European Federation of Pharmaceutical Industries and Associations

# Annual Regulatory GMP/GDP Inspection Survey 2025 Data

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Summary

Public version

# Key messages: Inspection schedules start to turn inspection reliance into routine practice

## Take aways

- **Foreign inspections are decreasing**, suggesting regulators are relying more on each other's inspections and reducing duplication
- **Inspections are becoming more focused and demanding**, with greater emphasis on systems, risk-based approaches, and targeted questions rather than simple procedure checks
- **Operational challenges remain**, including differing interpretations and formats, while unannounced inspections mainly affect logistics

## Calls to action

- **Inspectorates to collaborate** using the reliance toolbox e.g., PIC/S systematically, facilitating established trade relationships and extending recognition
- **Advocate for better cooperation on** scheduling, aligned scope, common report formats, and broader recognition of trusted authorities, especially PIC/S participating authorities
- **Companies to proactively identify potential duplicated inspection** situations and formally request reliance

# Background and history

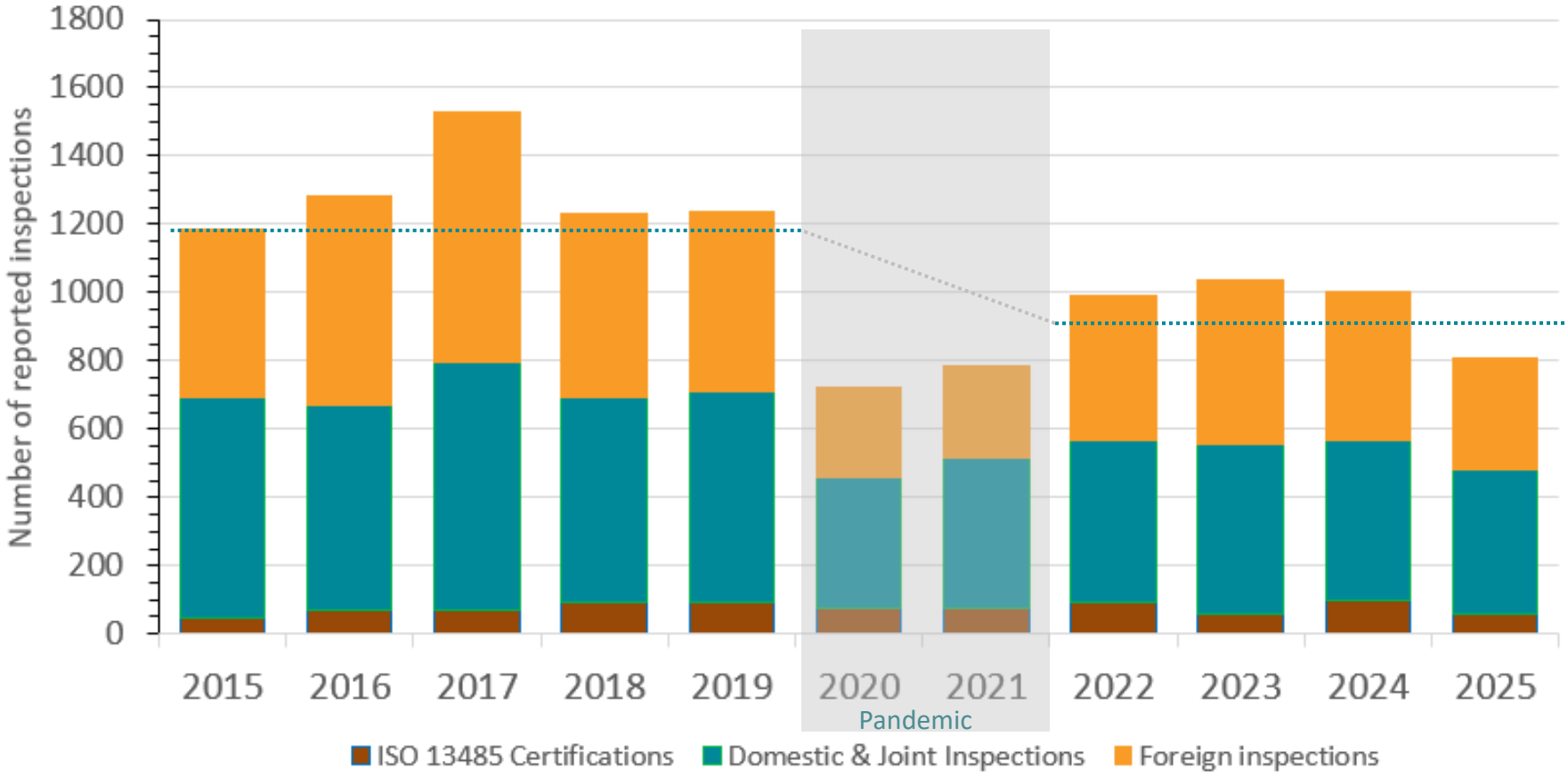
- **History**
  - The annual inspection survey was initiated in 2003 by the research-based industry association EFPIA
- **Scope**
  - Regulatory GMP/GDP inspections – all modes
  - Inside and outside the own borders (domestic and foreign*)
  - Manufacturing sites and commercial affiliates worldwide
  - Notified Bodies certifications for devices used in Medicinal Products
- **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 undertaken outside of the inspectorate's country.

# Trends on inspection modes


* performed mainly by Türkiye and Japan

# Reliance appears to materialise




✱ ≈ 25% less inspections compared to the data 2015-2019

# Did we cross the pivot point for the number of foreign inspections?


Inspection performed by foreign authorities ?

Yes

When yes, generally
- No reduction of time
- No reduction of scope

No
(rely)

Picture created by ChatGPT

# Outcome of the data for inspections at manufacturing sites

**Inspection process**

- **Onsite inspections are the norm**; 'remote' inspection remain as back up option
- **The implementation of GMP Annex 1** did not increase the number of inspections at sterile manufacturing sites of medicinal products nor APIs

**Outcome of inspections**

- **Continued supply**: No site reported interruption of supply as of inspections
- **'For cause'**: Numbers are decreasing & still result in no interruption of supply
- **Announced or unannounced** inspections yield **similar** outcomes

**Inspection practices**

- **Unannounced inspections** are mostly performed by China and the US-FDA*1
- **Same duration** for domestic and foreign inspections this year*2
- **Inspections reported as 'PAI'** are performed by many inspectorates (JP, EU,US,KR)

**Foreign inspections**

- **Positive indicator on reliance**: Number of reported inspections declined
- **1st time in 23 years**: no new country reported to perform foreign inspections

*1 The US-FDA is the only agency reported to perform foreign unannounced inspections

*2 Not including travel time

PAI: pre-approval inspection

# What do the data tell us on foreign inspections?

## *Overall trending down*

| | Tendency compared to last years | Inspectorates from |
|---|---|---|
|  | Significant increase | None |
|  | Increasing | None |
|  | Stable at a high level | EAEU*[1], Republic of Korea, Türkiye, Japan*[2], EU/EEA |
|  | Decreasing | USA, Brazil |
|  | Significant decrease | Mexico, Libya, Chinese Taipei |

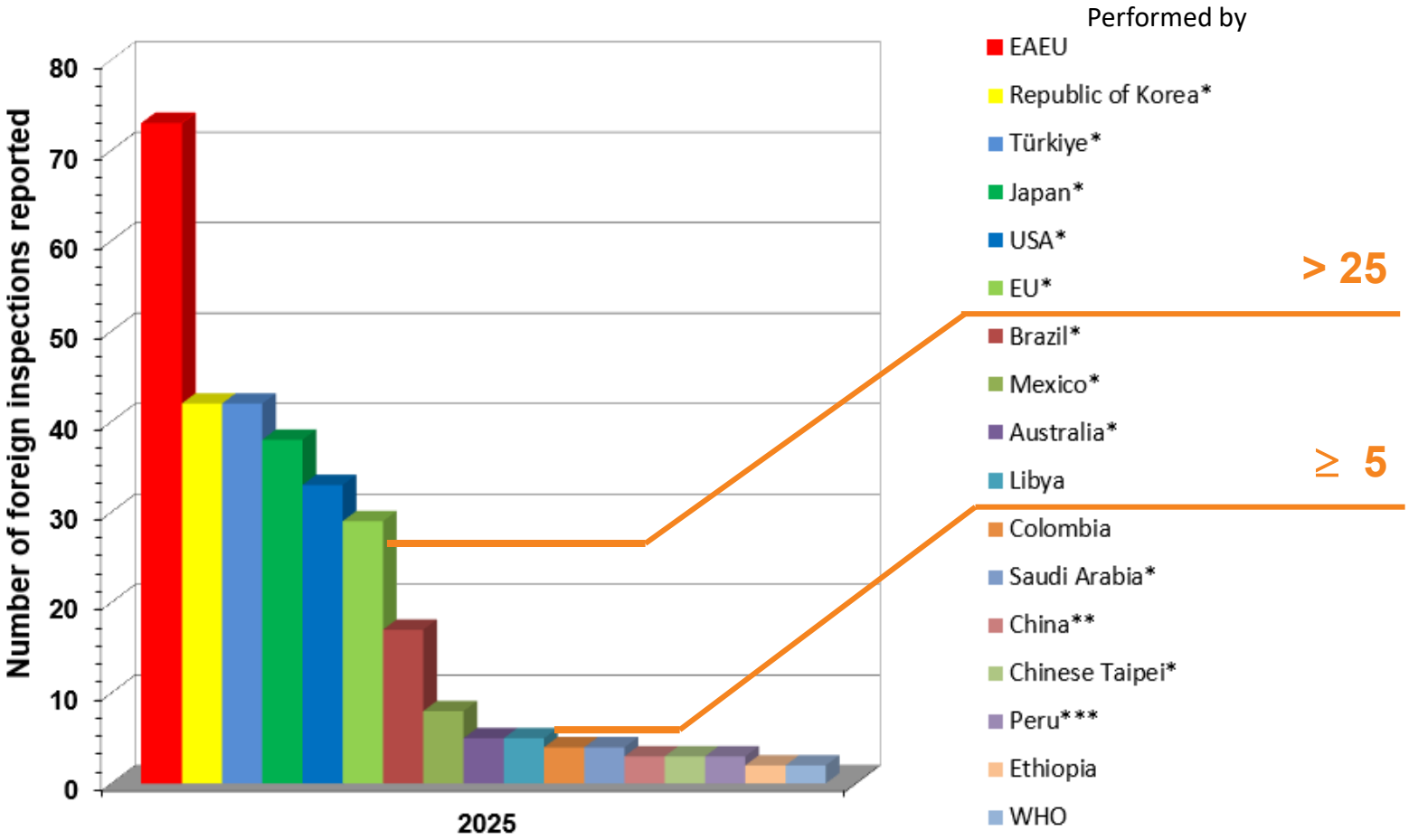


*1 'EAEU' and Armenia, Belarus, Kazakhstan, Russia

*2 The number of inspections in the EU are trending downwards since 2019

# Number of foreign inspections at manufacturing sites

## (EU and EAEU each as one entity; all inspection types and modes)

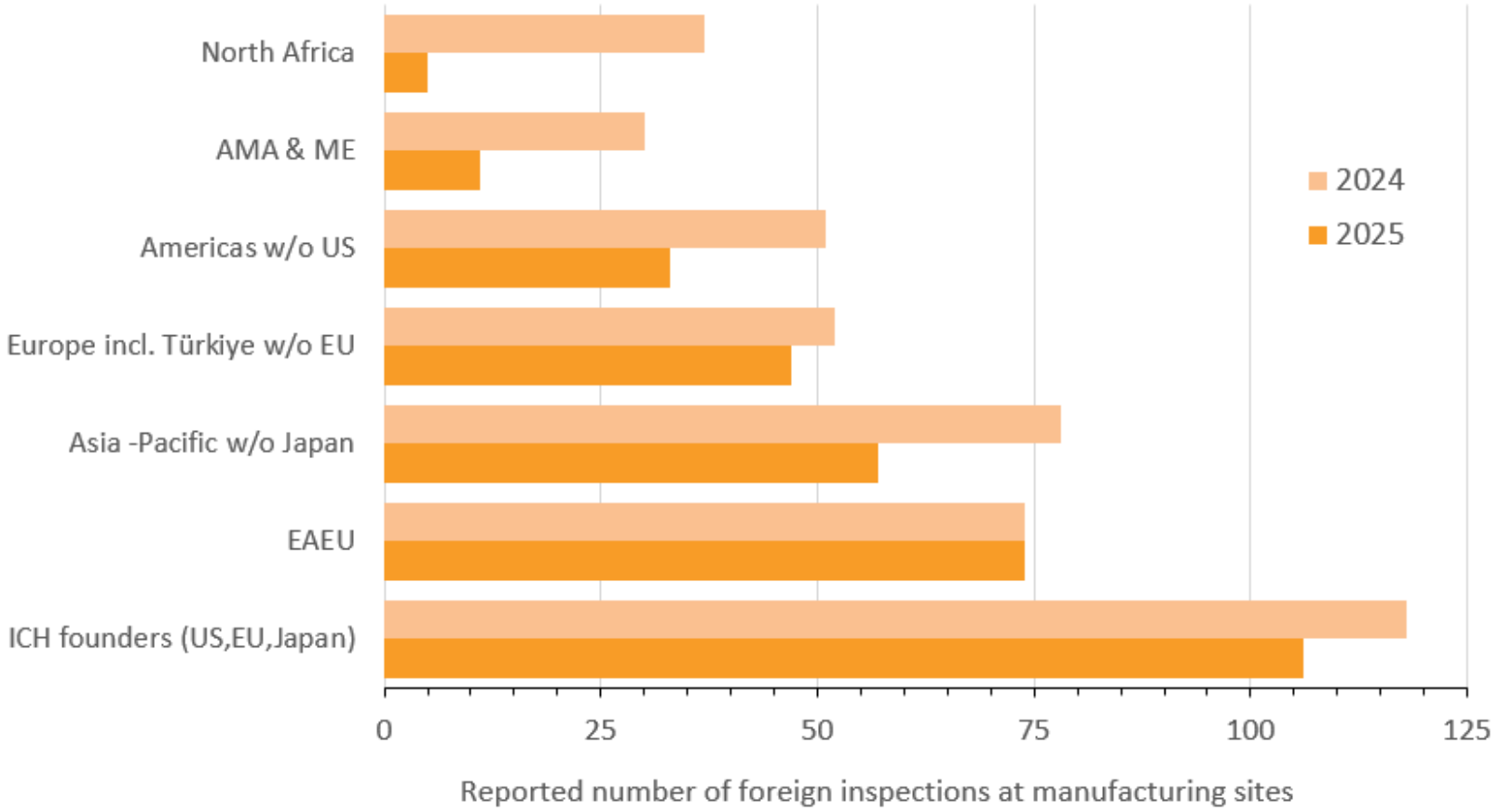



+ 12 countries with one foreign inspection

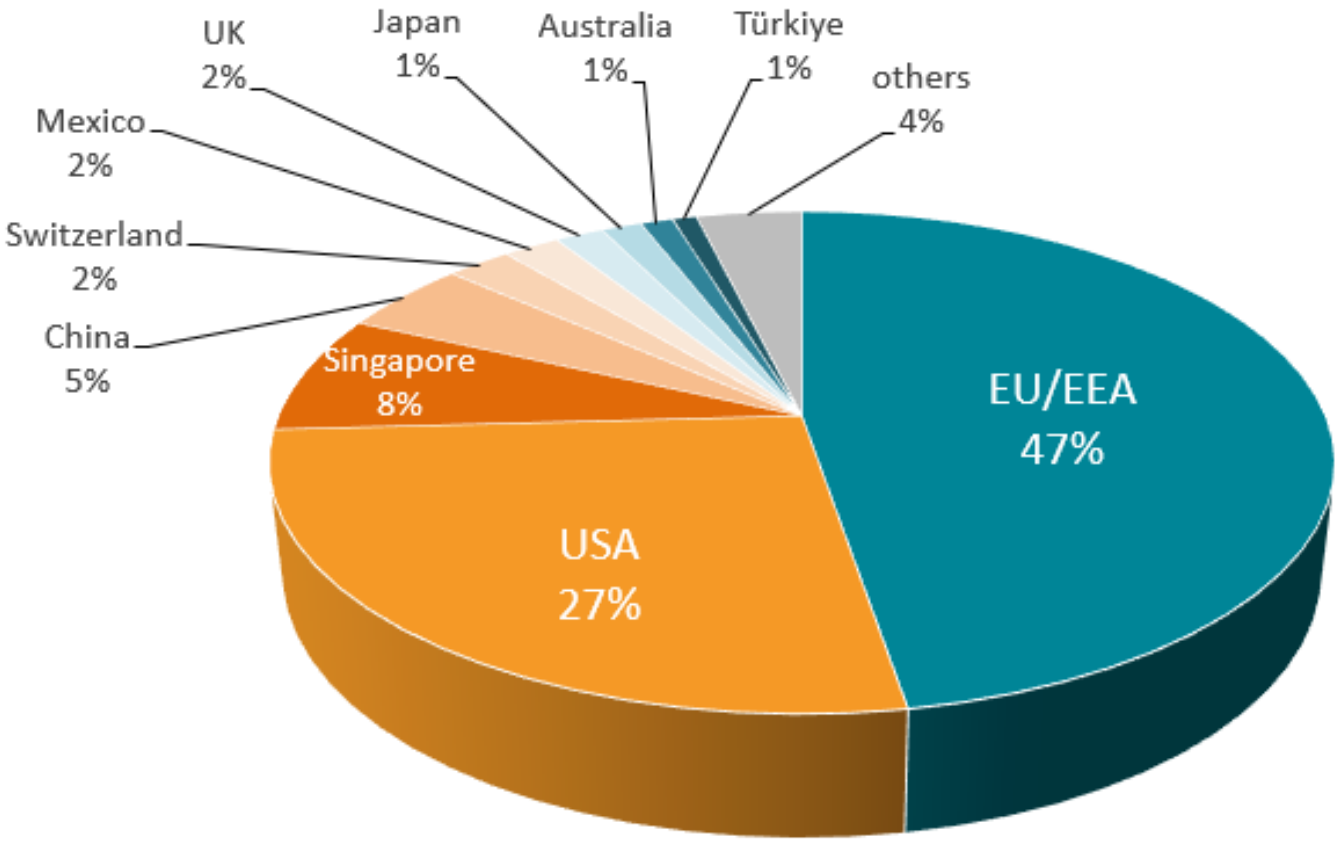
*Note: EAEU members combined the first time as many companies flagged 'EAEU' inspections*

