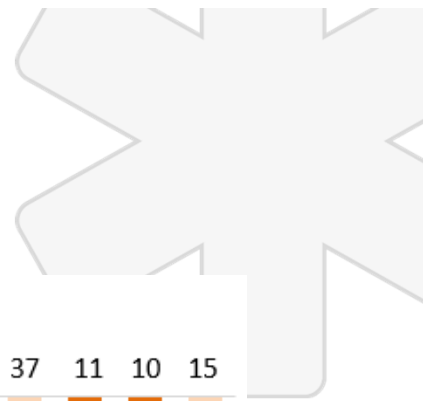
DOMESTIC INSPECTIONS AT MANUFACTURING SITES

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



DOMESTIC INSPECTIONS AT MANUFACTURING SITES

Inspection modes used in domestic inspections



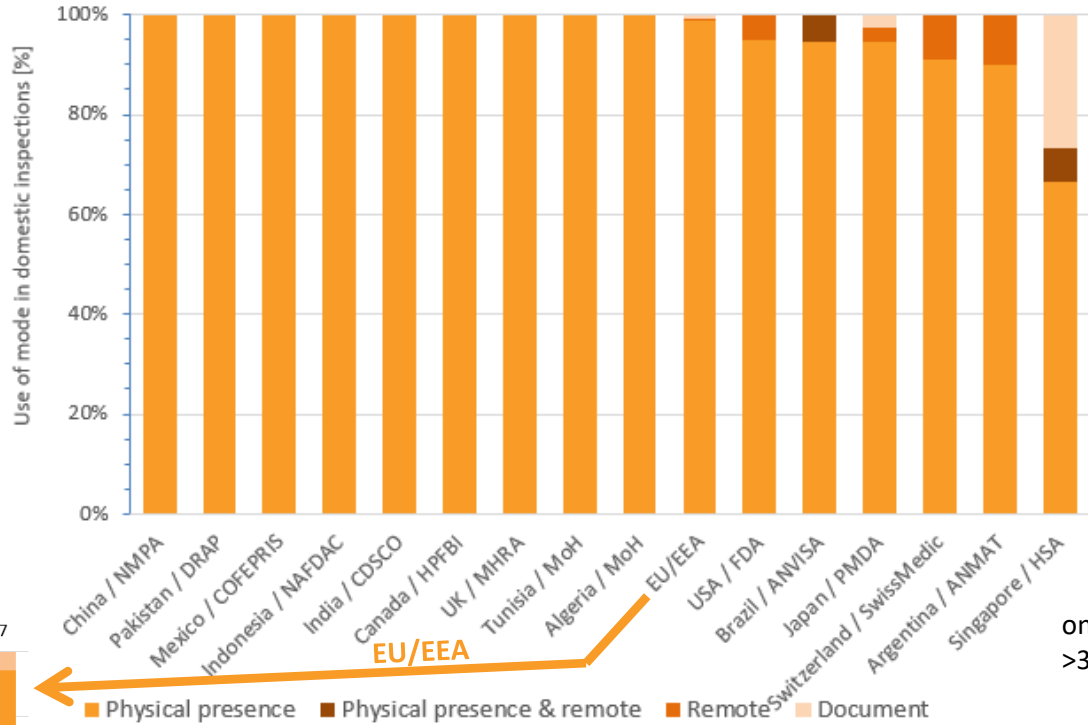
Modes used in domestic inspections in 2023

No of inspections reported

89 15 10 9 7 5 4 4 4 160 80 19 37 11 10 15

* Domestic inspections

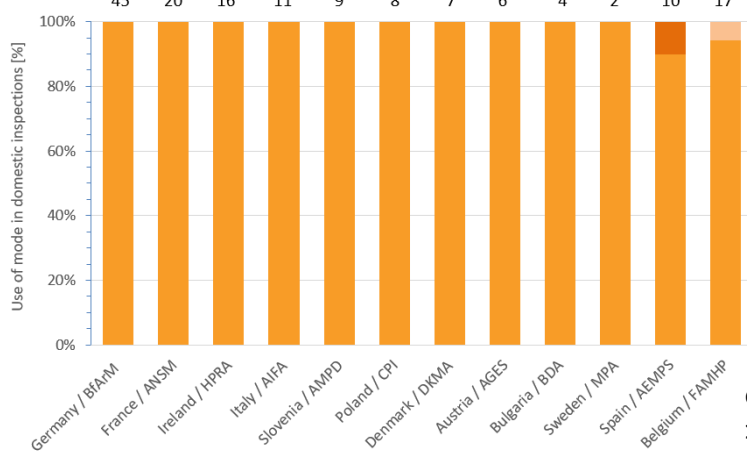
- * Physical presence is the preferred mode
- * The combination of physical presence and remote presence is rarely used