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

# Number of foreign inspections at manufacturing sites by region of the inspectorate is less duplicative

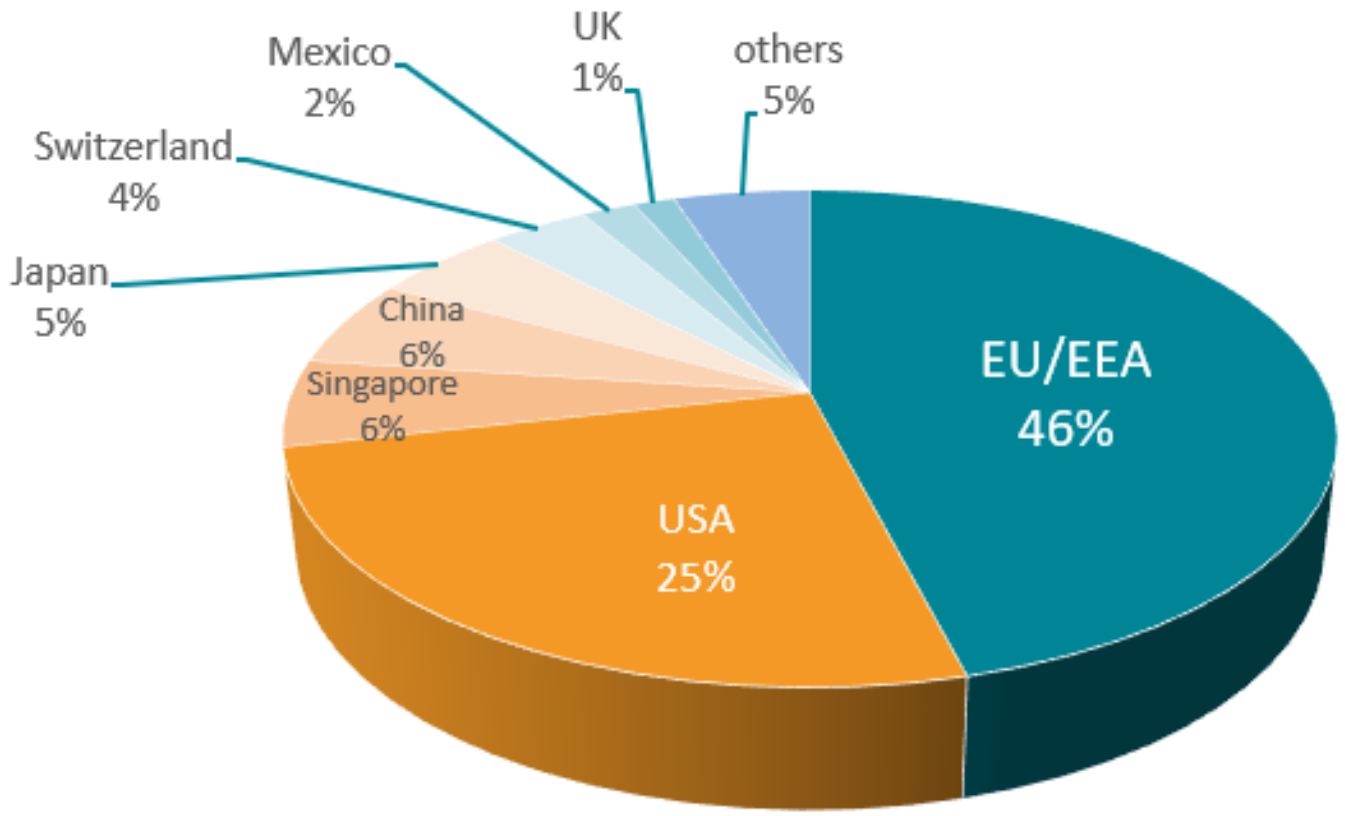


# Locations of manufacturing facilities hosting foreign inspections



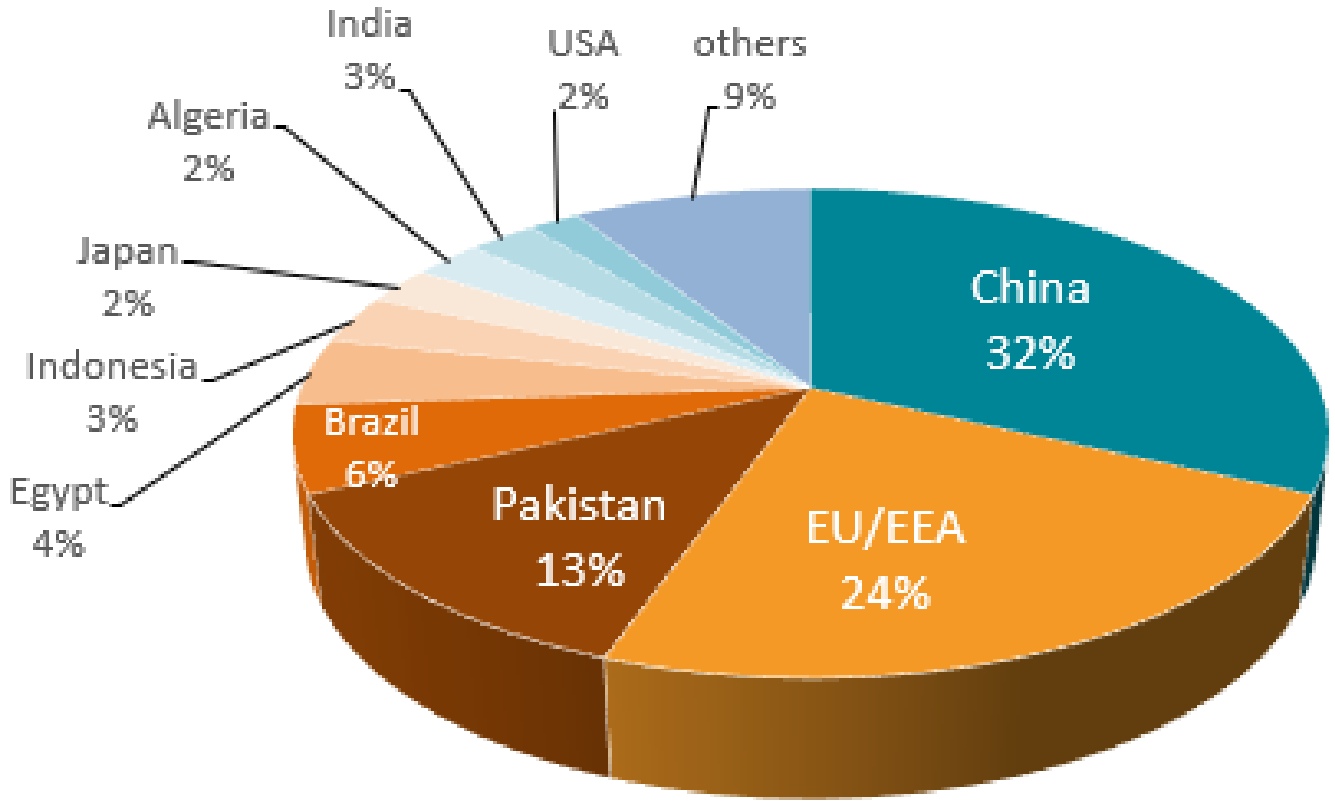

* The location, where conducting foreign inspections, demonstrate that research-based manufacturers are mainly based in EU/EEA, USA, and Singapore (>75%)

# Indication on locations of manufacturing facilities of research-based manufacturers for global supply




* The location for global supply, where inspections are performed in EU/EEA, US, Singapore, and China (>75%)

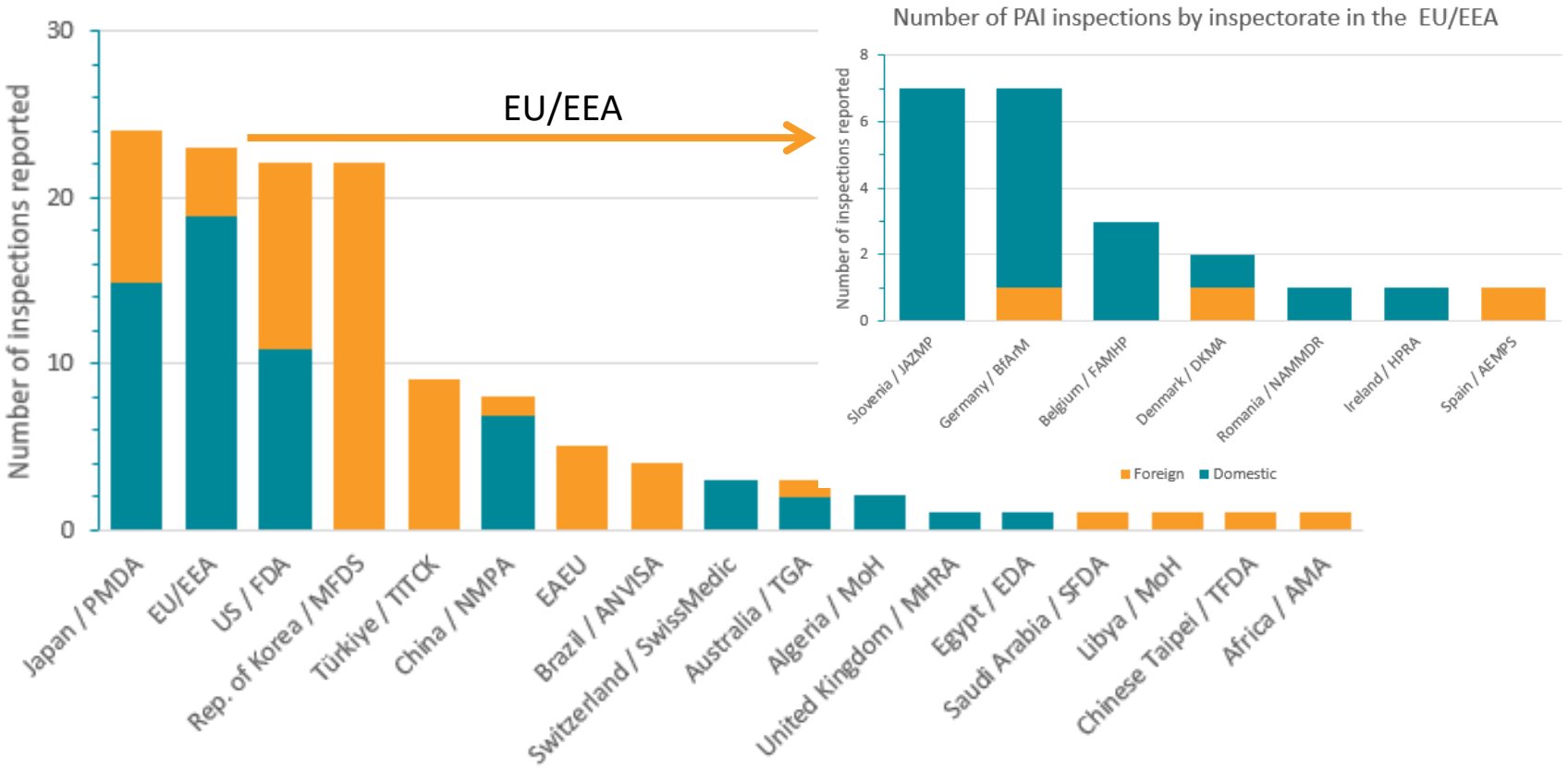
# Indication on locations of manufacturing facilities of research-based manufacturers for local supply




* The location for local supply, where inspections are performed in China, EU/EEA, Pakistan, and Brazil (>75%)

# Inspectorates performing inspection prior to approval*

- **Further opportunities for collaboration and reliance**
  - Inspections reported as 'PAI'* are performed by many inspectorates



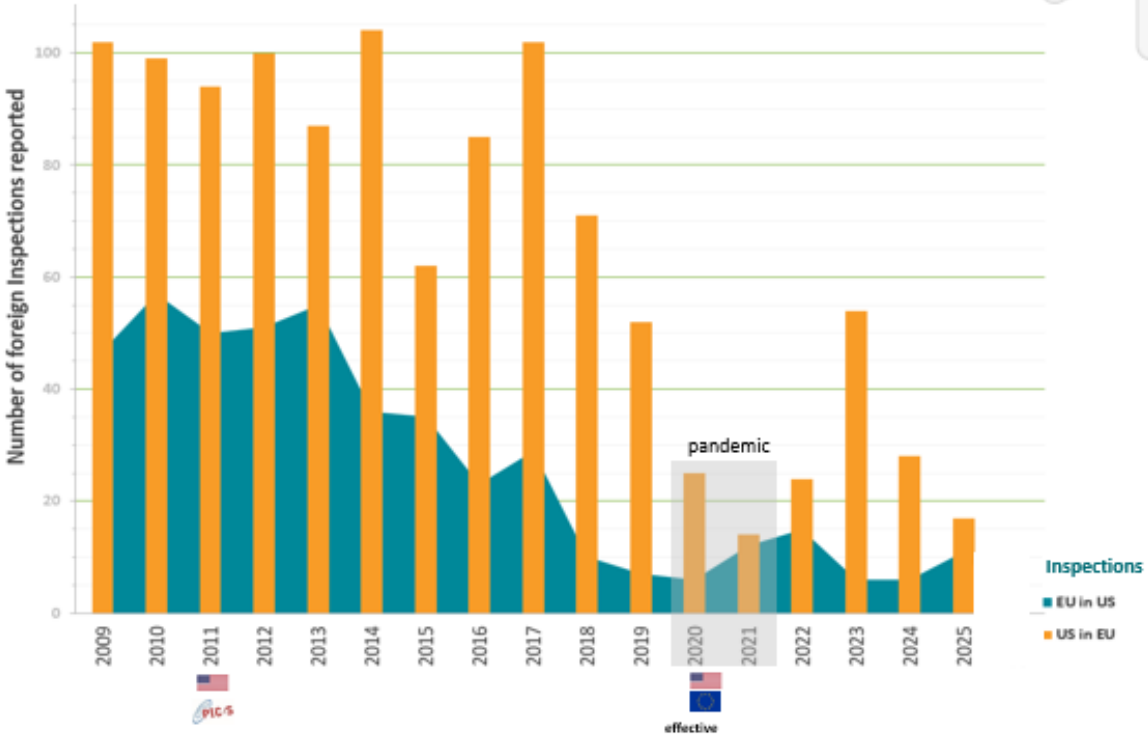

* Note: This also includes new facilities approval inspections see also *Coordinating GMP inspections for centrally authorised products, EC & EMA, Compilation of Union Procedures, 1 January 2025*



PAI: Pre-Approval Inspections

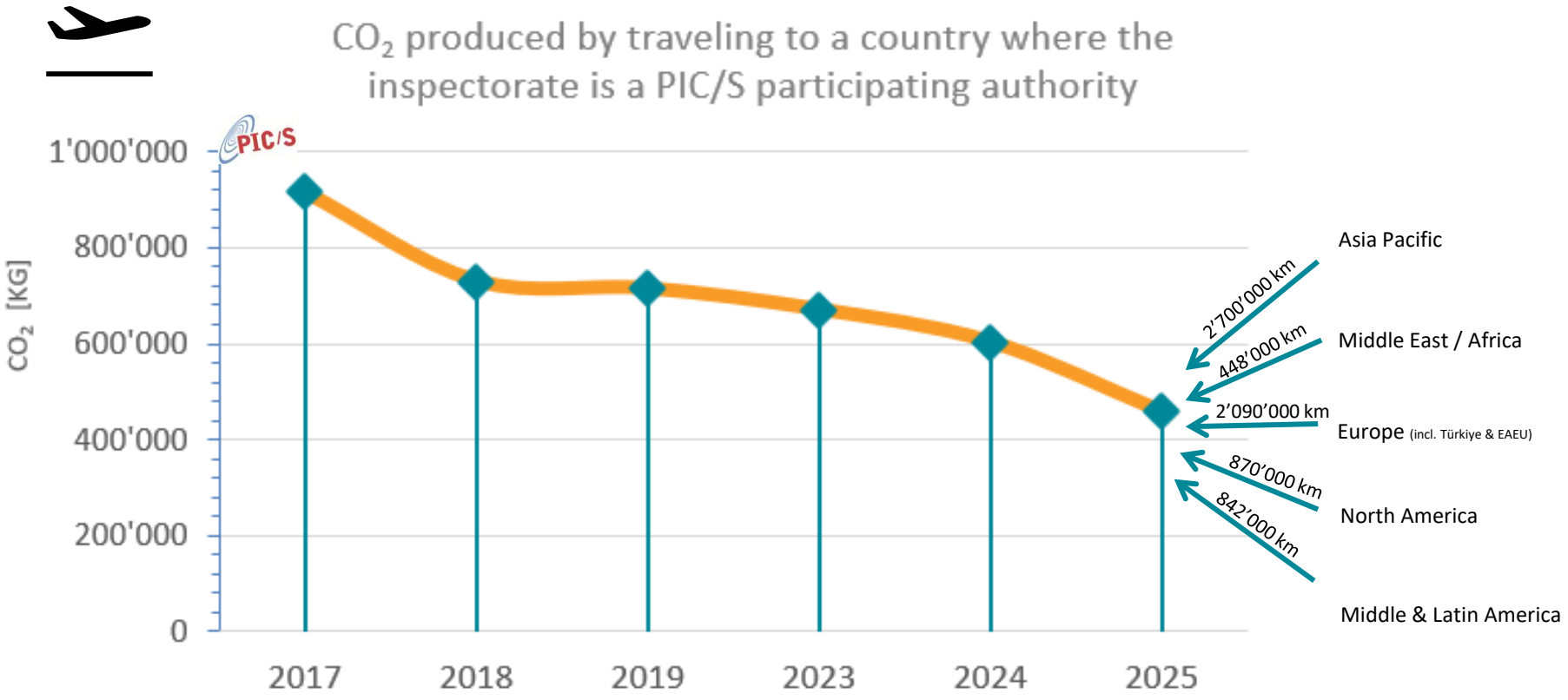
# Progress on MRAs

- **Positive effect on implemented reliance as of the MRA EU-US**
- **Opportunities for all MRAs to build on**
  - Routine and preapproval inspections
  - Expand to additional modalities e.g., Vaccines, plasma derived products, ATMP/CGT, and on medical devices / combination products
- **Additional challenges remaining**
  - Legal interpretations of terminologies e.g., 'PAI', 'GMP-certificate', ATMPs / CGTs, oligonucleotides



# Driving sustainability through inspection practices

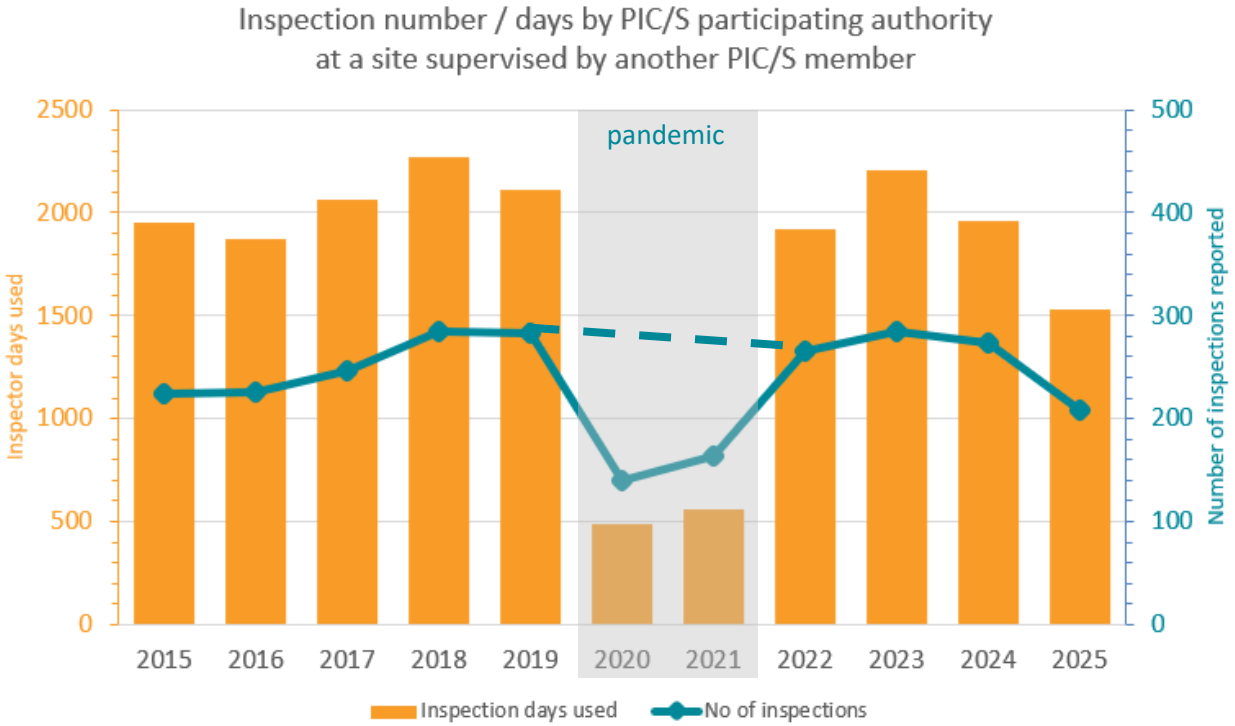
## A 50% reduction in total $CO_2$ emissions over the eight-year period may indicate that inspectorates further rely on oversight of the domestic inspectorate




2020-2022 excluded as of the health emergency

Assumption for travel per inspection: 500 km for in a regional flight; 8'000 km for interregional flight; km multiplied by 4 (inspectors & return flight); on average: 0.0658 kg $CO_2$ / flight km Switzerland: Bundesamt für Zivilluftfahrt (BZL)

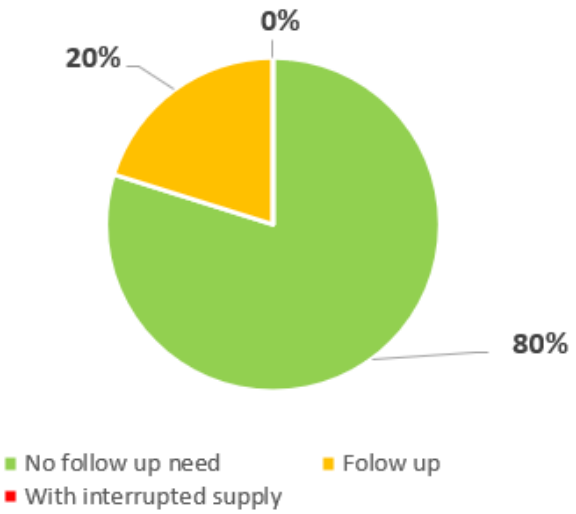
# The change is real on foreign inspections between PIC/S Participating Authorities

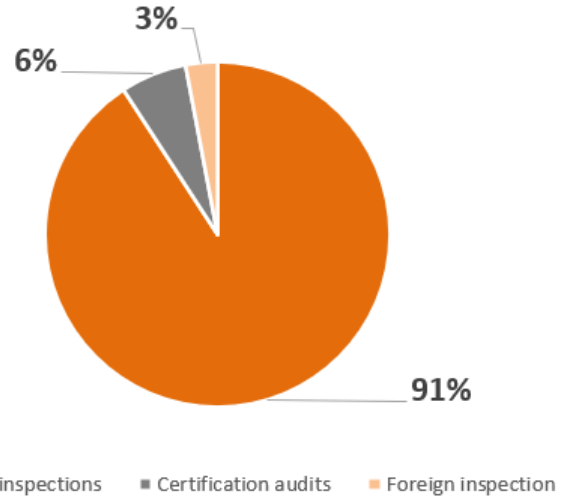



- **Lowest number and inspection days used since 2015 among each other**
- **Further opportunities**
  - For reliance: Türkiye, Republic of Korea, Japan, US, EU/EEA, Brazil
  - How can industry support to reach the vison of *'One inspection per site'*?

# Inspections at Affiliates / Marketing Authorisation Holder (MAH)

- **Consistency in the numbers of inspections year to year - across all regions; mostly domestic**
  - Some of the foreign inspections at affiliates are likely due to regional supply set up - some are unexpected
- **Focus reported on the role of the responsible person and newly the MAH oversight beside other elements of GDP/WDA, as expected**






WDA: Wholesale Distribution Authorisation

## PATHWAYS EMPOWERING LEGAL FRAMEWORKS FOR RELIANCE

# Explore how various Mutual Recognition Instruments can facilitate reliance

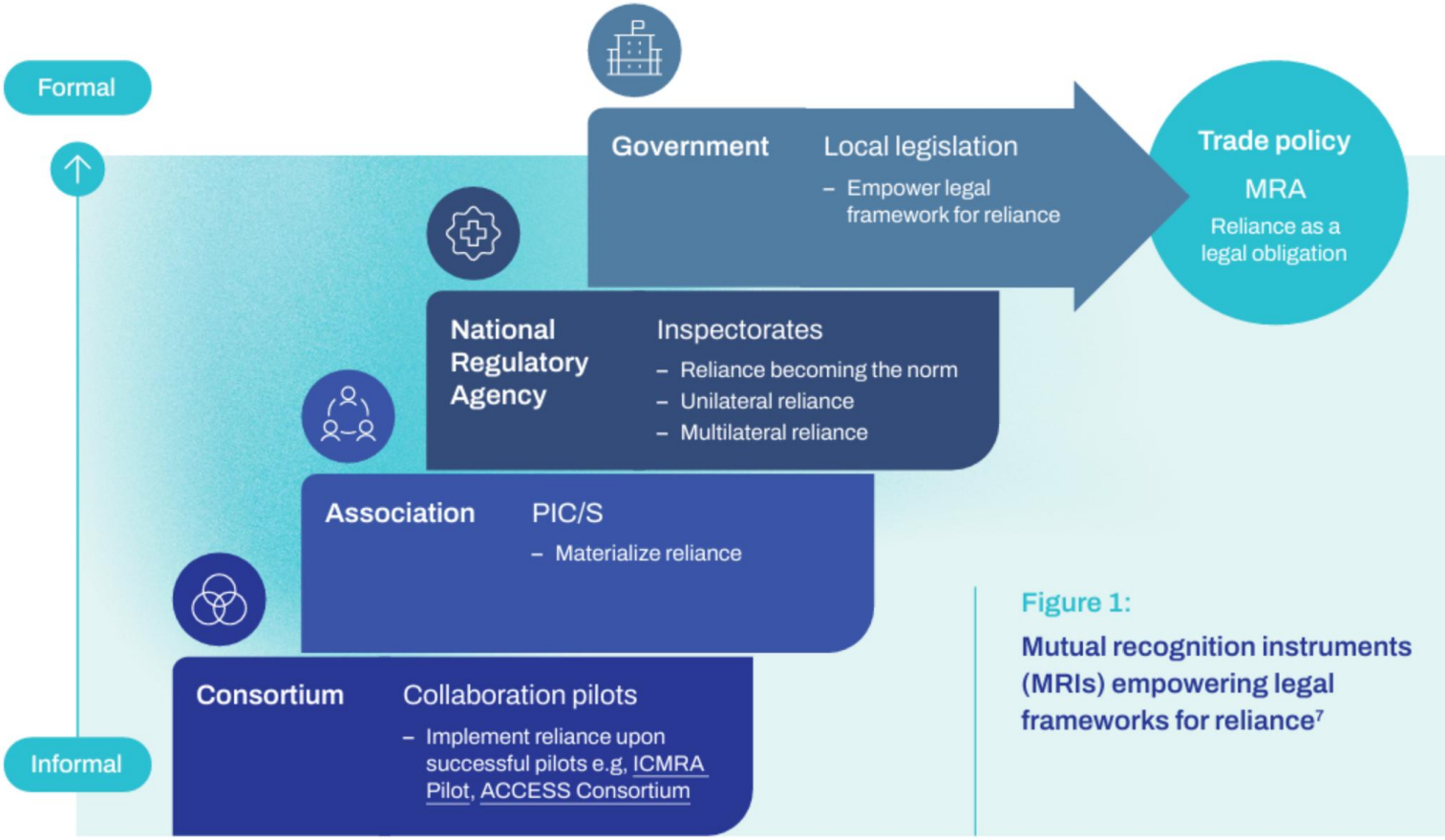



**Figure 1:**
**Mutual recognition instruments (MRIs) empowering legal frameworks for reliance[7]**

EFPIA supports the 'Advancing GMP Inspection Reliance – From Pilots to Practice' Position paper, IFPMA, April 2026

# Which coordination mechanisms between inspectorates EFPIA members companies find most beneficial

1
- **Stronger inter-agency coordination**
- **Expanded reliance frameworks used**

2
- **Coordinated or joint (e.g., CHIP) inspections**
  - Aligned inspection scopes, and
  - Shared or consolidated inspection reports

3
- **Consistent use of structured work-sharing**
  - MRAs and other bilateral agreements
  - PIC/S participating authorities, ICH members

## Opportunities that inspectorate share more experience among each other especially about

a. Pharmaceutical Quality System (PQS) elements - focus change control -, qualification data, and validation activities, and
b. Documentation requests especially for PAIs and license renewals

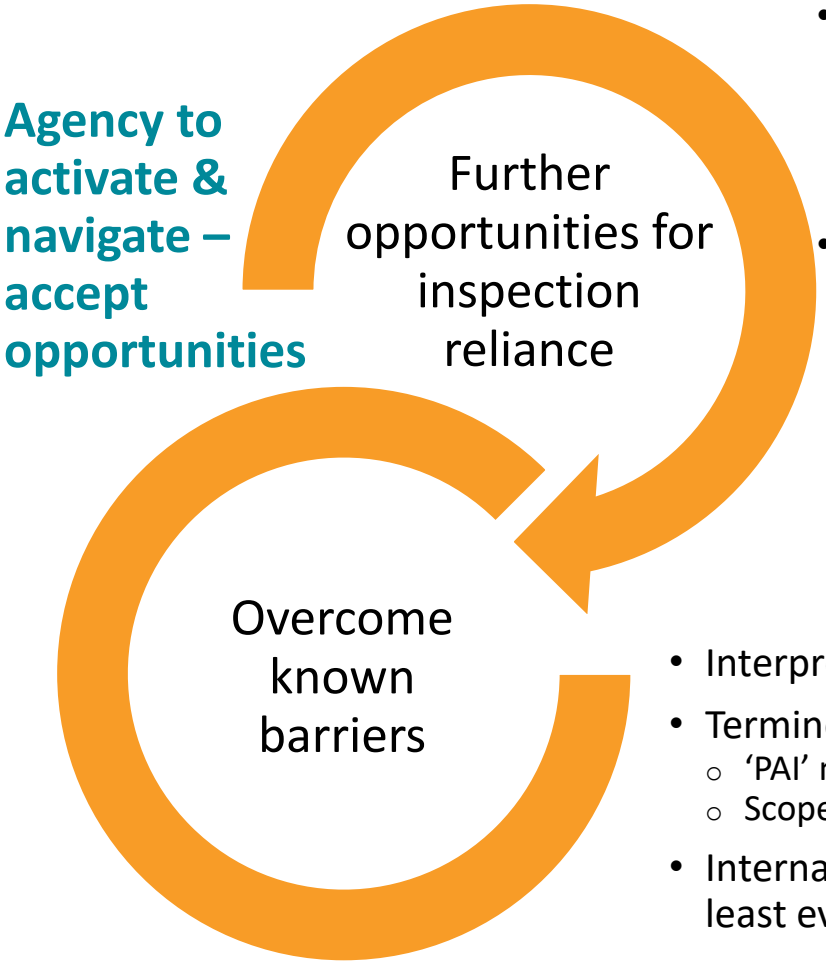
## Suggestions for operational coordination improvements e.g.,

- Early and transparent communication between inspectorates
  - Notification to local authorities before foreign inspections
  - Synchronized scheduling to avoid overlapping inspection windows
- Harmonized inspection report formats and deficiency classifications (e.g., based on PIC/S)
- Digital collaboration platforms for secure information exchange and structured data sharing to streamline documentation requests



CHIP: Collaborative Hybrid Inspection Pilot (by ICMRA)

# Facilitating inspection reliance




- Further opportunities for collaboration and reliance on PAIs and post approval changes
  - EMA pilot on 'PQS effectiveness'
  - Utilise PIC/S for inspectors as a model for assessors' cooperation
- Companies / their local affiliates could proactively ask for reliance
  - Identify scenarios where reliance could have been used
  - Companies may need internal guidance to proceed such requests
  - Example: Inspection conducted by a PIC/S member (HSA) and in the same year inspection by an EU-MS - same scope confirmed

- Interpretation of legal requirements in traditional ways
- Terminology issue when assessing inspection reports e.g.,
  - 'PAI' not mentioned
  - Scope is worded slightly differently
- Internal guidance for inspectors requires inspection at least every 5 years to be conducted by the agency

## EFPIA'S ANNUAL INSPECTION SURVEY - CALL TO ACTION

# How to catalyse inspection reliance?

## Opportunity for trusted non-EU authorities in the coming Delegated Act of the New Pharma Legislation (NPL), Directive, Art 190 1d

**Consider selecting a country, where the inspectorate is a PIC/S participating authority, following an already established approach**

- The selection process for eligible counties as of the written confirmation of the exporting country demonstrated success (Falsified Medicines Directive (FMD), Dir 2011/62/EU, Article 46f)
- Facilitate inspection recognition following a joint audit program like the EU inspectorates (e.g., as implemented by the PIC/S participating authorities)*1
- Other trusted non-Union regulatory authorities, beside MRA partners, where appropriate arrangements are in place*2
- Countries with established trade relationships e.g., Singapore, Brazil, Türkiye

*1 PIC/S process for accession and reconfirmation

*2 for instance, based on a trade agreement, which does not cover medicines e.g., for Singapore/ASEAN, Turkey, Republic of Korea, Brazil/Mercosur, where a formal GMP annex to the Mutual Recognition Agreement - even with expanded scope to Vaccines, ATMPs or other modalities - is deemed resource intensives and bureaucracy heavy or the Co-operation arrangement between the Director General for Health and Food Safety (D.G. Sante) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S), EC, Ares(2022)5237301-19/07/2022, 19.07.2022, and Working arrangement between DG SANTE/EMA and PIC/S for the exchange of non-public information on medicinal products, EC Ares(2022)5237302-12/08/2022, 12.08.2022

# From principle to practice

**Collaborate** ✓
- Share experiences to identify similar approaches and best-practice despite differences in terminology

**Build trust** ✓
- Enable confidence-building between inspectorates & with assessors to support common understandings

**Legal Basis**
- Allow interpretation to review '*official documents*' from other agencies*

**Implement**
- One domestic on-site inspection and reliance on its outcome by all others

* Mutual Recognition Instruments; but also, even in the absence of explicit provisions

## FOR FURTHER READING

# Explaining reliance in the inspection landscape

- **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.
- Alternative GMP/GDP Inspection **Practices in a Pandemic Situation** (COVID-19) and Beyond EFPIA position paper, 28 May 2020.
- 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
- Proposed process to flag inspection inconsistencies, EFPIA Position paper 31. October 2024.
- **Enhanced Good Manufacturing and Distribution Practices (GMDP) Inspection Efficiency**, EFPIA position paper, 12. November 2024.
- **Inspection landscape: Good Manufacturing and Distribution Practices** EFPIA infographic, March 2024
- EFPIA: Annual Regulatory GMP/GDP Inspection Survey's ;
- Inspection Infographic

- 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.** IC, 26 November 2022. Inspection pilot
- **IC Collaborative Hybrid Inspection Pilot (CHIP),** Summary Report March 5th, 2025.