EU/EEA: Modes used in Domestic Inspections in 2023

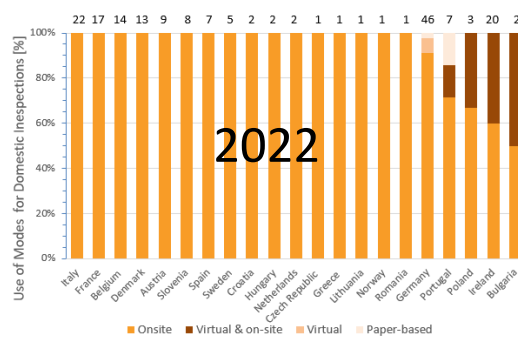
No of inspections reported

45 20 16 11 9 8 7 6 4 2 10 17



only listed if >2 inspection

EEA-MS Modes used in domestic inspections in 2022



2022

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

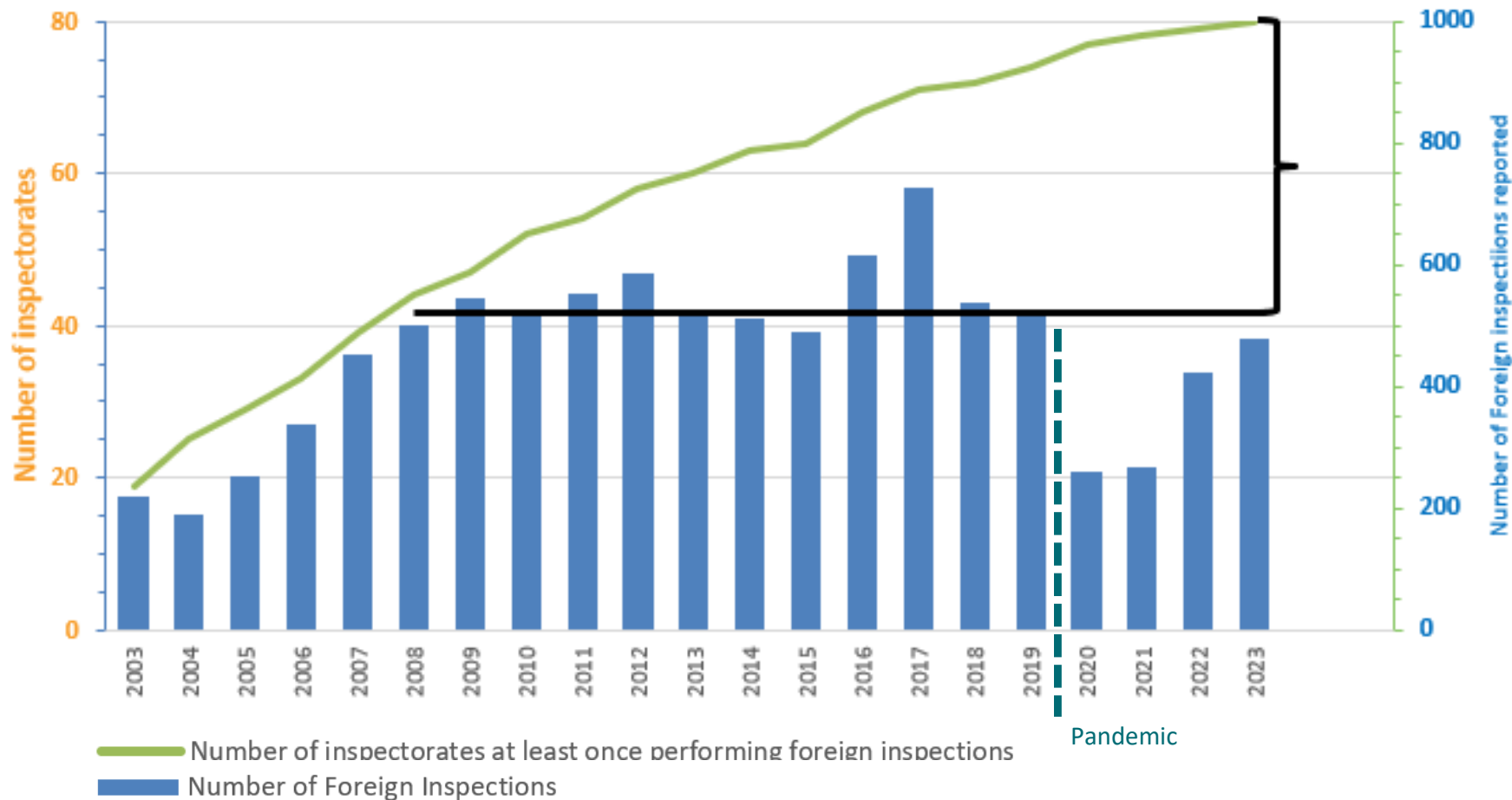


Foreign Inspection Activity



FOREIGN INSPECTIONS AT MANUFACTURING SITES

We broke the trend but back to the previous behaviours



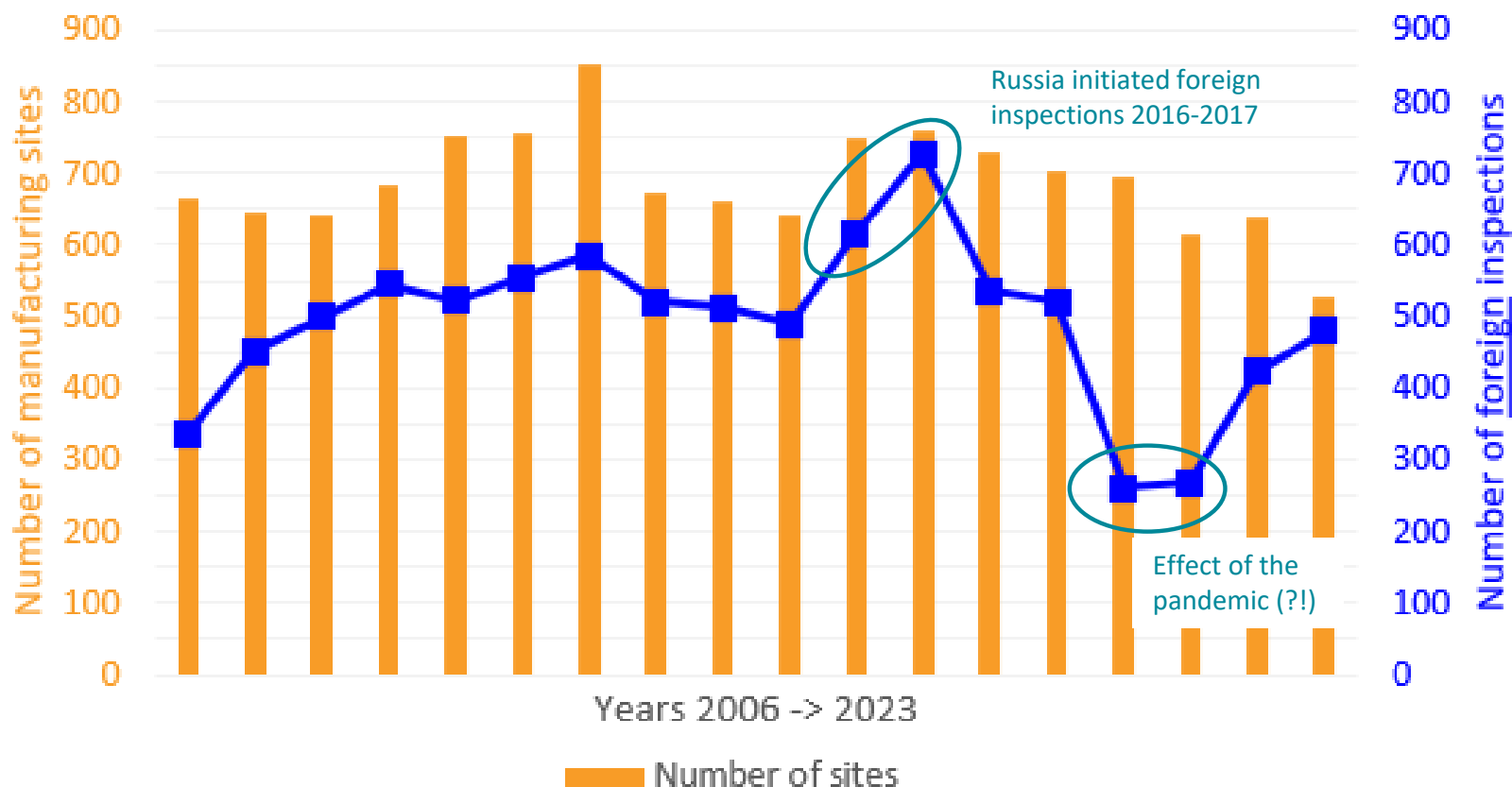
Is this only the backlog or a trend upwards?



FOREIGN INSPECTIONS AT MANUFACTURING SITES

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

Evolution of number of manufacturing sites versus number of foreign inspections

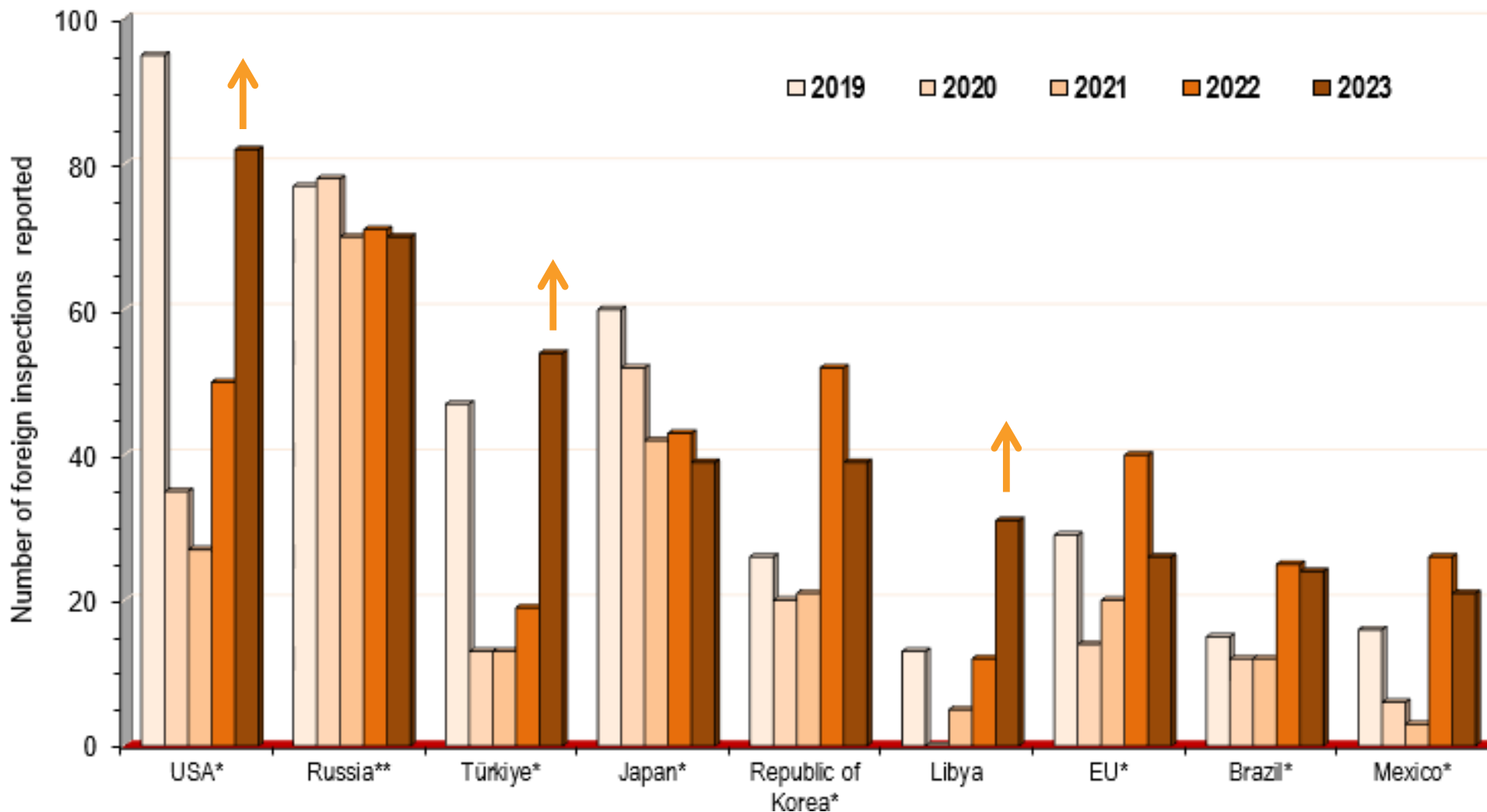


There are no indicators that oversight of the sites was impacted



FOREIGN INSPECTIONS AT MANUFACTURING SITES

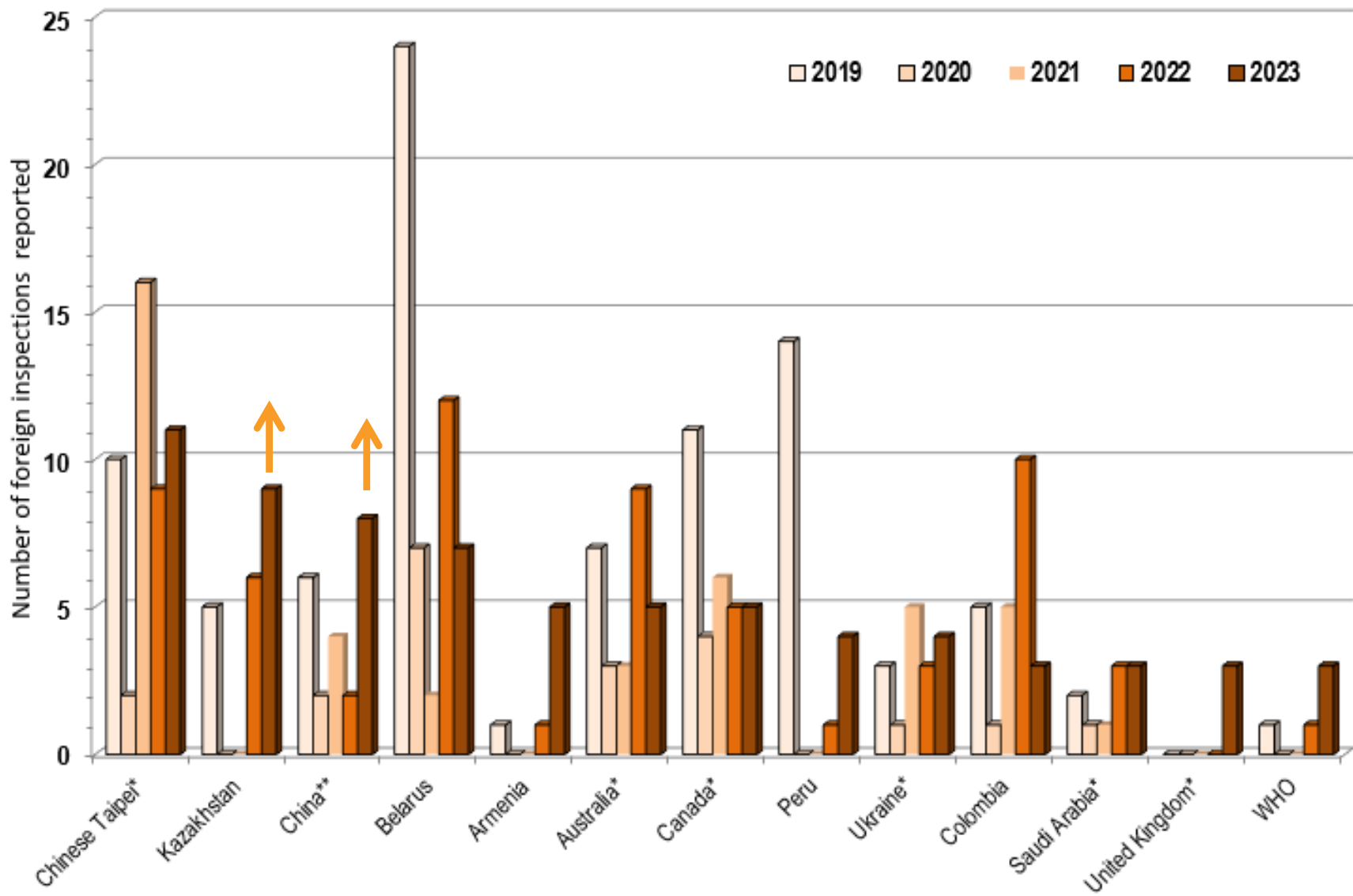
Number of foreign inspections by country 1/2