- **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'
- Related: import testing
- **Advancing GMP Inspection Reliance – From Pilots to Practice** Position paper, IFPMA, April 2026
- Inspections **Infographic**

- **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.
- **Remote assessments**, PIC/S guidance PI 056-1, 1.Jan 2025


- 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: Example EU/US,** *Pharm. Tech.* **,** 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

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# Contributors to the EFPIA inspections survey 2025

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- CSL Behring
- Daiichi Sankyo
- Eli Lilly and Company
- Grünenthal GmbH
- GlaxoSmithKline
- Johnson & Johnson
- Lundbeck
- Moderna
- Merck
- MSD
- Novartis
- Novo Nordisk
- Pfizer
- Roche
- Sanofi
- Servier
- Takeda*
- UCB

## National Trade Associations

- Apifarma (Portugal)
  The Binding Site Portugal, Specialist Protein Company, Unipessoal, Lda., Laboratório EDOL, Produtos
- LEEM (France)



* Only answered the questions

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## ABOUT THE ANNUAL INSPECTION SURVEY - DISCLAIMER

# Limitation of the data assessment

- **Out of scope**
  - Inspections at Contract Manufacturing Organisation (CMO) - because of the risk of double counting
- **Excluded from the assessment**
  - All inspections referencing only to
    - 'other GxP' only (e.g., R&D facilities for GCP/GLP)
    - 'other' products as there was no GMP/GDP inspection relevant activity (e.g., OTC, cosmetics)
    - ISO 9000 certifications, because they are no required by regulatory statutes (even marked as 'GMP')
  - Mock inspections = for profit organisation preparing for e.g., a FDA inspections (e.g., arca, spcm, dsp, Presafe)
- **Consideration**
  - We consider not having the full overview on inspections with document review only (paper-based) incl. the duration of such inspections; an assessment with one agency over 3 years resulted in about 37% coverage of their inspections
  - We are asking for only one response per company, in time and include all manufacturing sites
  - Companies may have reported the first and last day of an inspections with document review even if there had been days with no inspection in between. In this case, the inspector days had been set to 'n.a.'
  - Some companies did not mention any product, but 'GMP'. We added 'DP' (mostly affiliate inspections)
  - If numbers of inspectors had been named but no duration, we noted the average 2.5d (domestic); 5d (foreign)
  - If inspection days have been provided but no numbers of inspectors had ben named, we noted the average 1.5d (domestic); 2d (foreign)
- **Note**
  - Insufficient data (e.g., no product category named, Listing of GxPs) -> added GMP for manufacturing sites / GDP
  - All local inspectorates are listed under the name of the inspectorate of the country

# Inspection position paper and infographic

EFPIA inspection infographic, March 2024 uploaded on the EFPIA manufacturing webpage

# EFPIA position paper: Enhanced inspection practices

**Domestic inspectorate as primary body**

Use unilateral / mutual reliance & certificates

1

**Use different inspection modes**

Risk-based approach for on-site, remote / hybrid or document inspections; consider reliance approach

2

**Sharing of inspection results**

by using existing platforms and tools, such as EudraGMDP and elements provided by PIC/S and WHO

3

**GMP/GDP-certificate format**

Globally accepted incl. a compliance risk-ranking

4

**Harmonised regulatory expectation**

on innovative approaches

5

**Regulatory agency collaboration**

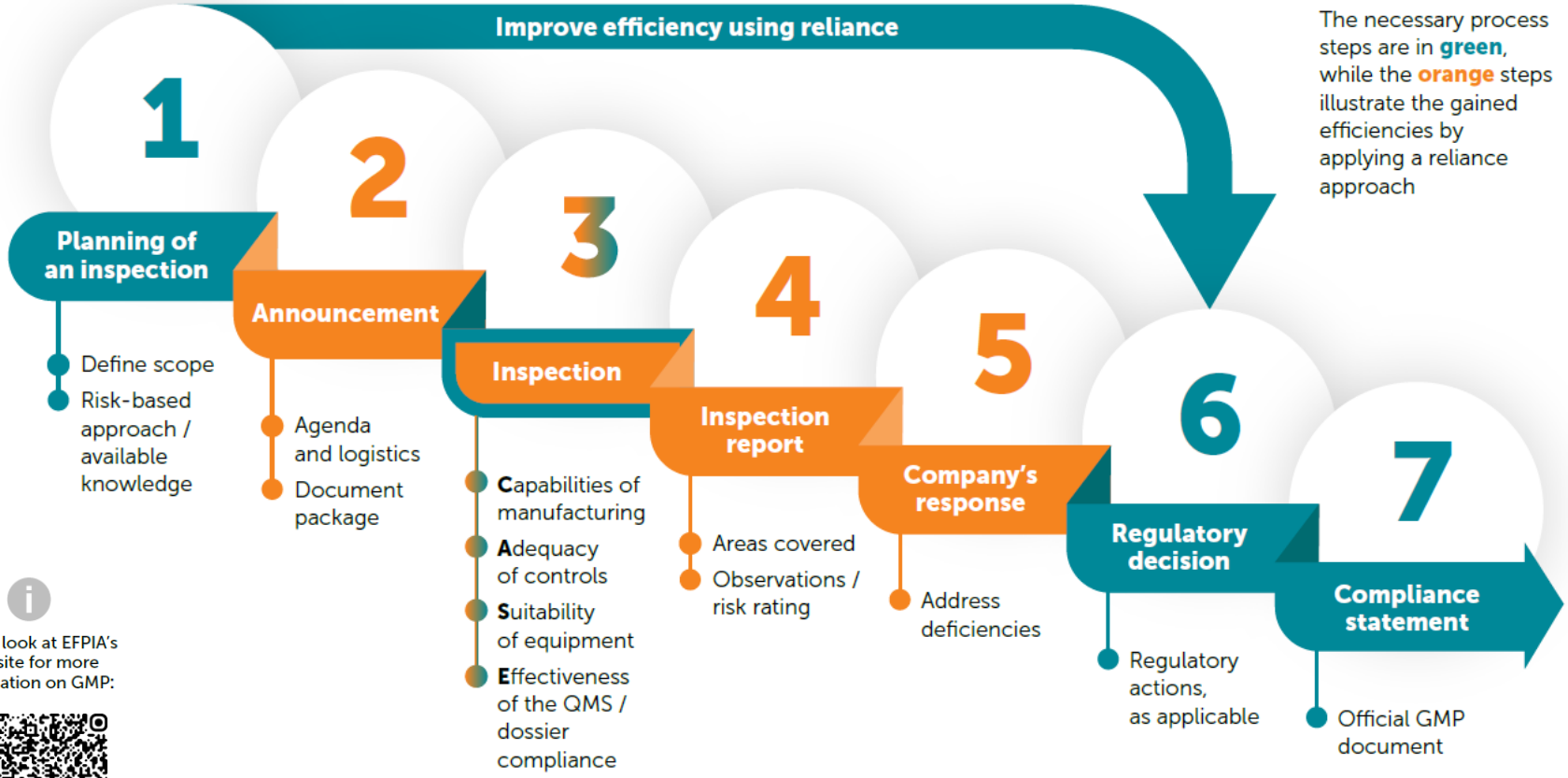
Achieve harmonized and standardized inspection principles and outcomes

6

**Enhanced Good Manufacturing and Distribution Practices (GMDP) Inspection Efficiency**, EFPIA position paper, 12. November 2024.

## EFPIA INSPECTION INFOGRAPHIC

# Seven steps of any inspection process




Have a look at EFPIA's website for more information on GMP:

EFPIA inspection infographic, March 2024 uploaded on the EFPIA manufacturing webpage

## FOR FURTHER READING

# Overview of IC, ICH and PIC/S Pilots

| Enabler | Efforts under way |
|---|---|
| **Harmonized regulatory requirements** across regions | **ICH** Q GLs; Q12, M4Q(R2), SPQS (expected start 2025) |
| **Comparable/convergent basis for** making regulatory **assessments**; reports | **IC** PQKM--PACMP and CHIP collaboration pilots<br>**IPRP** QWG & surveys |
| **Readily accessible** and usable **"reports"** for reference by other regulators | **ICH** PQKM Task Force<br>**PIC/S** – more structured data in inspection reports |
| Assure **non-disclosure** of confidential trade secret information | **IC** PQKM pilot design<br>**ICH** PQKM Task Force |
| Regulators reviewing **same product, quality dossier, PAC-related submissions, etc.** | IC PQKM WG on Identifiers to enable greater reliance |
| **IT tool(s)** to facilitate review and collaboration | Technological solution |

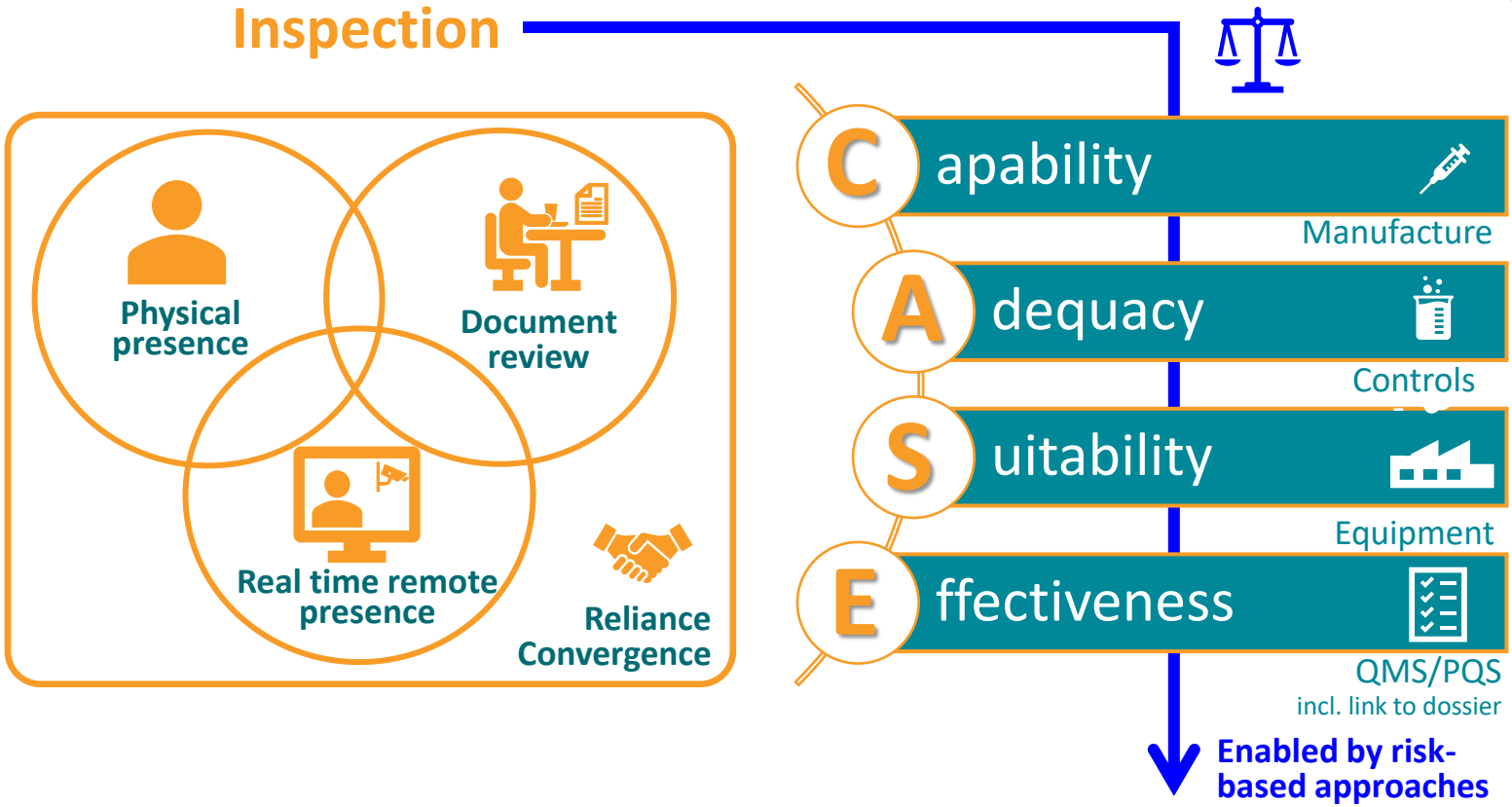
*IC slide presented by Brendan Cuddy EMA @ DIA Europe 2025*

# Inspection modes

## KEEP IN MIND THE PURPOSE OF AN INSPECTION

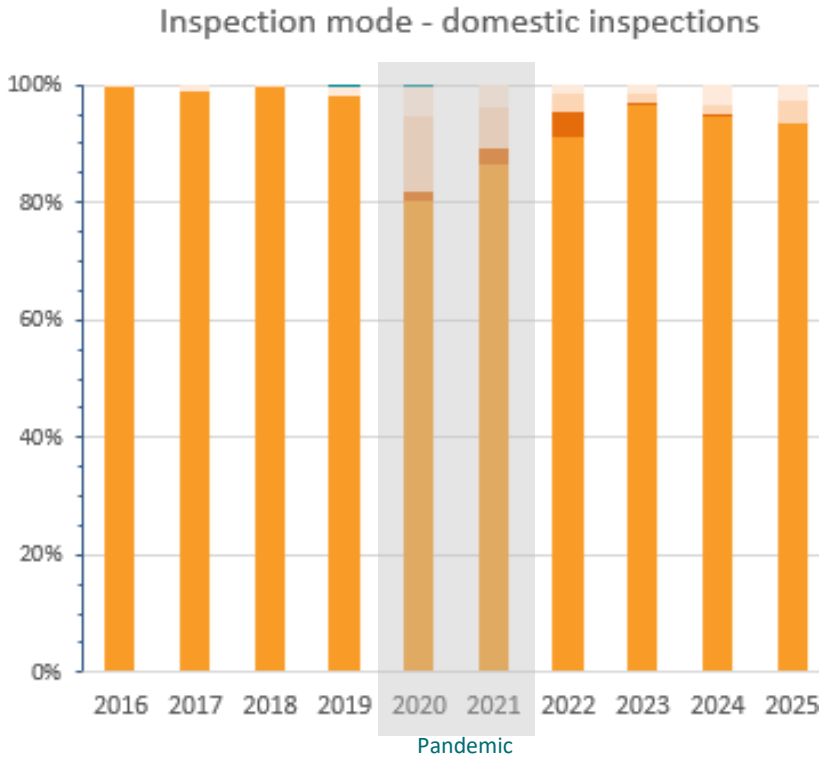
# Is a site compliant?

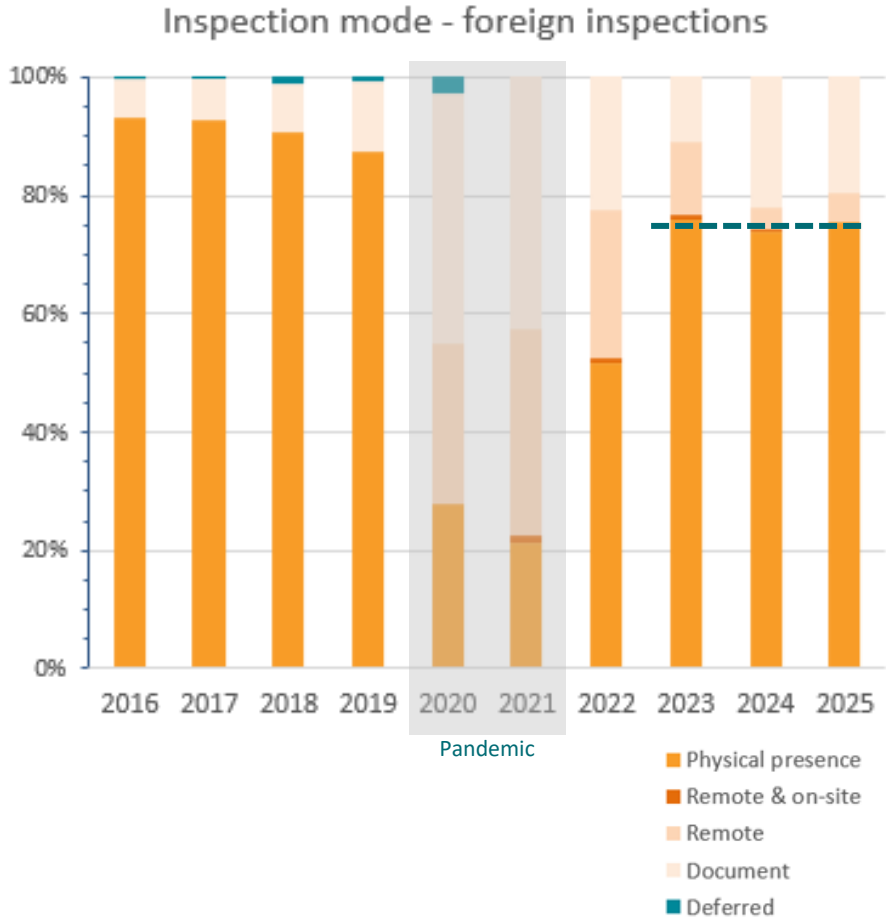
**No difference in inspection types (PAI*, routine, surveillance, for cause)**




* 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.

# Trending inspection modes




- **On-site presence in**
  - Domestic inspection is about 95%
  - Foreign inspections is stable on +/- 75 % over the last 3 years

## DOCUMENT INSPECTIONS

# 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

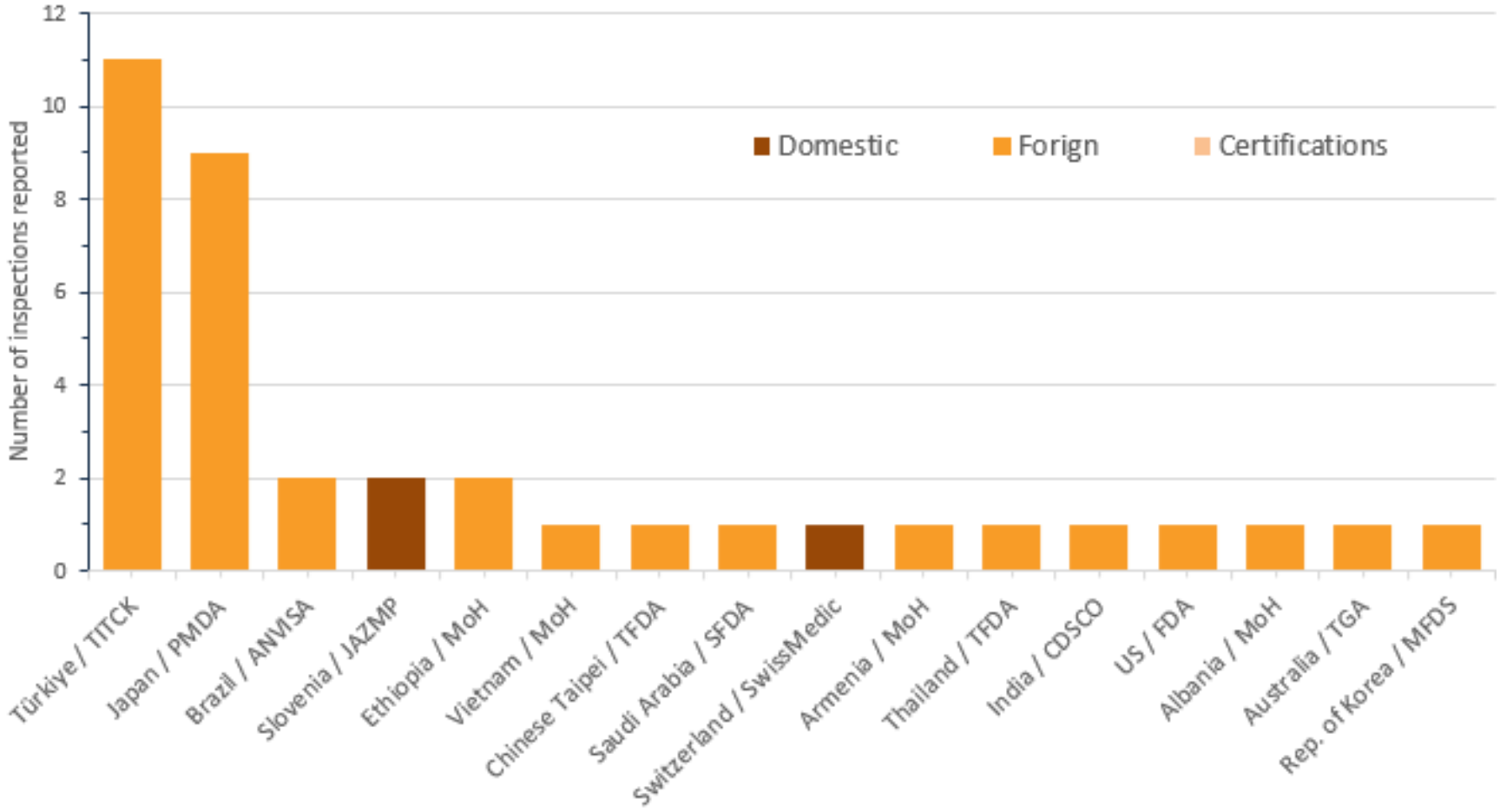
Enhanced GMP/GDP Inspection Efficiency, EFPIA, Position Paper 19. May 2014.

Adobe Acrobat Document

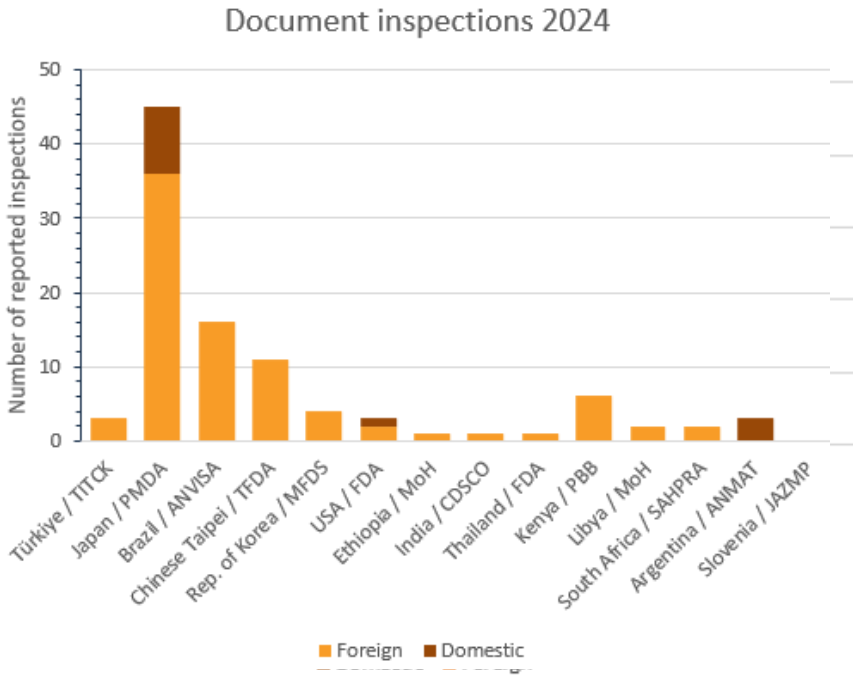
Optimising the GMP paper-based Inspection Process EFPIA, Position Paper 26. June 2019.

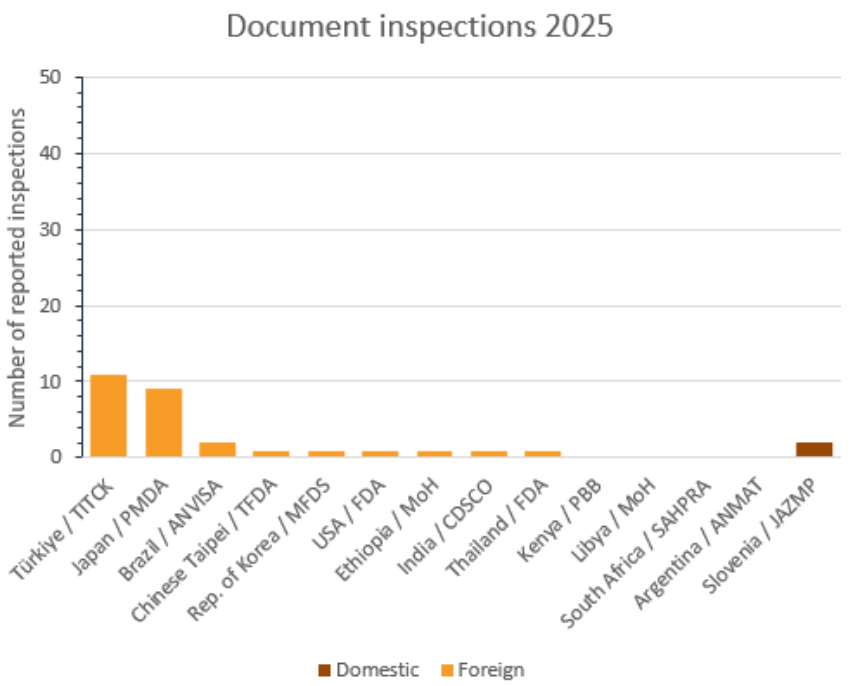
*EXPLANATORY NOTES FOR PHARMACEUTICAL MANUFACTURERS ON THE PREPARATION OF A SITE MASTER FILE, PIC/S PE 008-4, Annex 1, January 2011

# Inspectorates performing document inspections



# Inspectorates performing document inspections

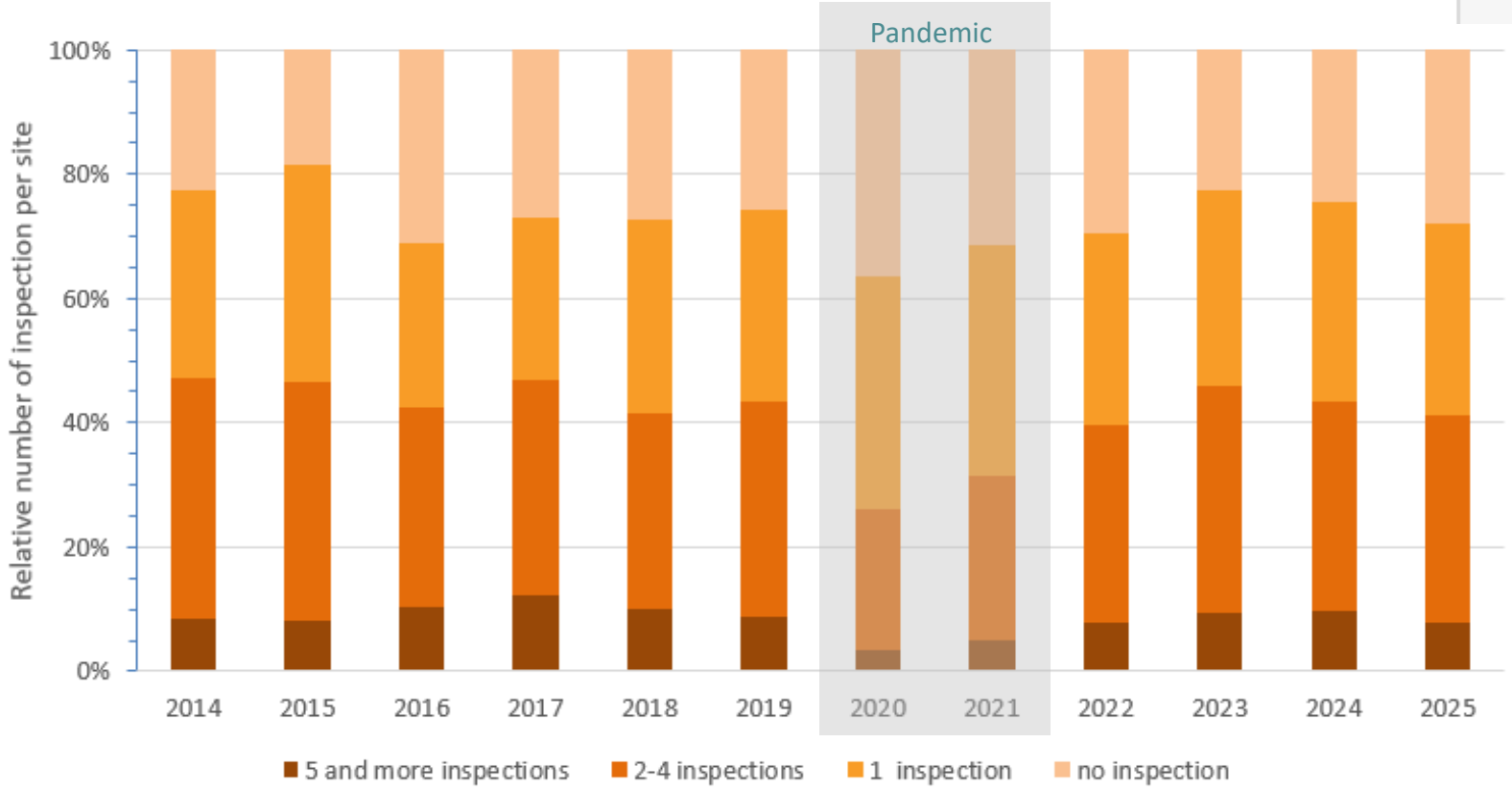



* **A cut of about 70% (111 to 36) on the reported document inspections 2024 to 2025**

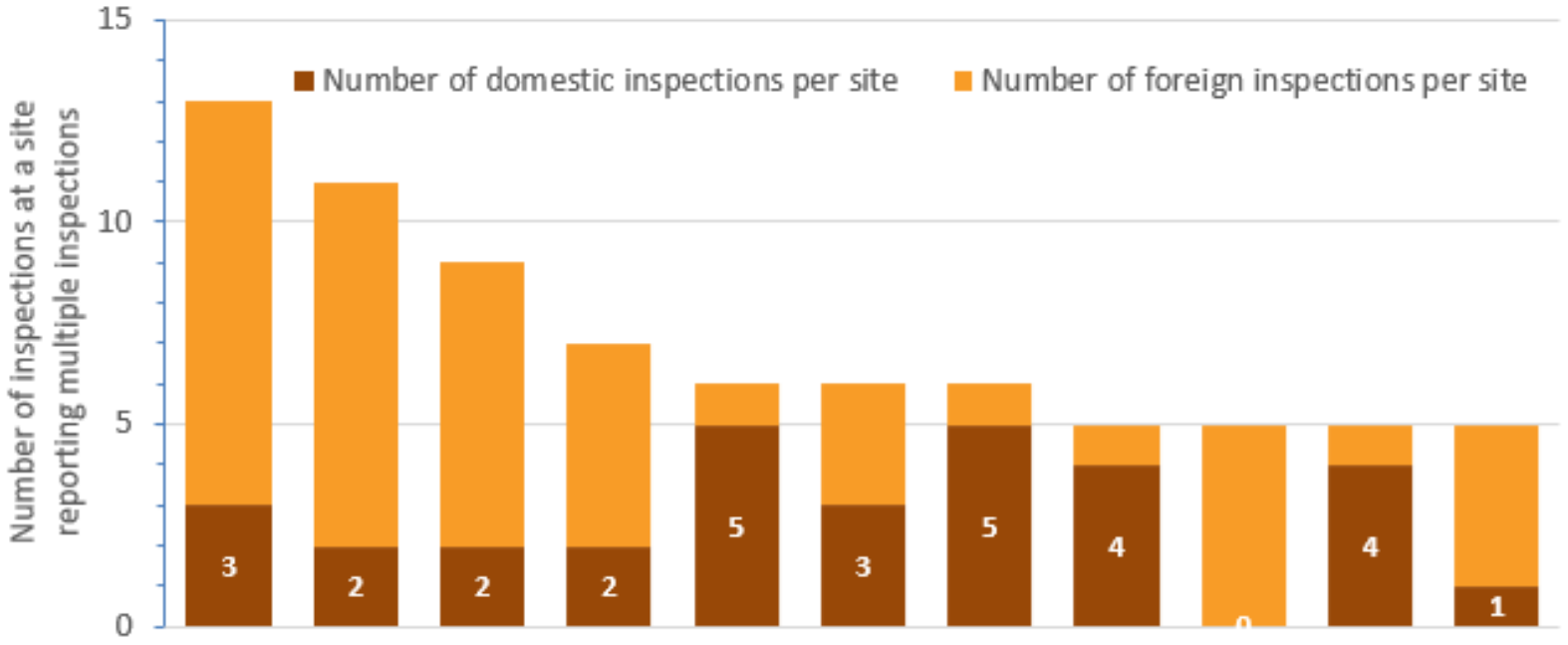
# Inspections at Manufacturing Sites

# Number of inspections reported per site is still constant




- **Data**
  - Currently at the level of 2014-2019
  - During the pandemic, the focus was to have more towards 1 inspection per site

# Multiple agencies inspect at one manufacturing site's location




**USA 1**
- Japan (9)
- Australia (1)

**Denmark 1**
- Türkiye (5)
- Rep. of Korea (2)
- EAEU (1)
- Japan (1)

**USA 2**
- Japan (2)
- Brazil (1)
- EMA (1)
- China (1)
- Columbia (1)
- Rep. of Korea (1)

**USA 3**
- Türkiye (3)
- Brazil (1)
- Italy (1)

**China**
- Denmark (1)

**USA 4**
- Brazil (1)
- EUAU (1)
- Japan (1)

**Japan**
- Rep. of Korea (1)

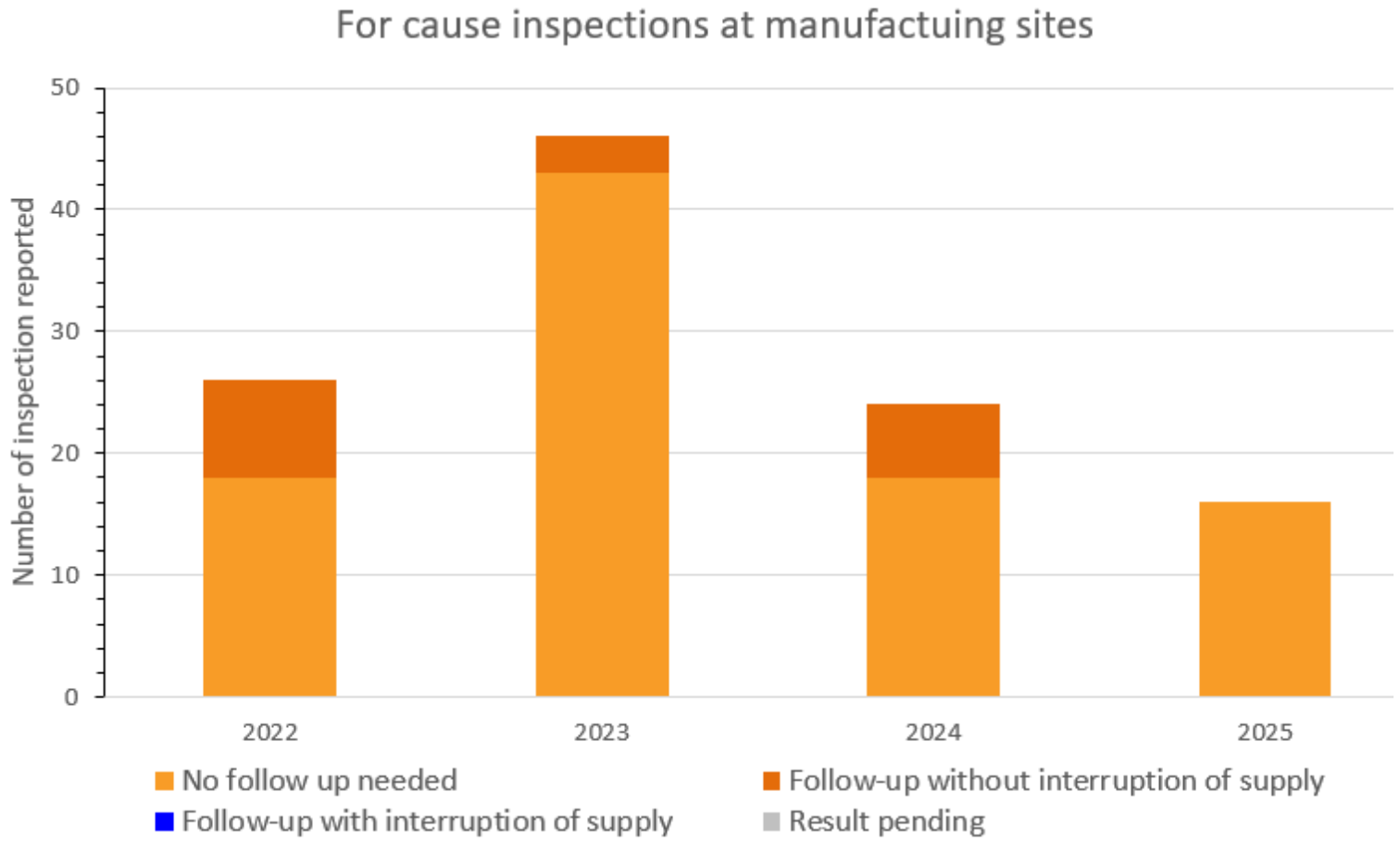
**China**
- Denmark

**Denmark 2**
- Türkiye (4)
- EAEU (1)

**Slovenia**
- Saudi Arabia (1)

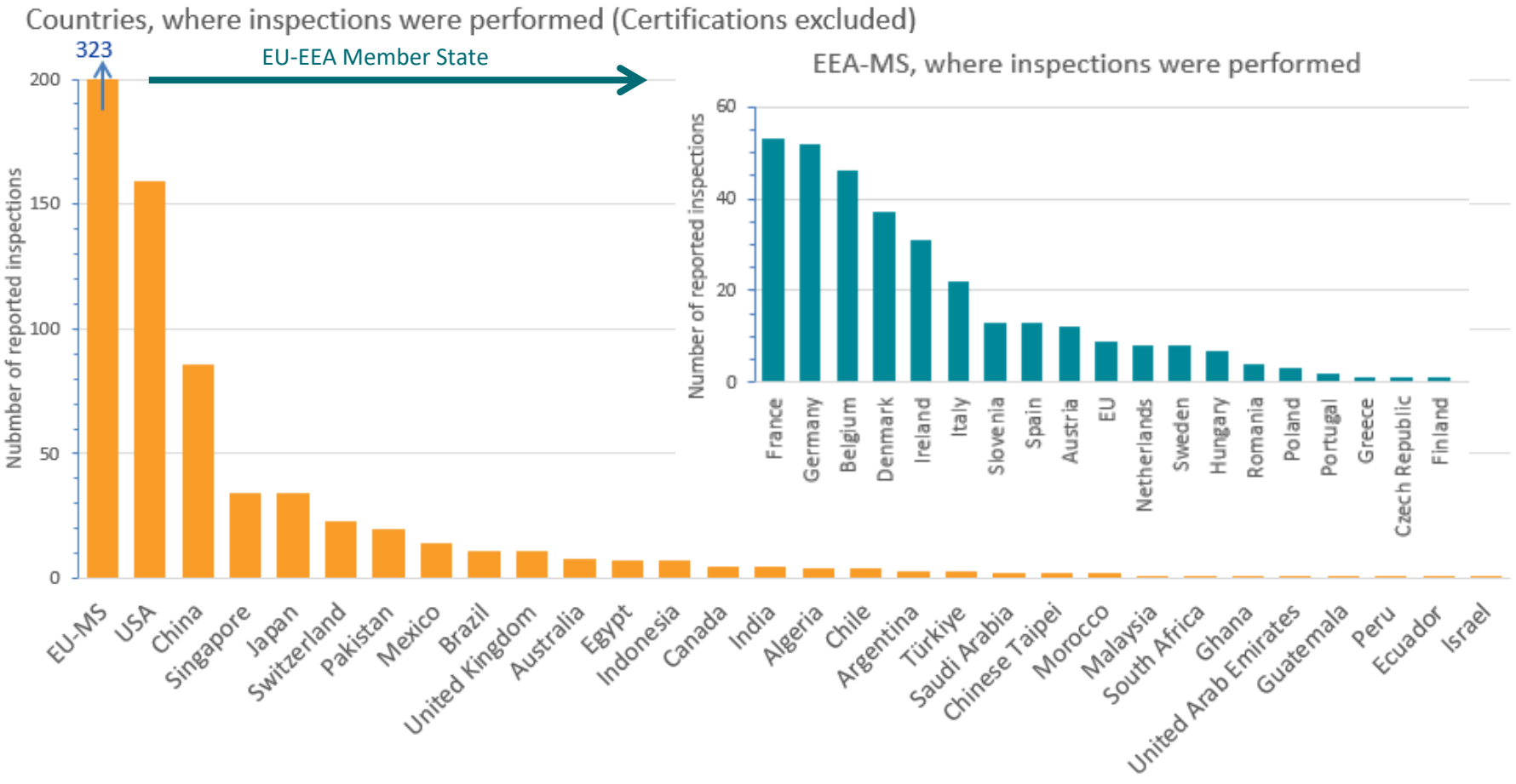
**Singapore**
- Brazil (1)
- France (1)
- Japan (1)
- USA (1)