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

FOREIGN INSPECTIONS AT MANUFACTURING SITES

Number of foreign inspections by country 2/2

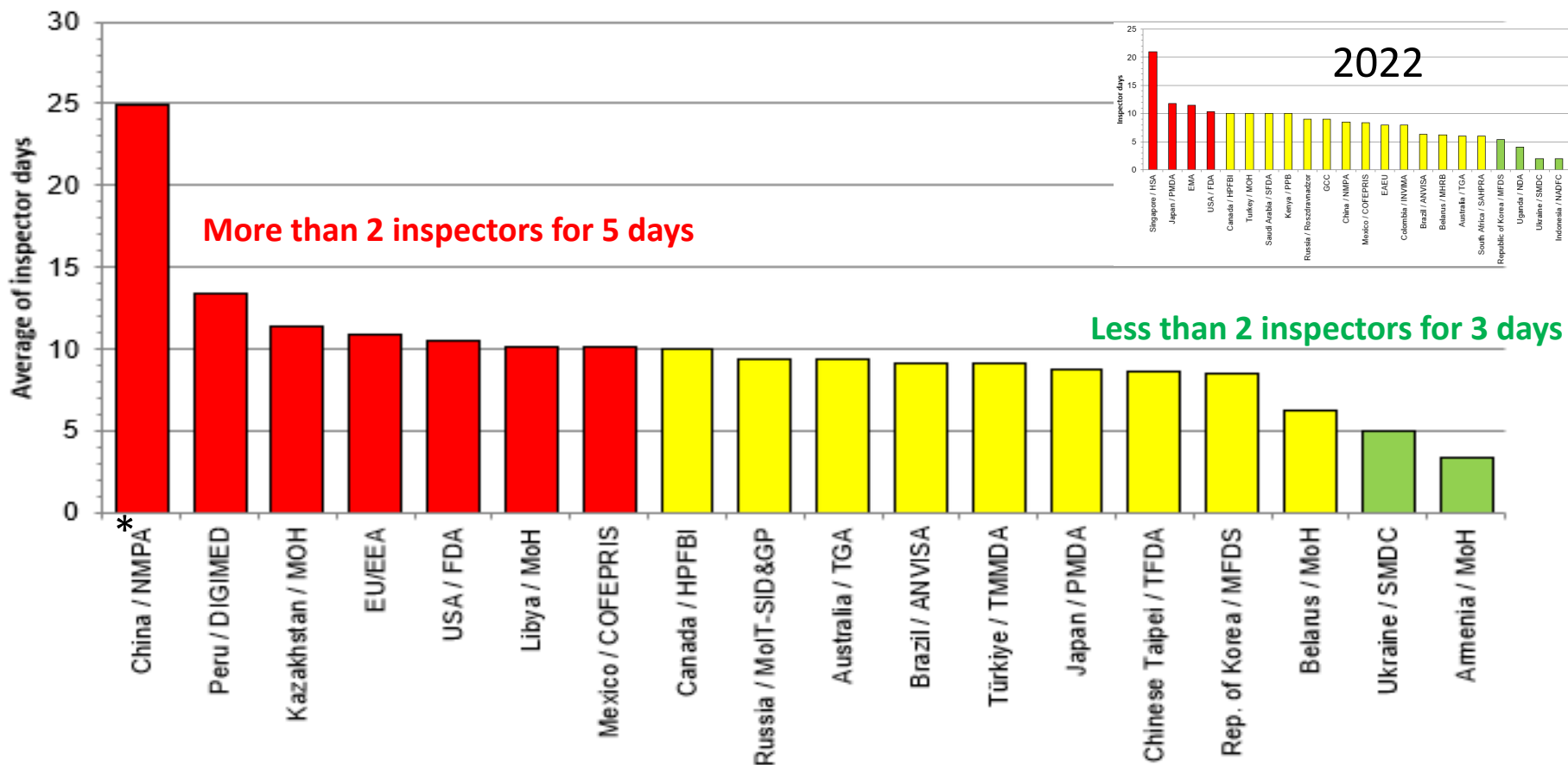


*Inspectorate is a PIC/S member **PIC/S Applicant

FOREIGN INSPECTIONS AT MANUFACTURING SITES

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

Average inspector days - foreign onsite inspections
(only if more than 3 foreign inspections)

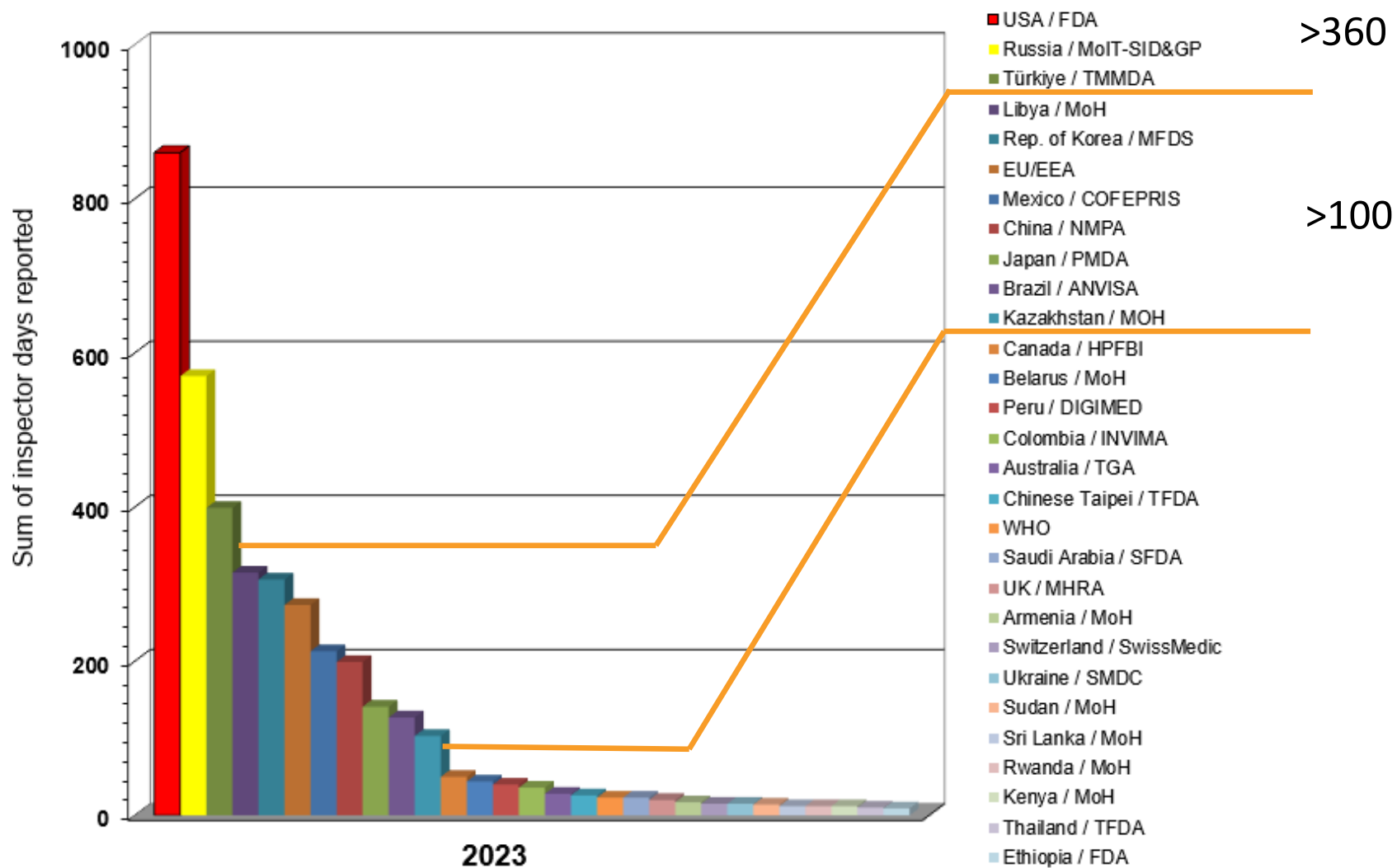


We observe an increasing average of inspector days
Why? - Additional inspectors for training purposes?



FOREIGN INSPECTIONS AT MANUFACTURING SITES

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



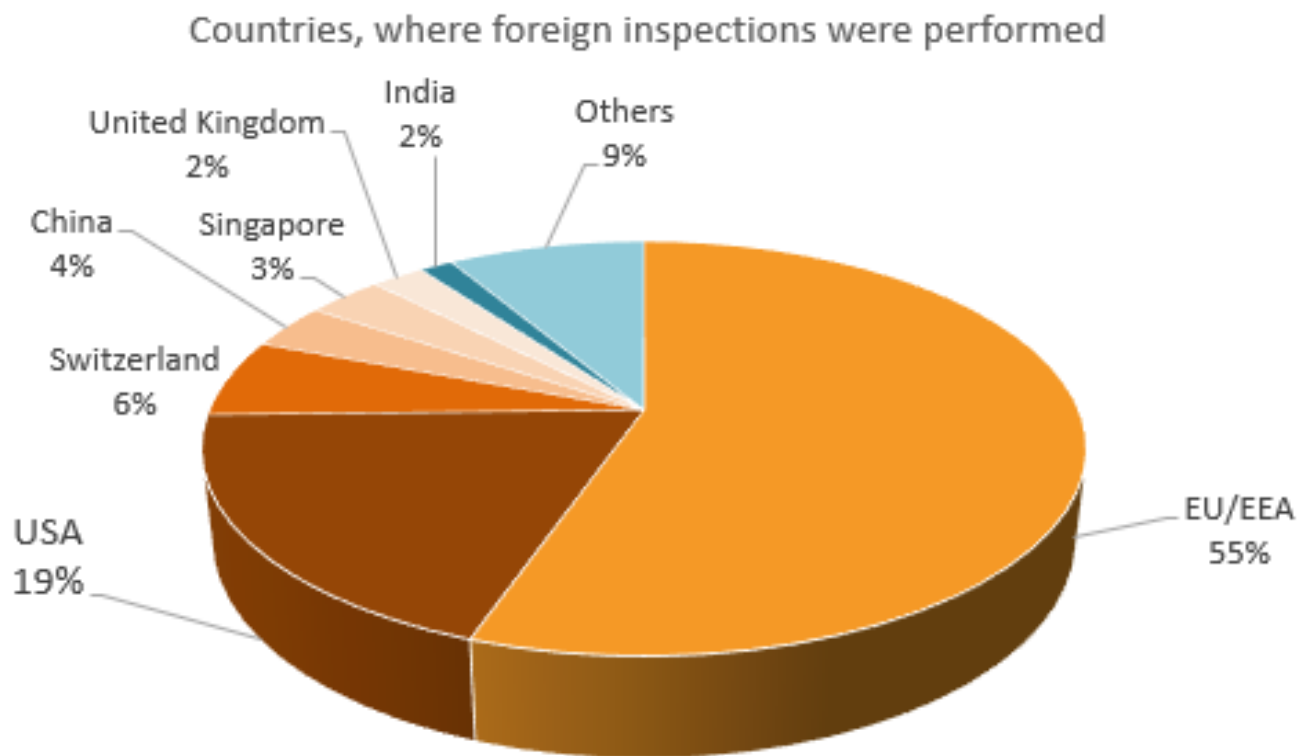


FOREIGN INSPECTIONS AT MANUFACTURING SITES

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



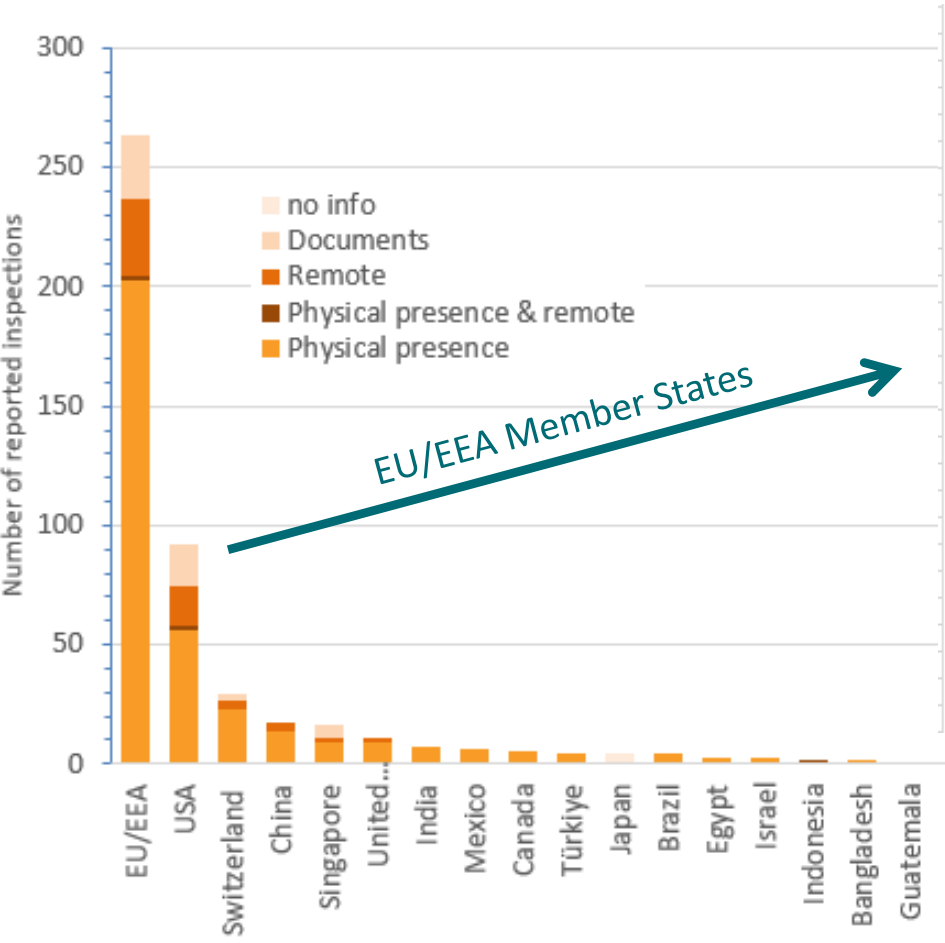
About 80% of the foreign inspections are conducted in EU/EEA, US and Switzerland



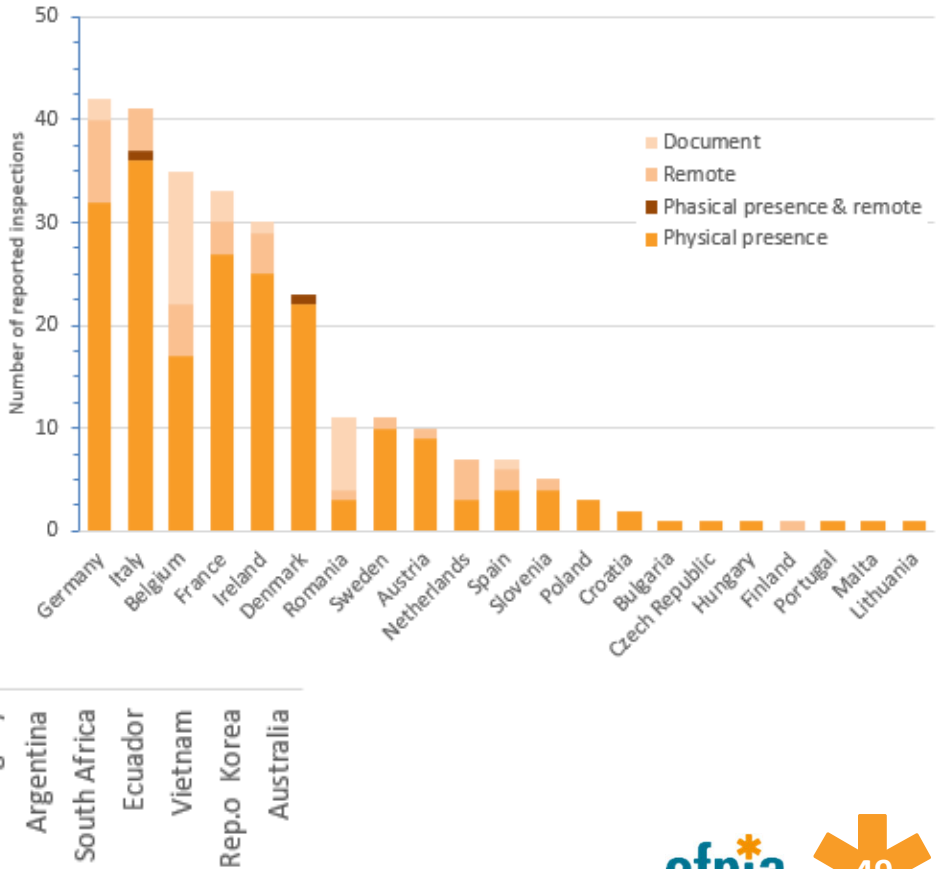
FOREIGN INSPECTIONS AT MANUFACTURING SITES

Locations of Manufacturing Facilities Hosting Foreign Inspections

Countries, where foreign inspections were performed

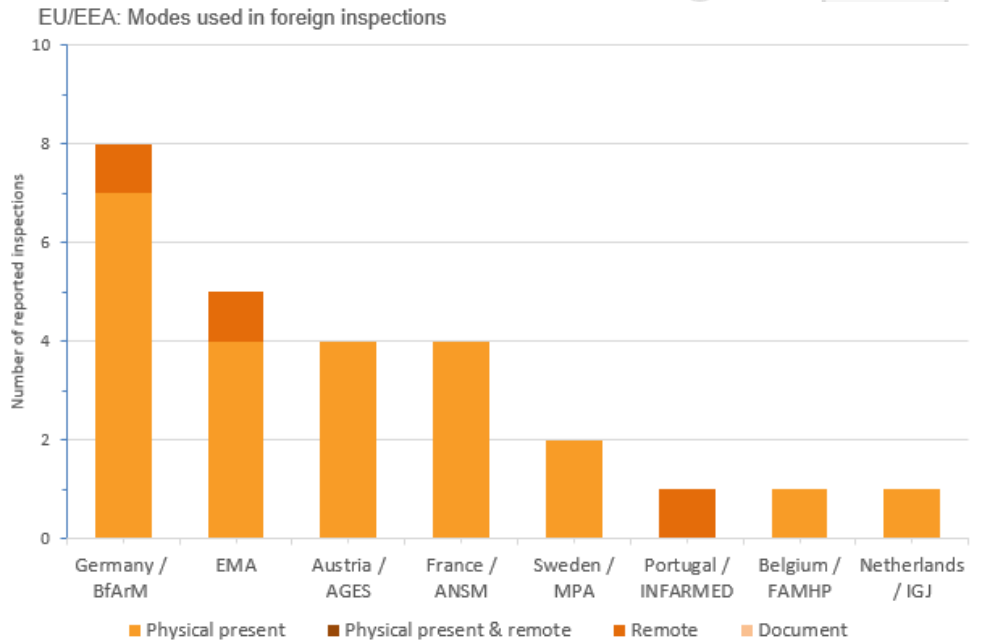
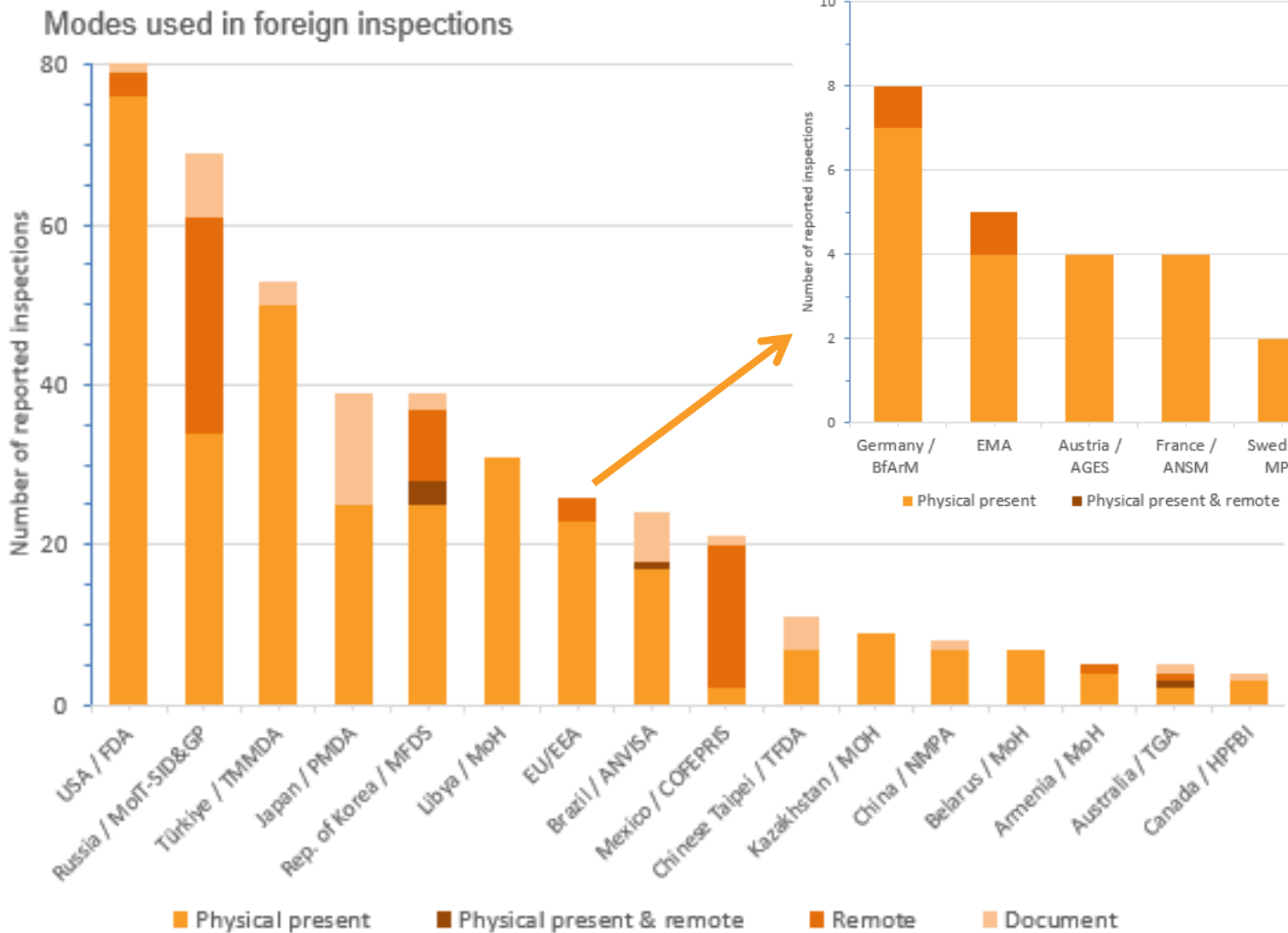