# For cause inspections do not result in interrupted supply



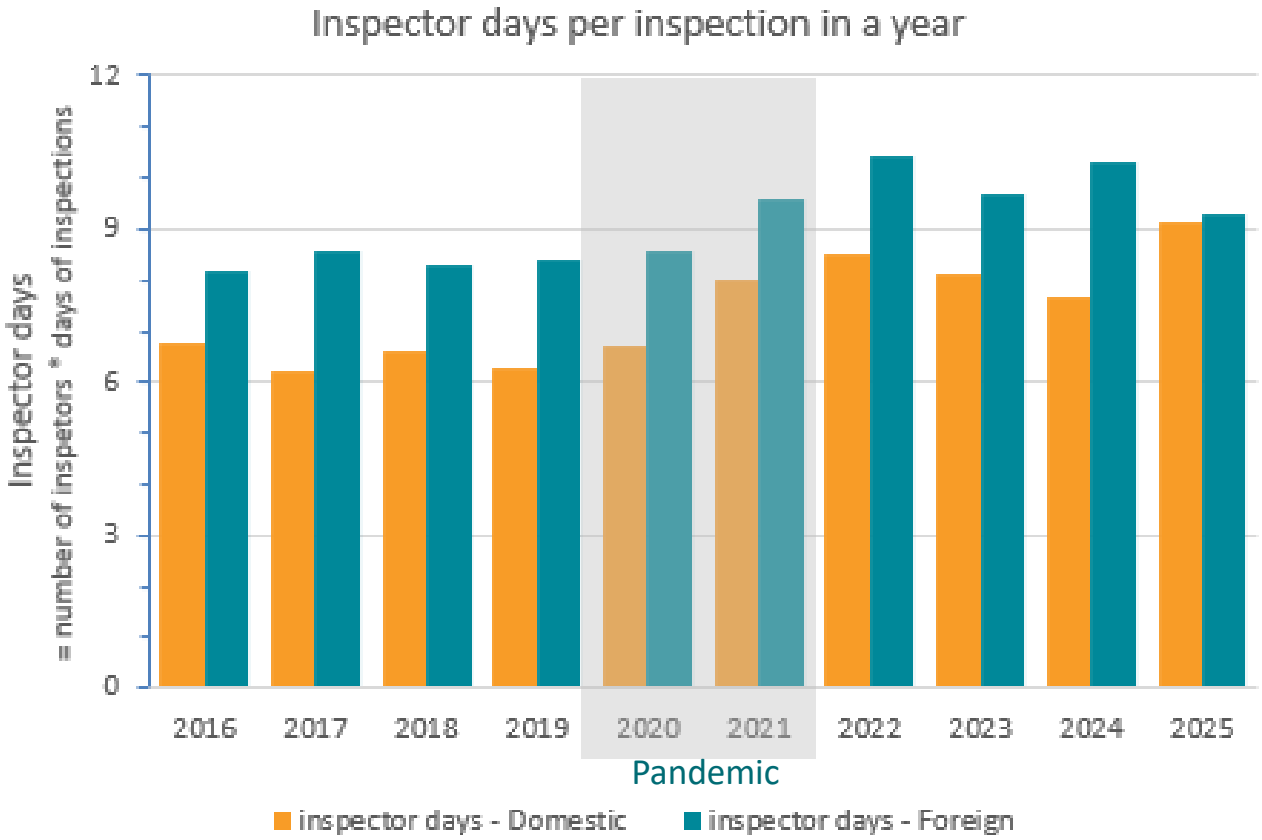

* The number of 'for cause' inspections are decreasing and still without interruption of supply

# Number of inspections (domestic and foreign) per country highlight's locations of manufacturing sites




'EU': companies did not disclose the Member State, where the site is located

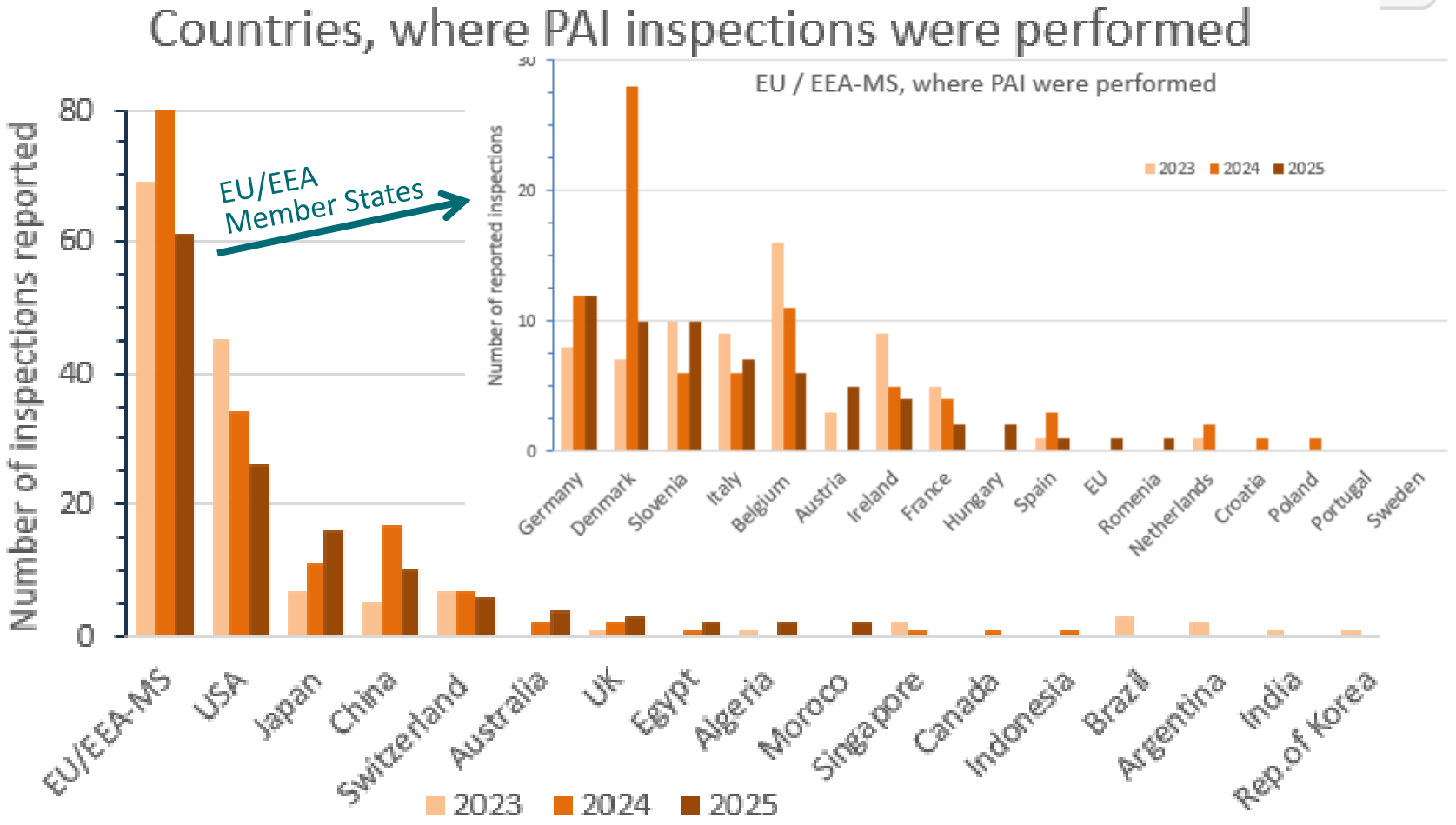
# Average of inspector days spend in domestic and foreign inspections (only onsite inspections)




* Domestic inspection have about the same days than foreign inspections (but not including travel!)

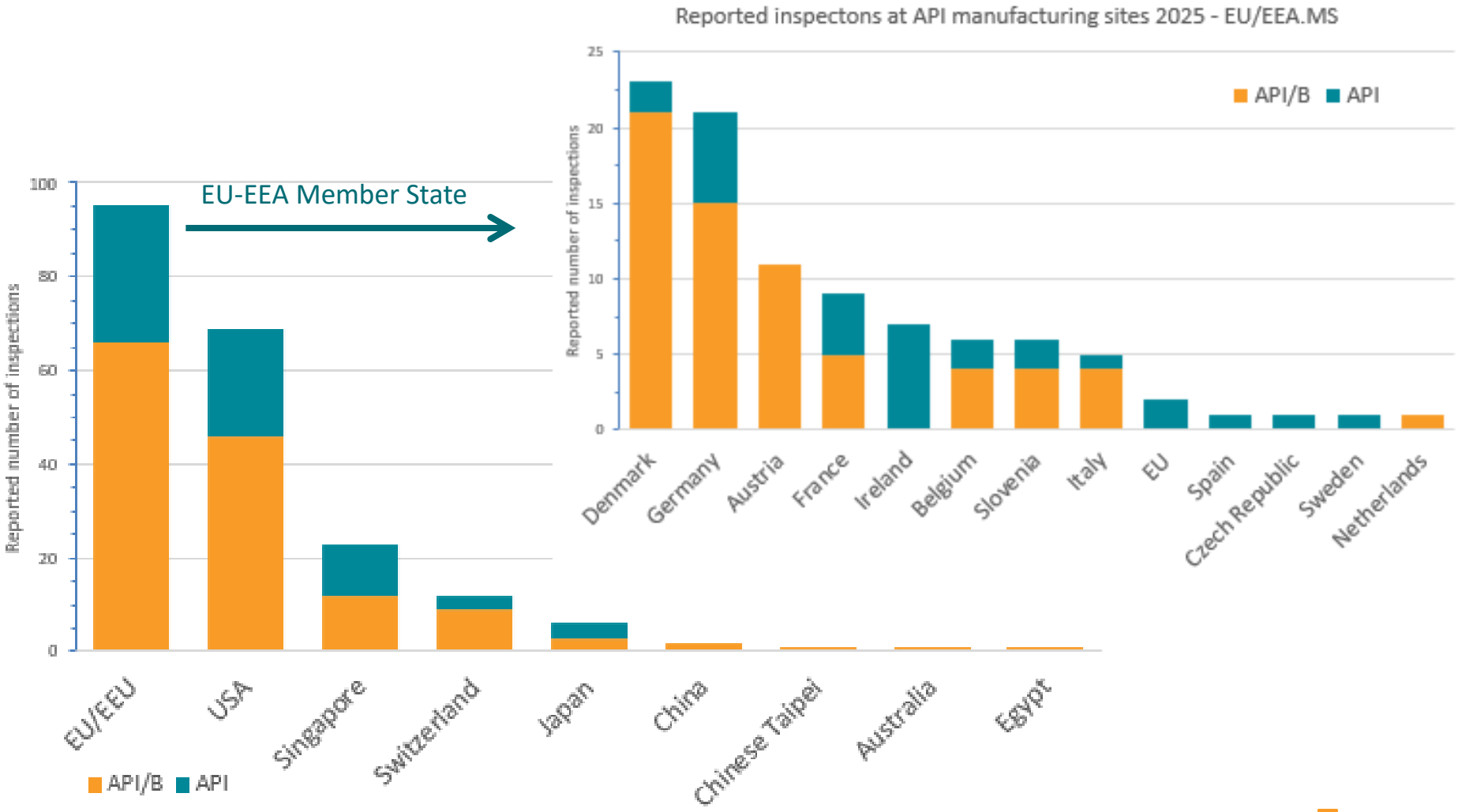
# INSPECTIONS AT MANUFACTURING SITES - PAI

## Locations of manufacturing facilities reporting PAI demonstrating where innovative products are manufactured – EU again number one