EEA-MS, where foreign inspections were performed



FOREIGN INSPECTIONS AT MANUFACTURING SITES

Modes used by inspectorates in foreign inspections

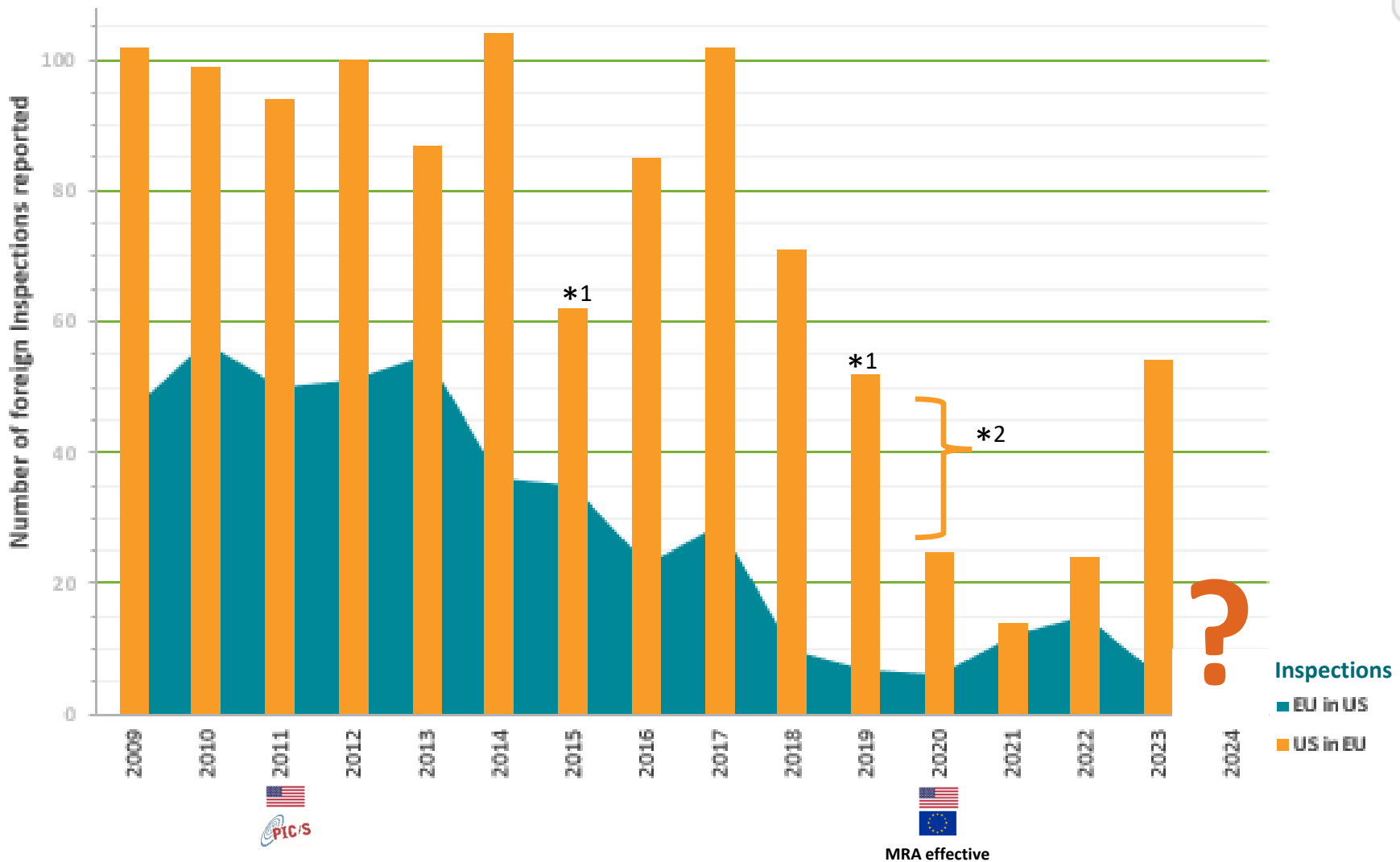




Mutual Recognition Agreements

ANNUAL EFPIA INSPECTION SURVEY – MRA US/EU

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%)

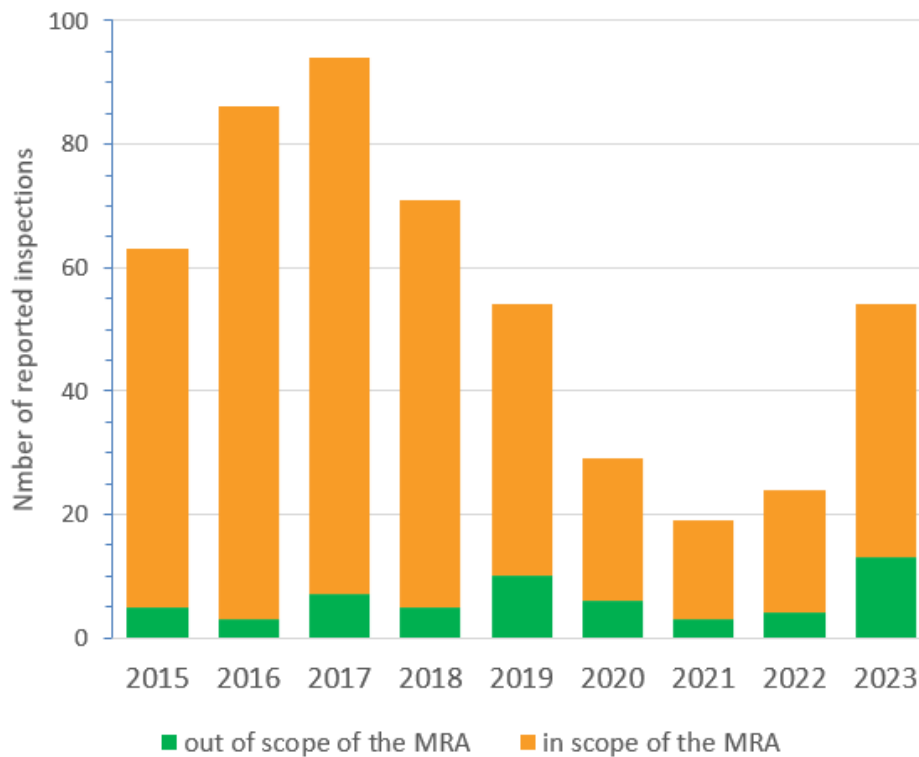
*3 7 out of 15 inspection from the EU in US had been reported to be for vaccines or ATMP



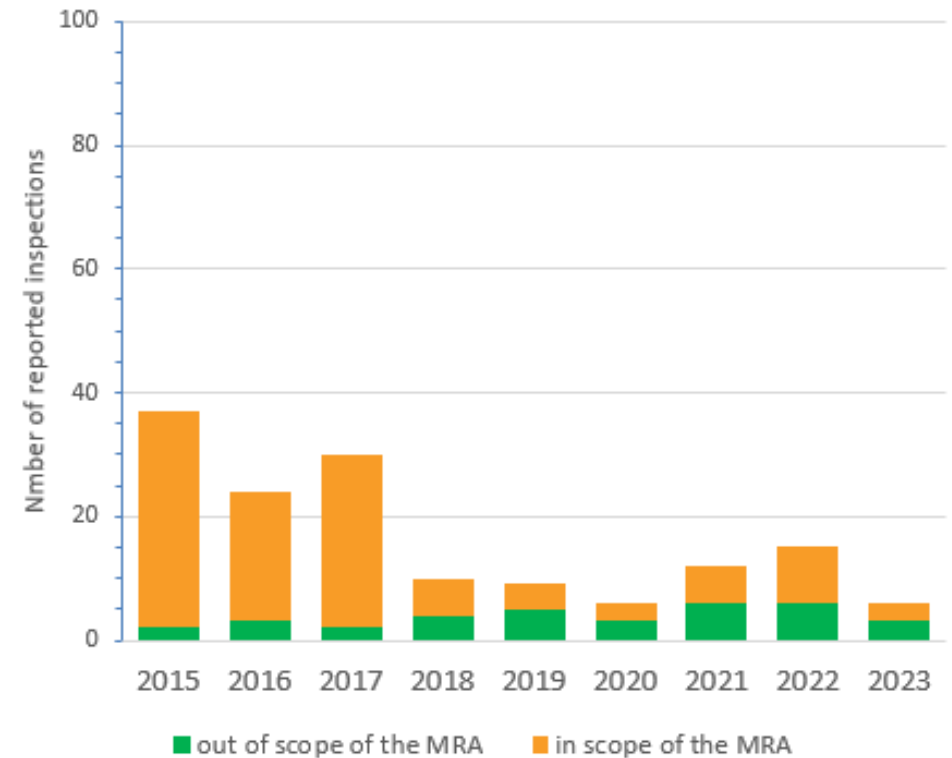
ANNUAL EFPIA INSPECTION SURVEY – MRA US/EU

Inspections in each other territory as of scope

Inspections by US-FDA in EU/EEA



Inspections by EU/EEA inspectorate in US

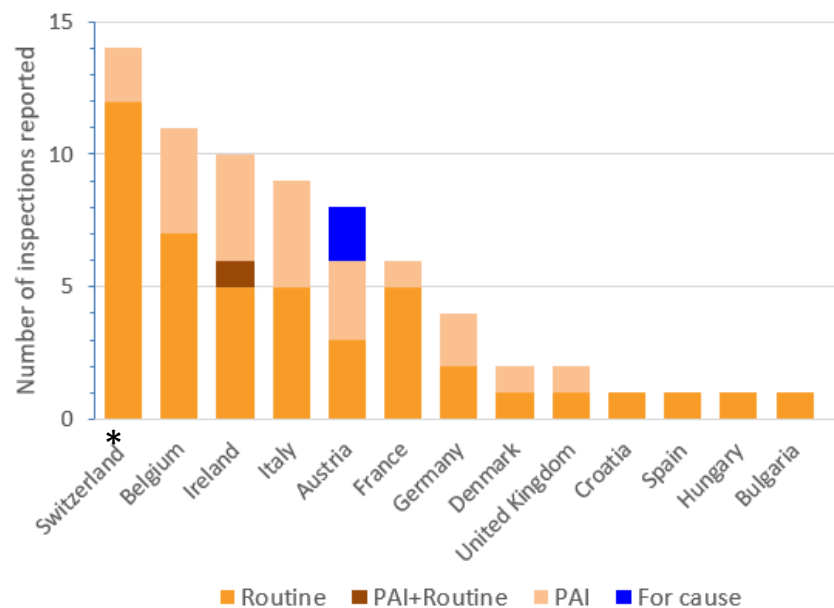




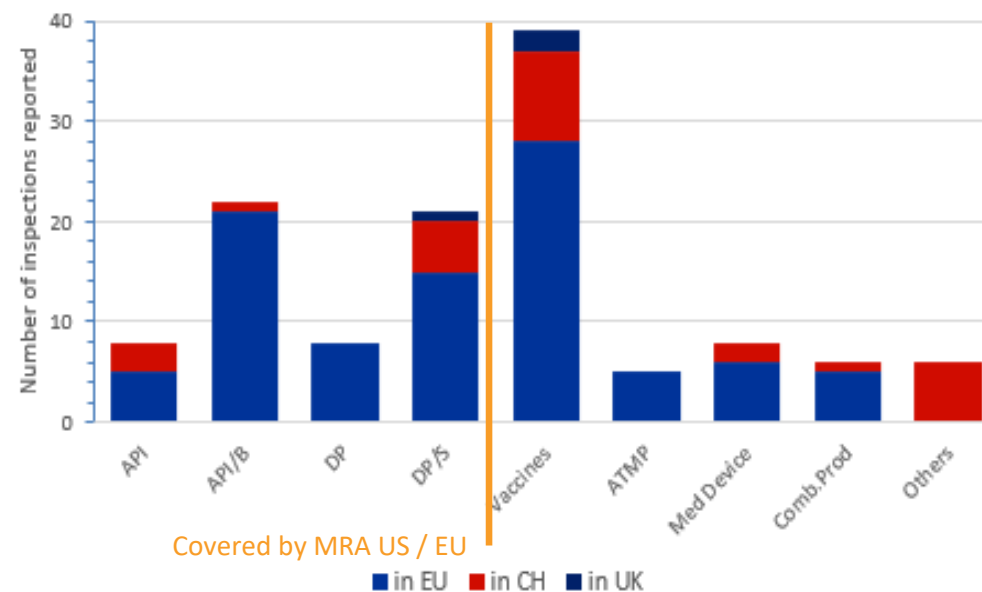
ANNUAL EFPIA INSPECTION SURVEY – MRAs OF US

Full MRA implementation could leverage further benefits

Inspections by US FDA in an MRA country



Inspections from US in MRA countries by product type



- * 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

SPECIFIC INSPECTION ACTIVITIES



PIC/S

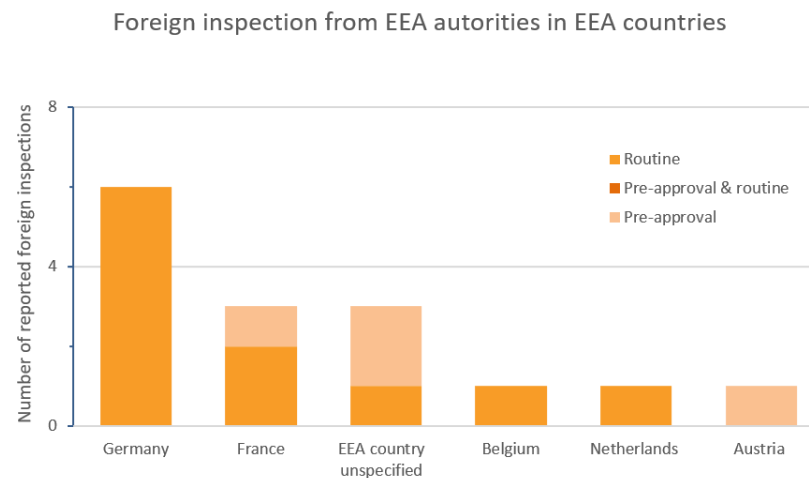
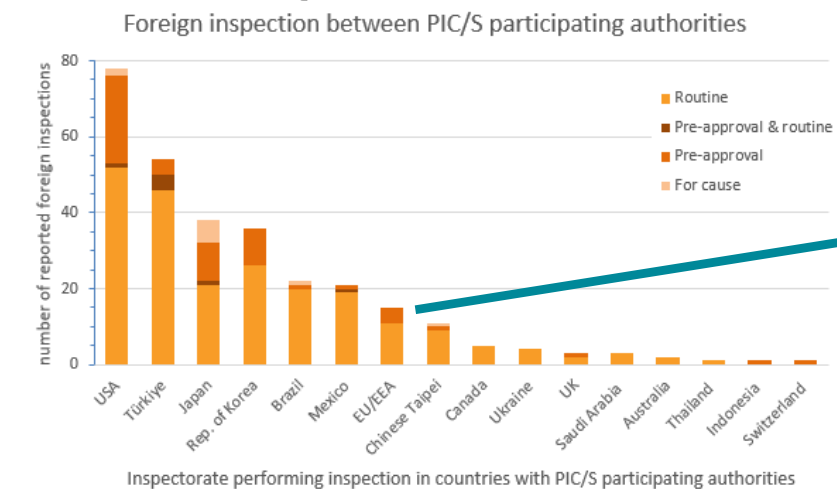
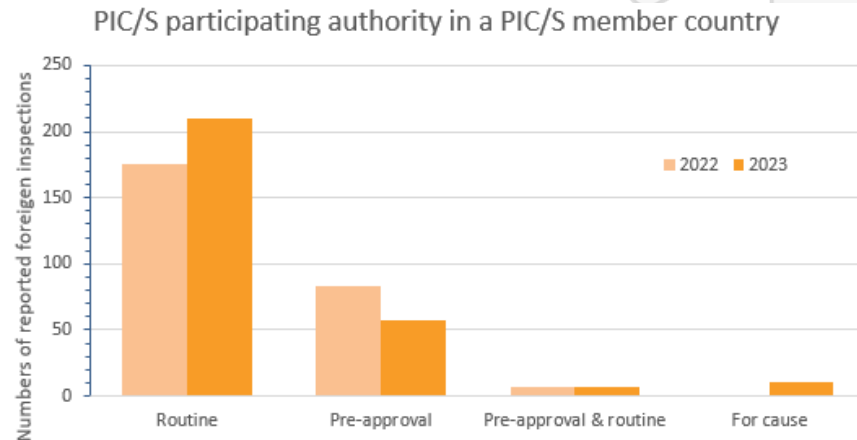
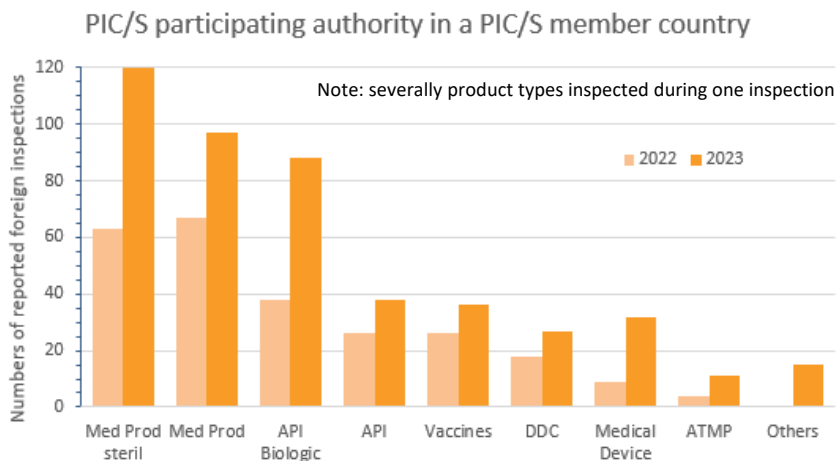
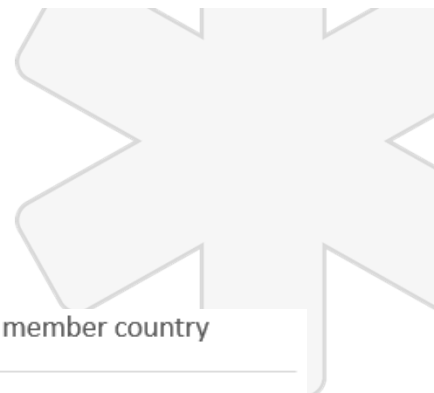
LEVERAGE TOOLS e.g.,

- **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

INSPECTION SURVEY - 2023 DATA

PIC/S Participating Authorities

≈2'500
inspector days used

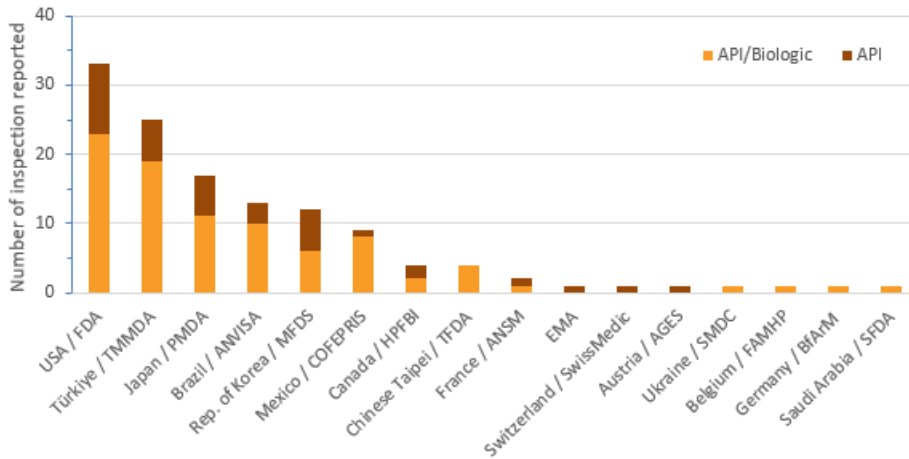


* 295/480 (62%; 63% in 2022) of the reported foreign inspections at manufacturing sites are amongst the PIC/S participating authorities