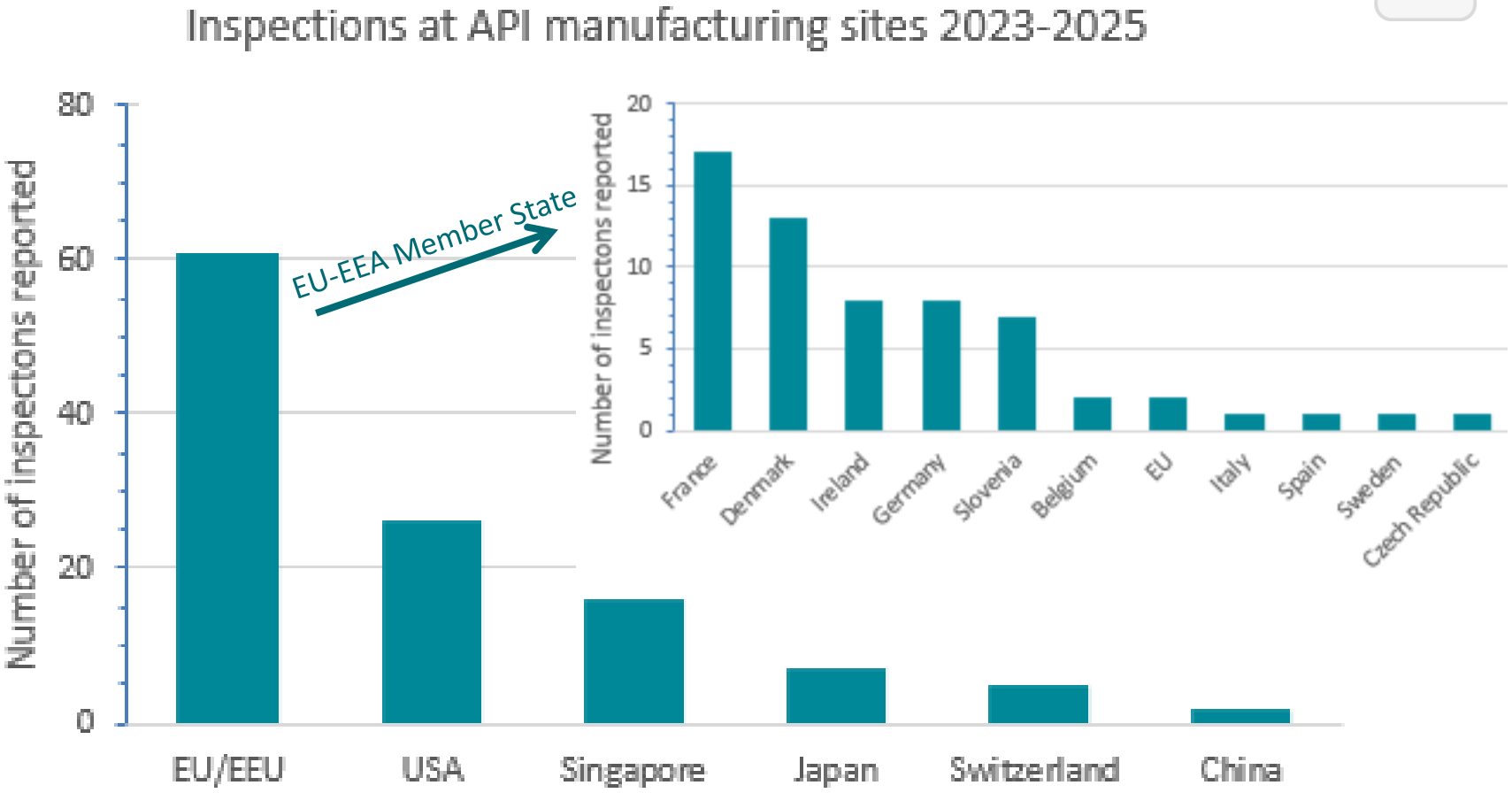

PAI: Pre-Approval Inspection

# Locations of inspected API manufacturing sites




'EU': companies did not disclose the Member State, where the site is located

# Locations of inspected small molecule API manufacturing sites
## (over 3 years)

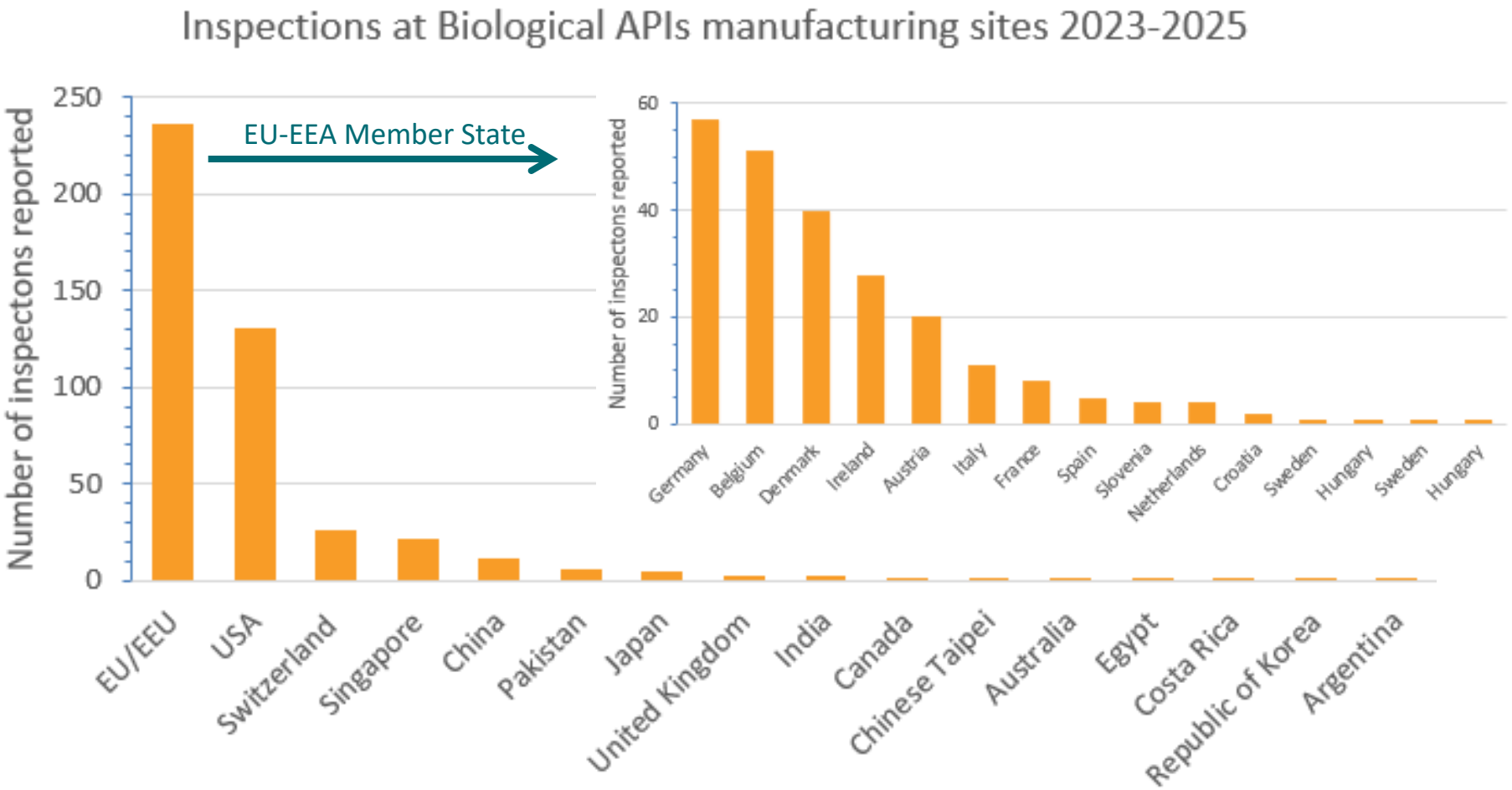



'EU': companies did not disclose the Member State, where the site is located



API / Drug substance used interchangeable

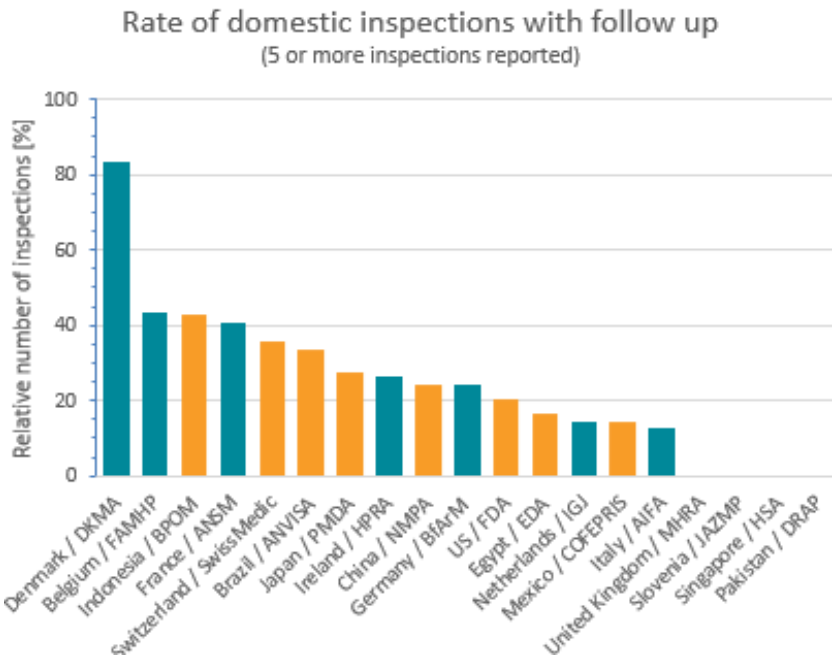
# Locations of inspected Biological API manufacturing sites
## (over 3 years)

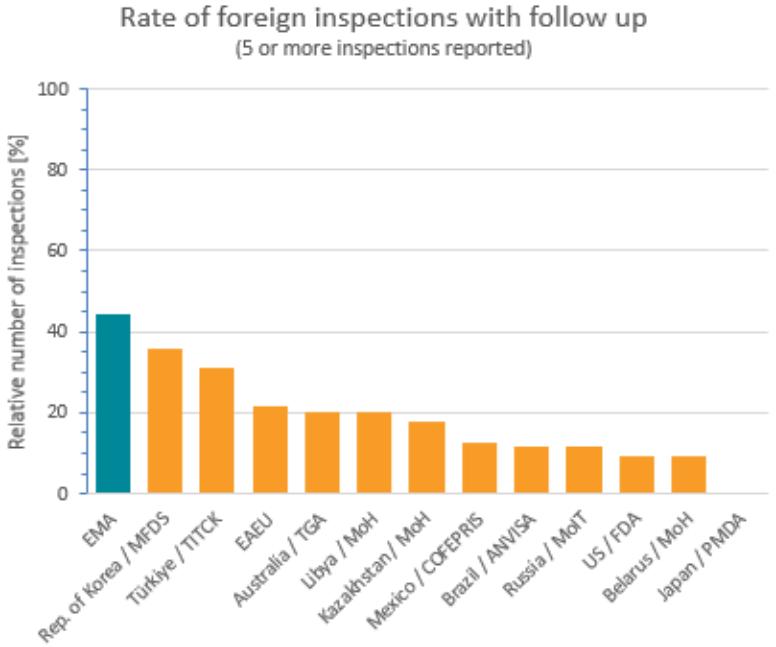





API / Drug substance used interchangeable

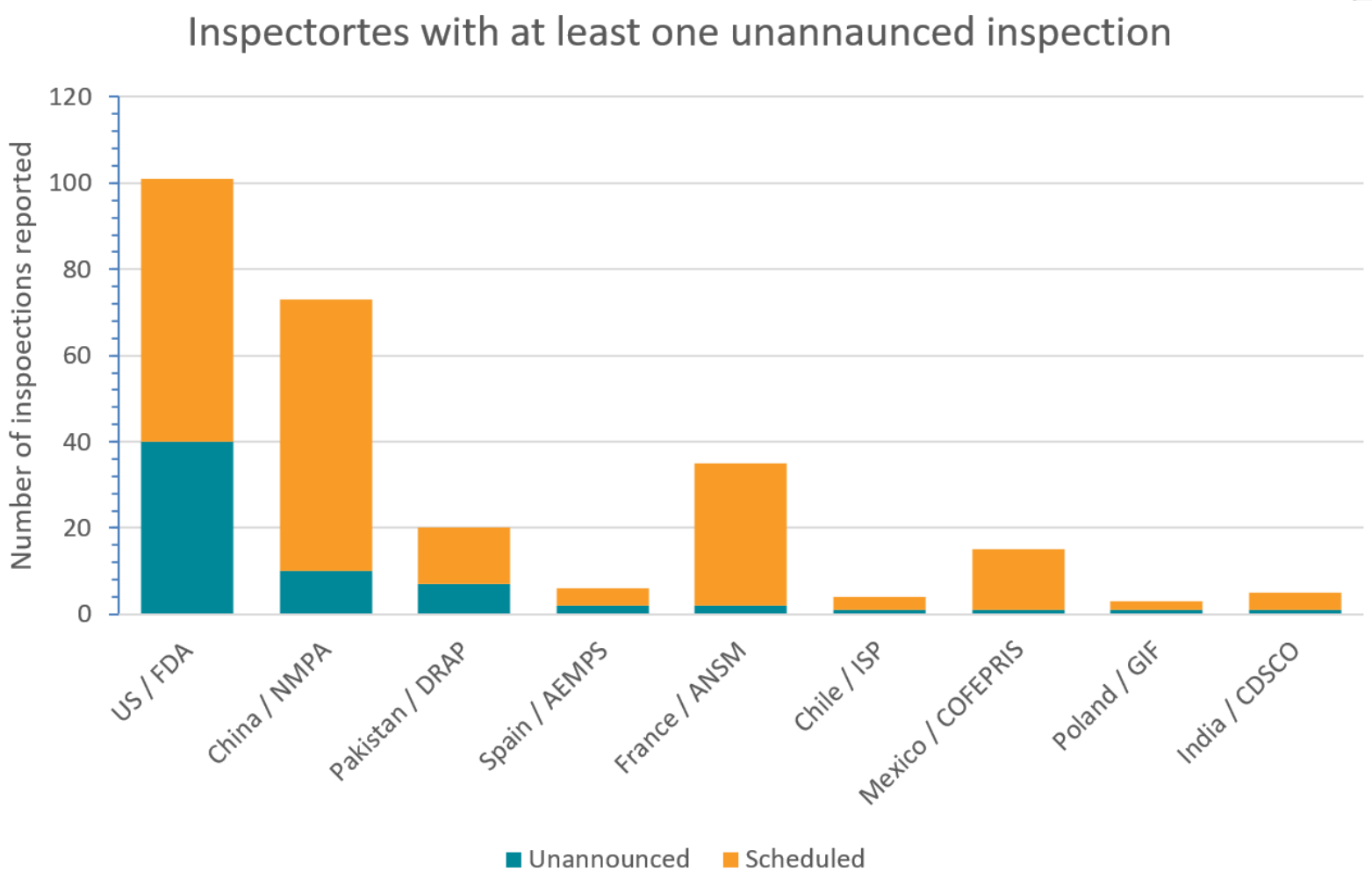
# Rate of follow up action by agency's inspections



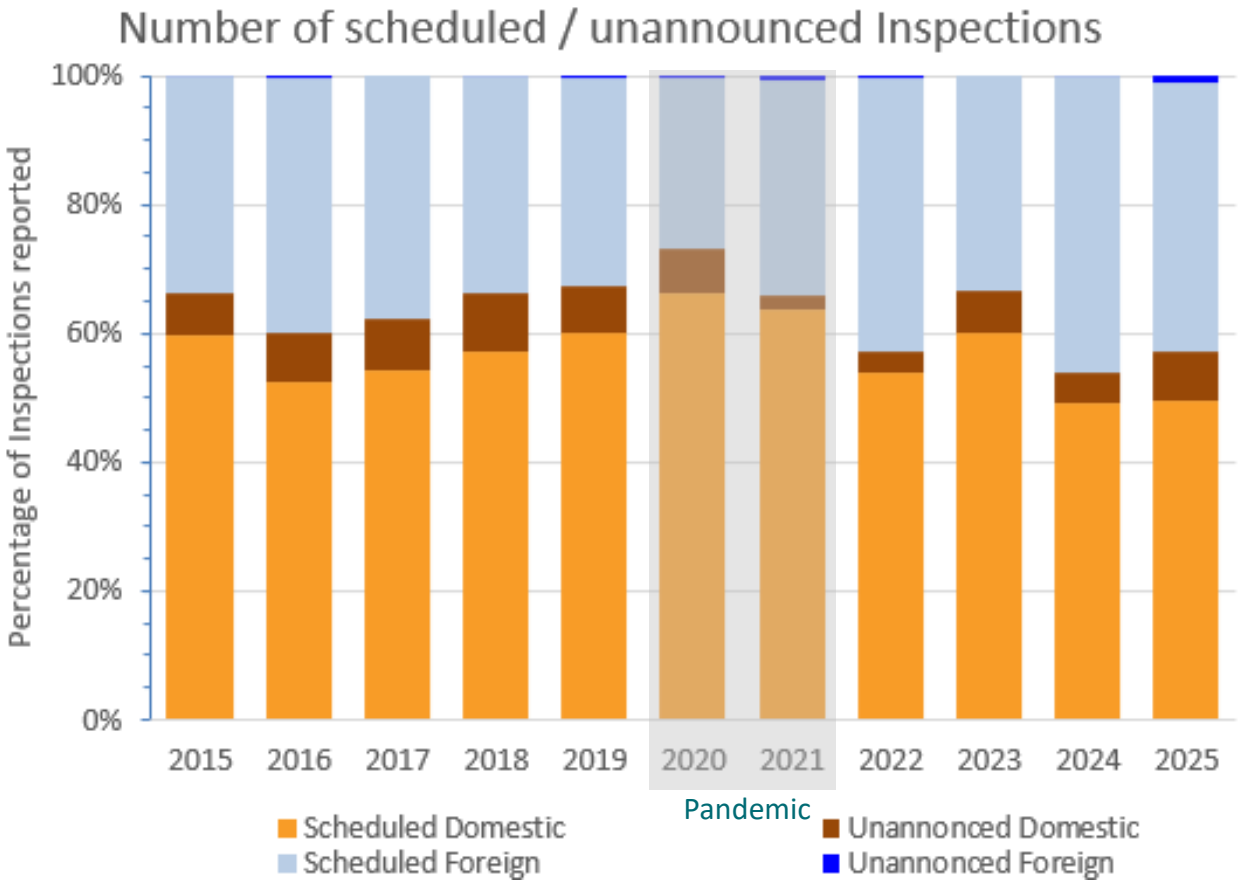




* **Whether announced or unannounced inspection the outcomes are similar by this year**

# Inspectorates reported to perform unannounced inspections



# Scheduled versus unannounced inspections

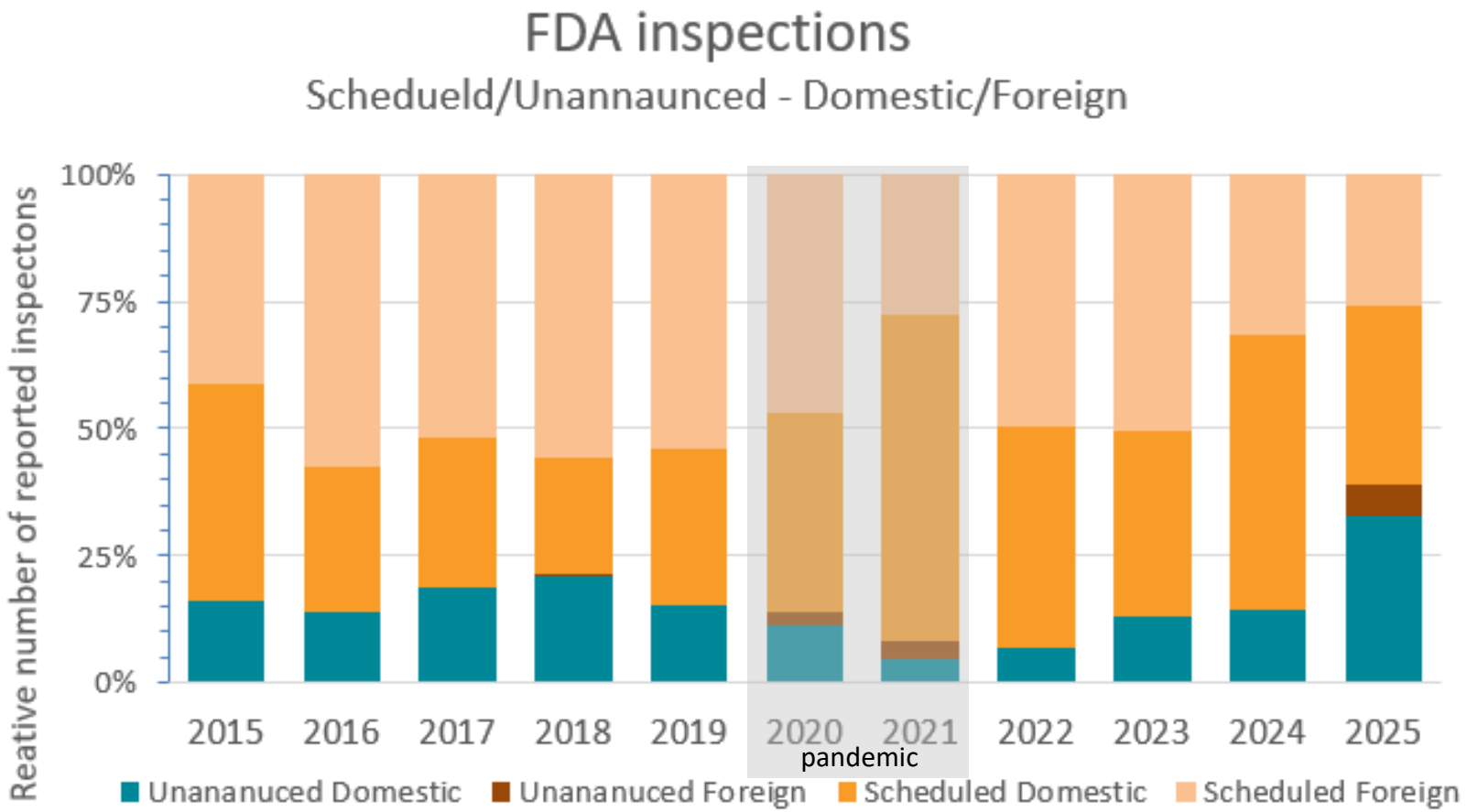



| Inspectorate | Reported number of unannounced domectic inspections in 2025 |
|---|---|
| US / FDA | 33 |
| China / NMPA | 10 |
| Pakistan / DRAP | 7 |
| France / ANSM | 2 |
| Spain / AEMPS | 2 |
| Poland / GIF | 1 |
| Chile / ISP | 1 |
| India / CDSCO | 1 |
| Mexico / COFEPRIS | 1 |

| Inspectorate | Reported number of unannounced foreign inspections in 2025 |
|---|---|
| US / FDA | 7 |

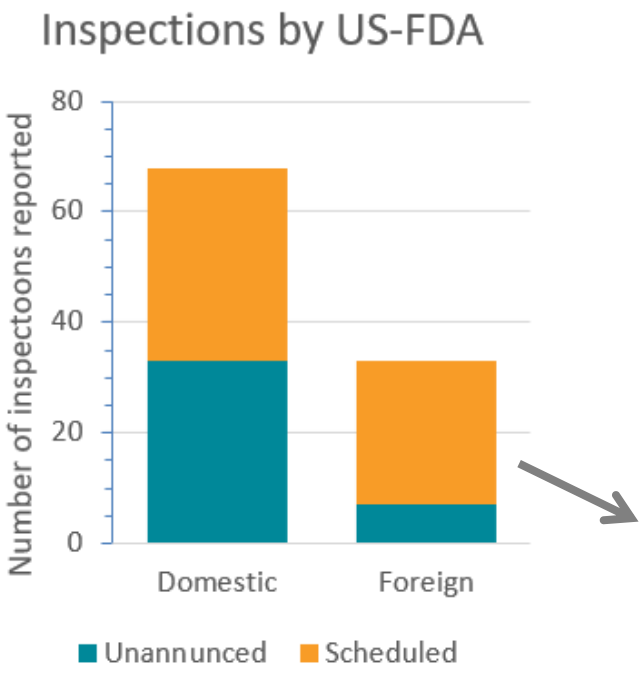
- China and the US are reported to perform the most unannounced inspections
- The US/FDA is the only agency reported to perform unannounced foreign inspections (in China, Ireland, and Singapore)