INSPECTION SURVEY - 2023 DATA

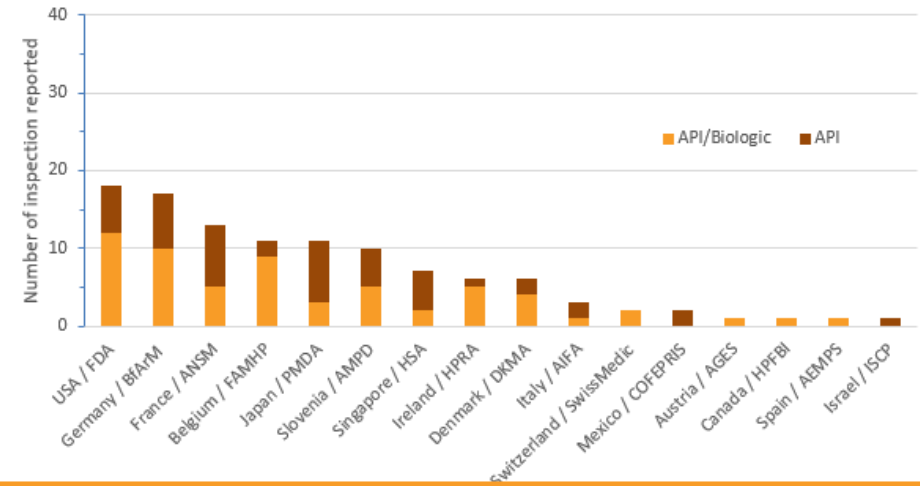
API inspections among PIC/S members

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

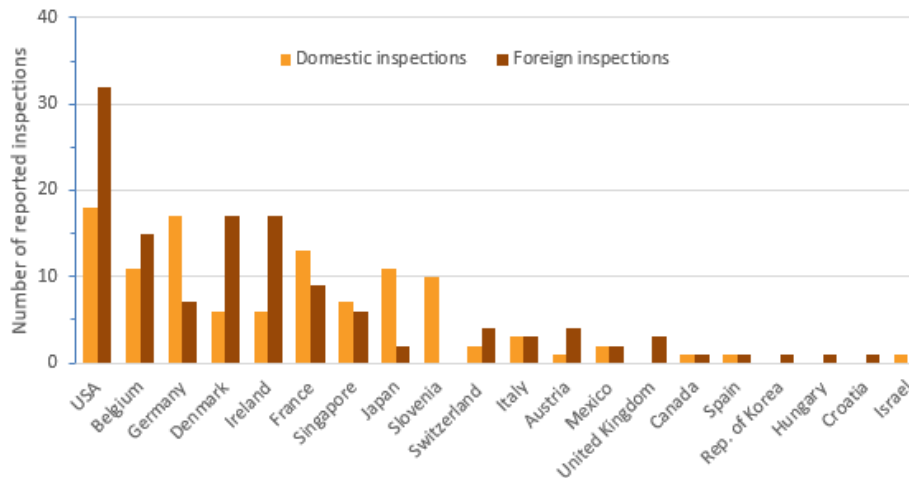


Domestic oversight by inspectorates

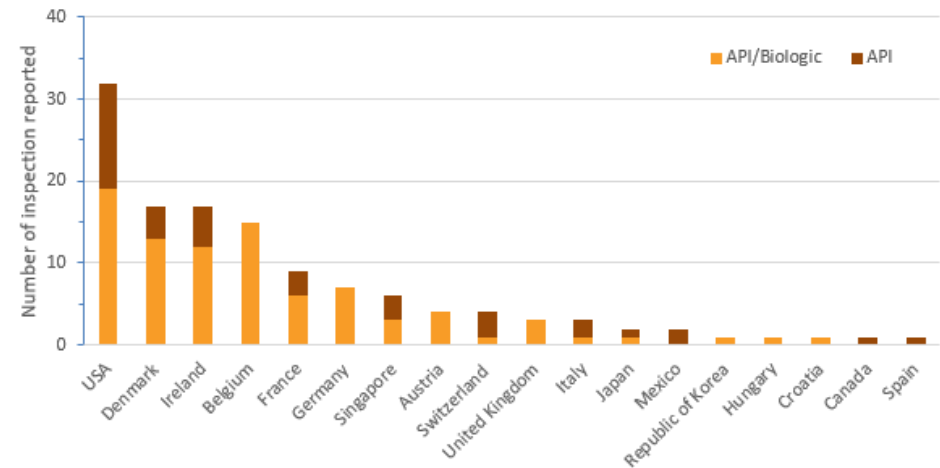
PIC/S member inspectorate performing domestic API inspections



Sites receiving inspections



Sites receiving foreign inspections



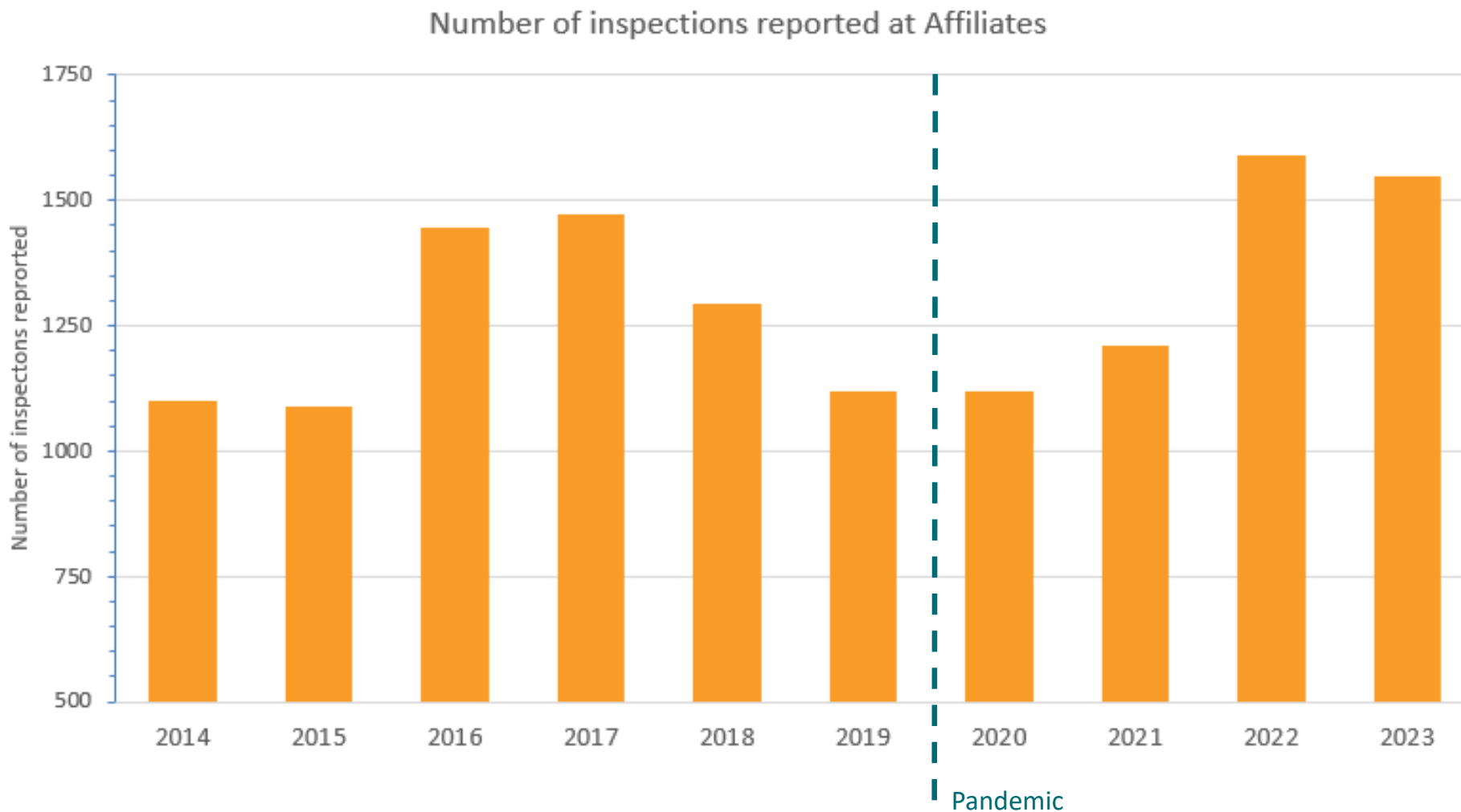


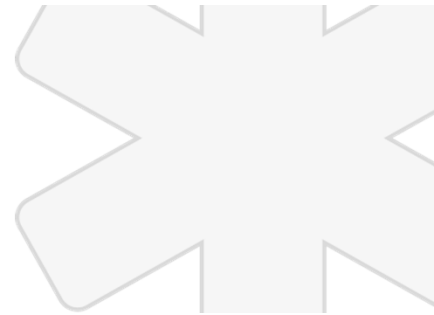
Inspections at Affiliates



INSPECTIONS AT AFFILIATES

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

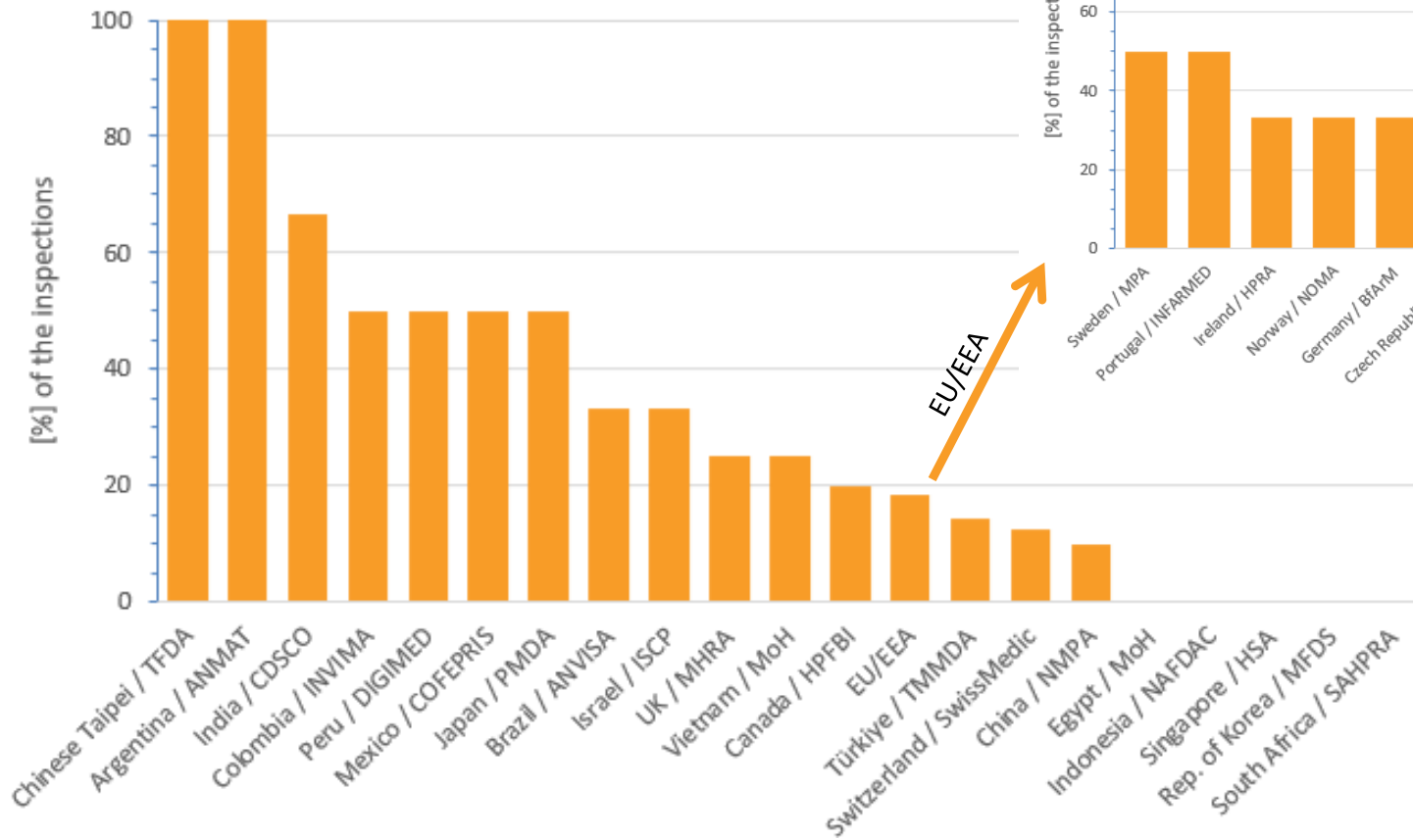




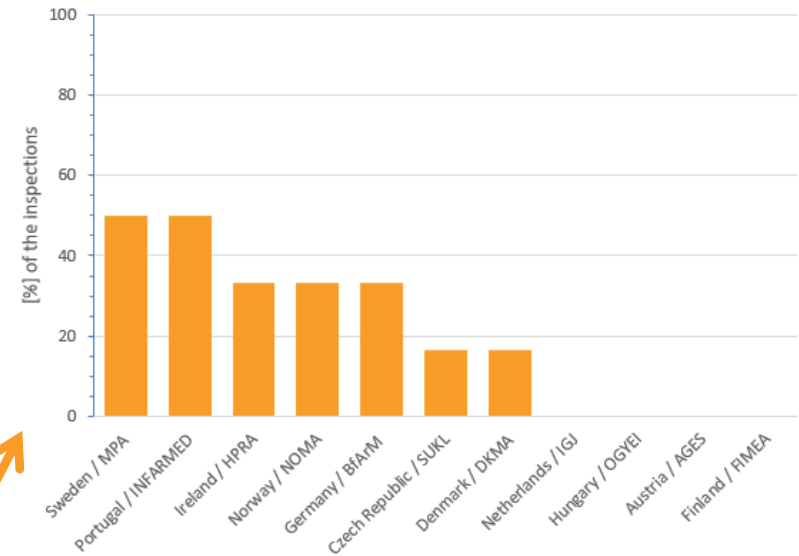
INSPECTIONS AT AFFILIATES

Inspection with assessors over all

Inspections at affiliate with assessors (>5 inspections)



Inspections at affiliate in EU/EEA with assessors (>5 inspections)



For PAI only 'no' or 'unknown' reported

EFPIA ANNUAL INSPECTION SURVEY - 2023 DATA

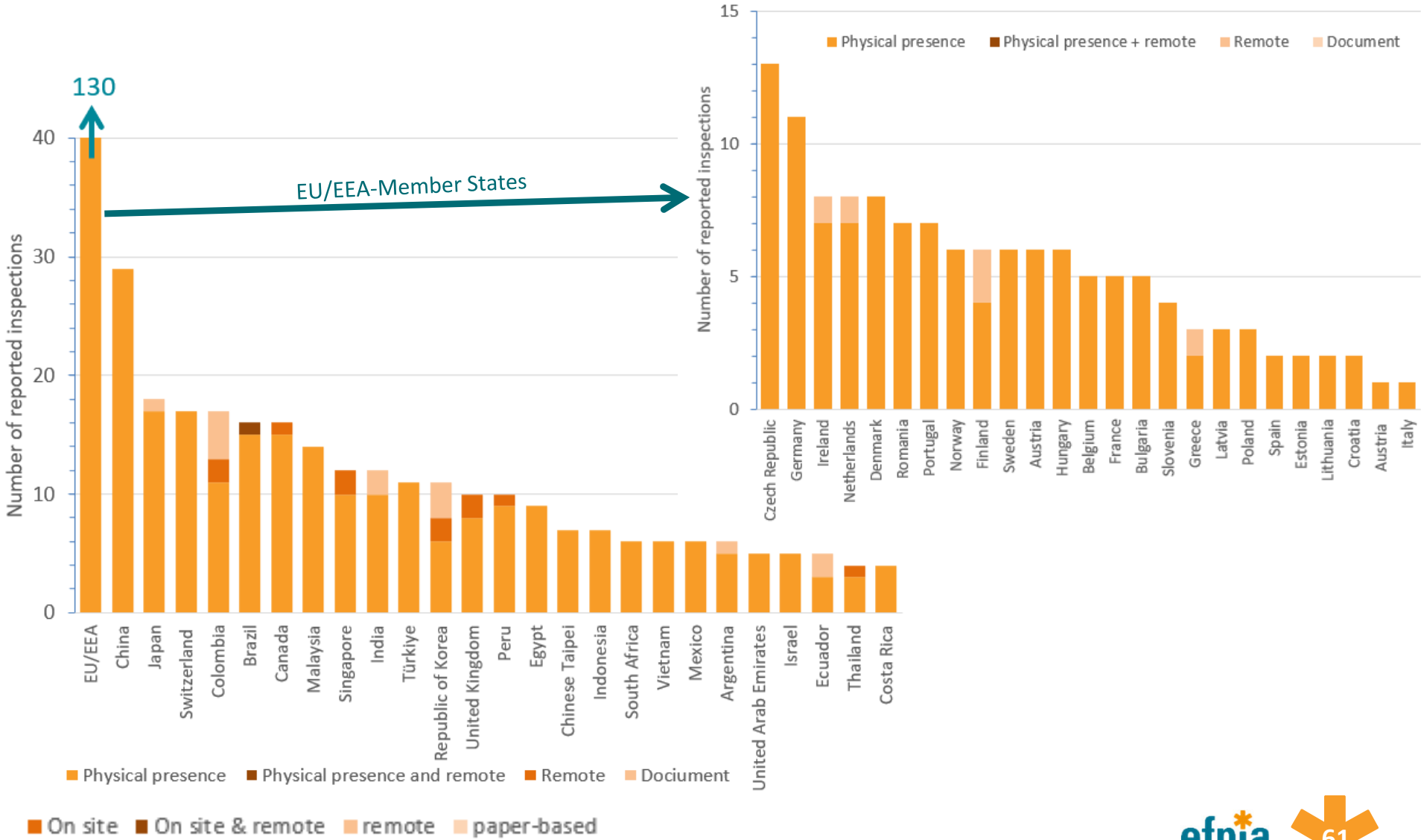
Answers giving 'unknown' are excluded



INSPECTIONS AT AFFILIATES

Local affiliates have received inspections – no trend by region

Affiliates inspected in EU/EEA

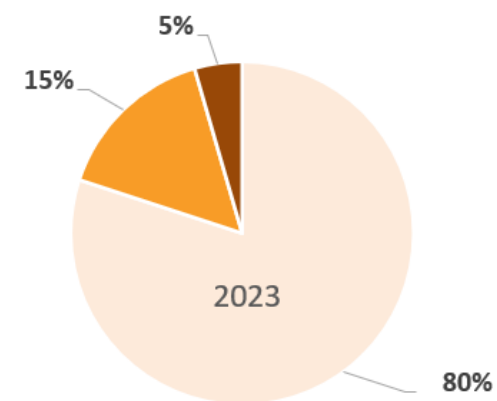
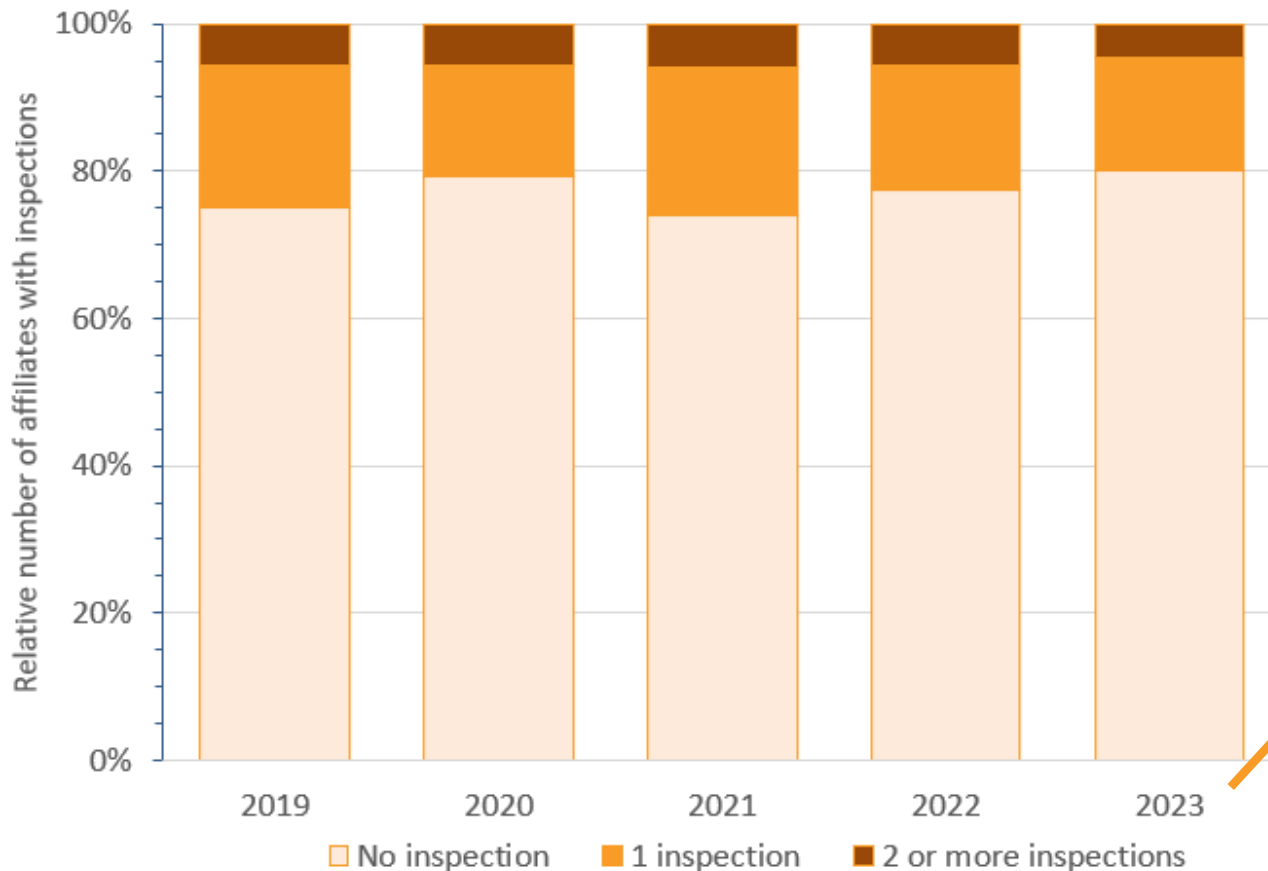




INSPECTIONS AT AFFILIATES

Number of affiliates inspected

Inspections at affiliates



* Facts

* Number of oversight constant

* 80% without inspections – assumption: inspections every 5 years?



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