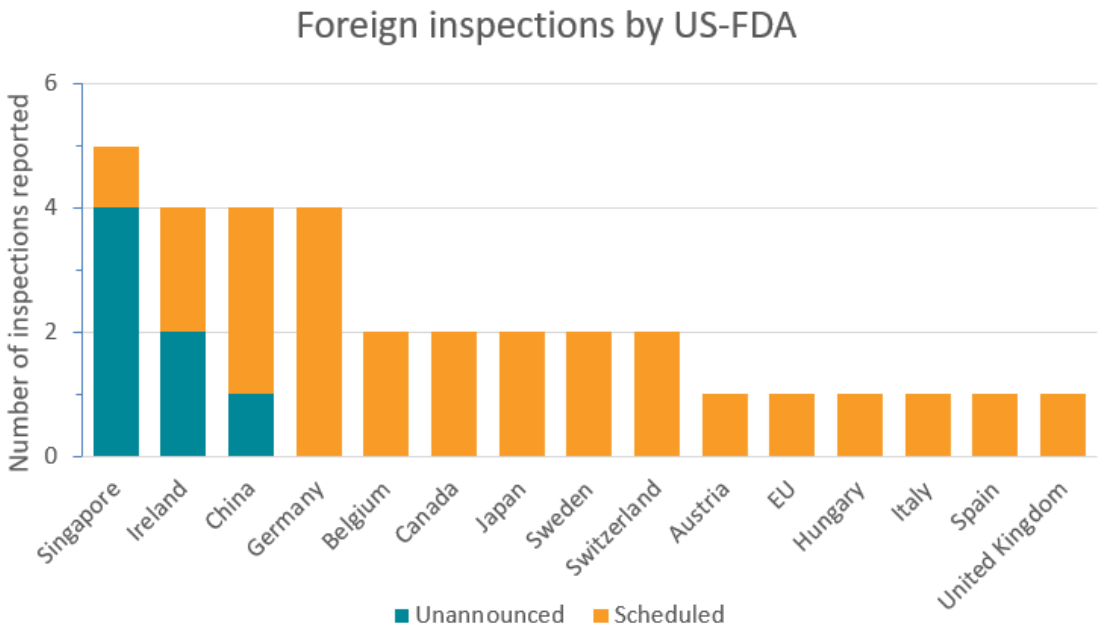
# US/FDA - scheduled / unannounced vs domestic / foreign




* FDA always did unannounced inspections, but more than twice as much in 2025

# Inspections performed by US/FDA - Scheduled/Unannounced



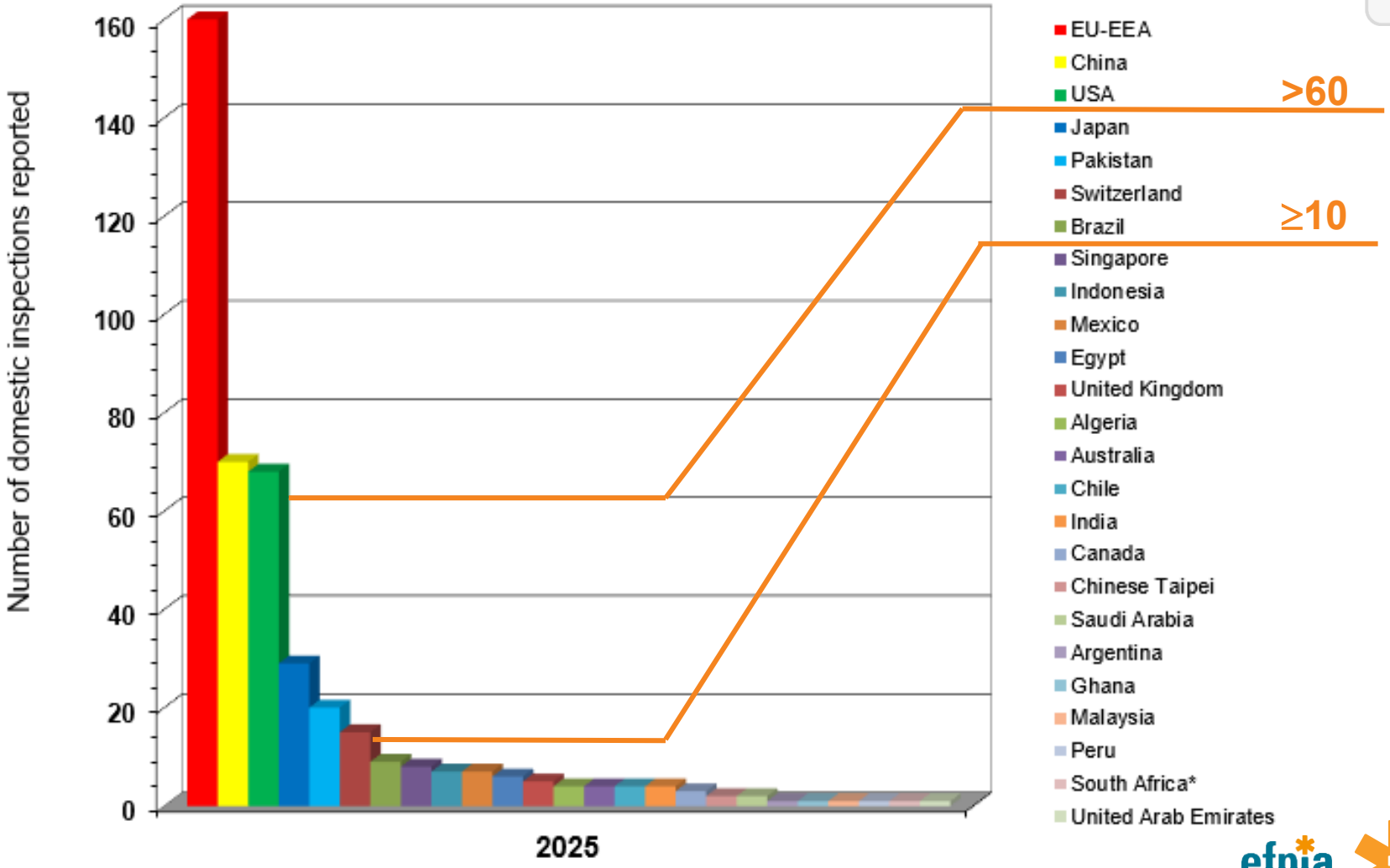




'EU': companies did not disclose the Member State, where the site is located Note: Inspection during the clinical phase are not in scope

# Domestic Inspection Activity

# Number of domestic inspections

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

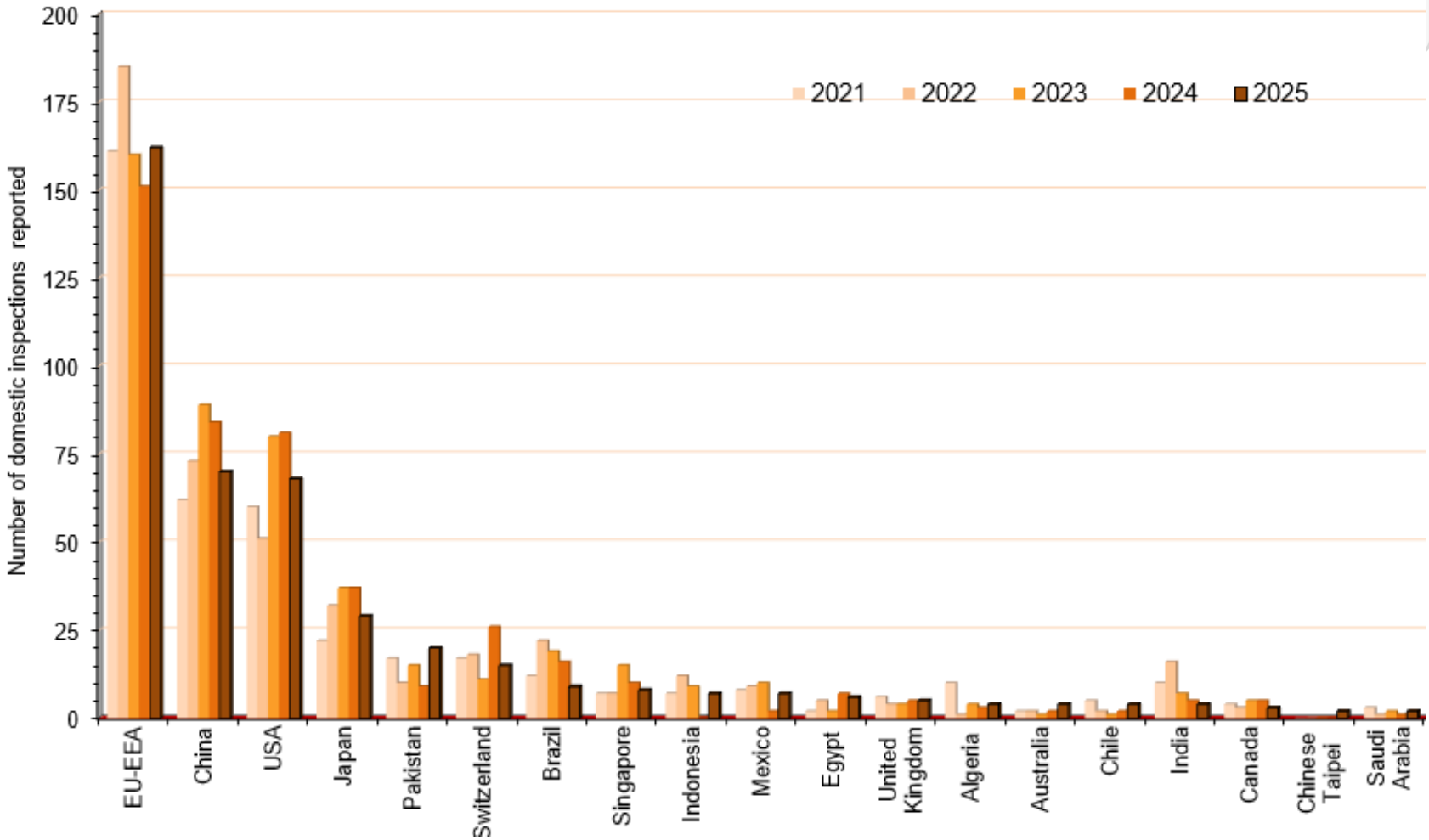





Note: Notified Bodies doing certifications for devices included in Medicinal Products

## DOMESTIC INSPECTIONS AT MANUFACTURING SITES

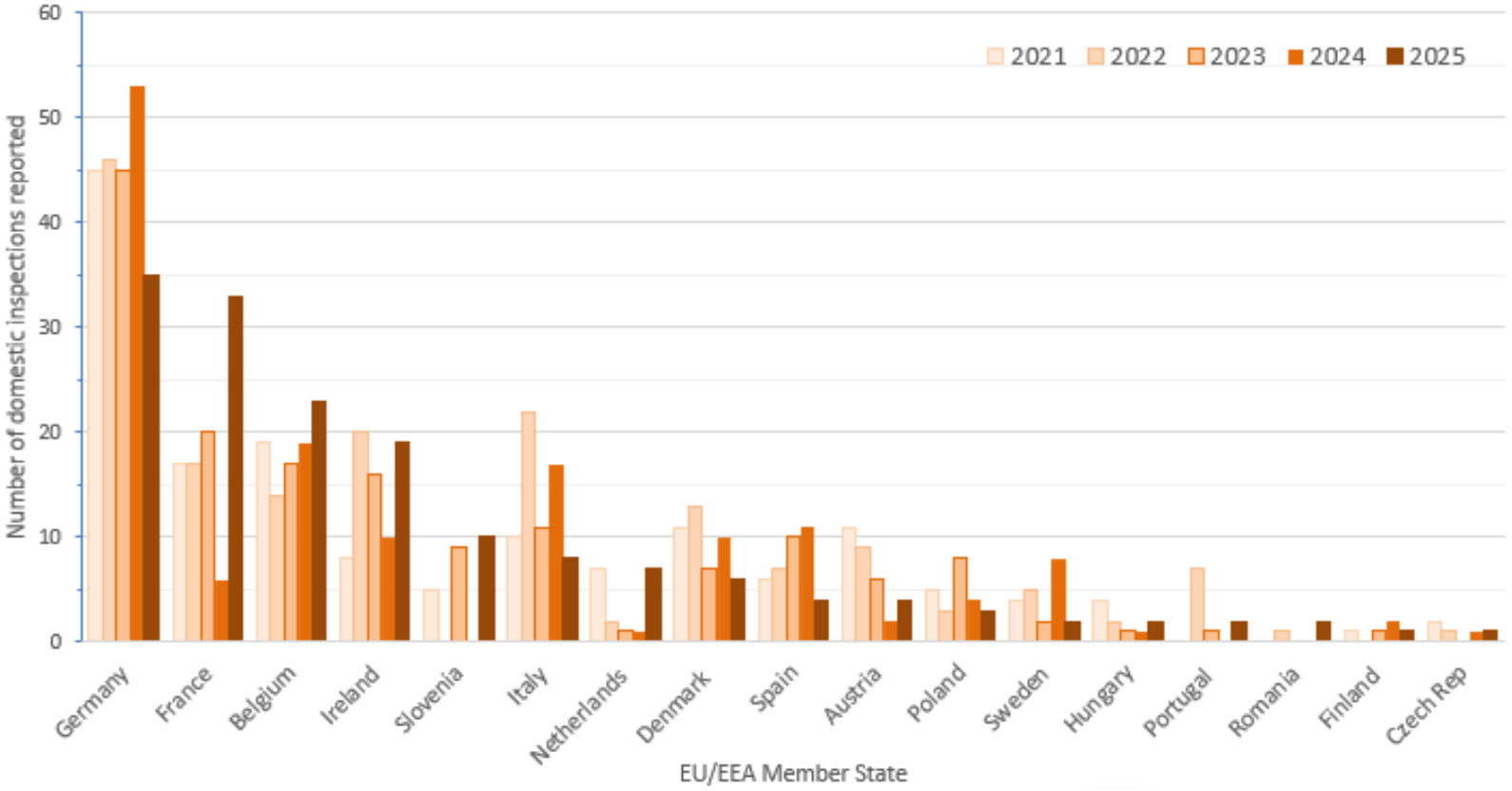
# Number of reported domestic inspections




Only listed if more than 2 domestic inspections reported

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

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

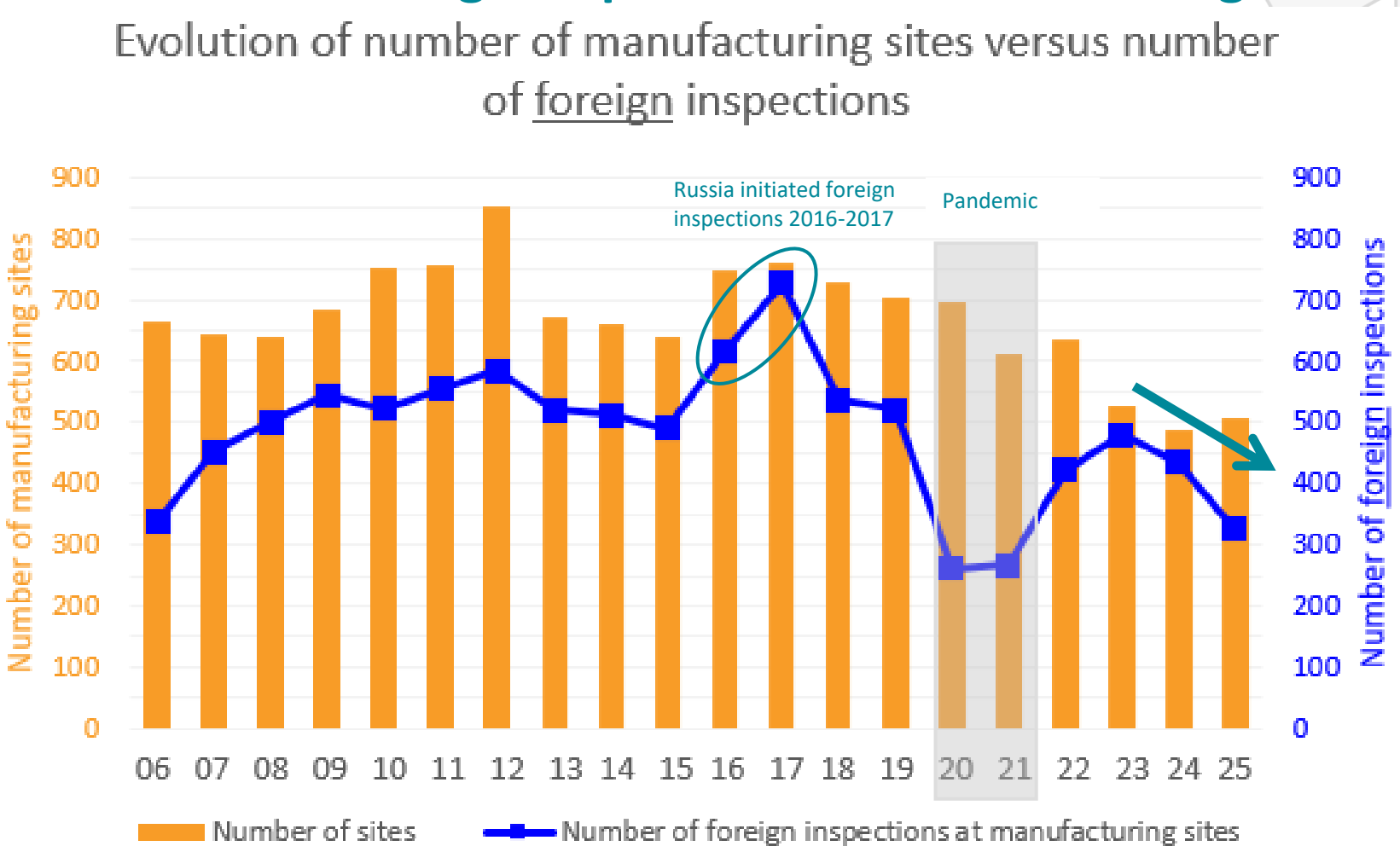



✱ **More inspections than 2024 (151 to 162)**

*Country only listed if an inspection is reported in 2025*

# Foreign Inspection Activity

# Number of foreign inspections at manufacturing sites

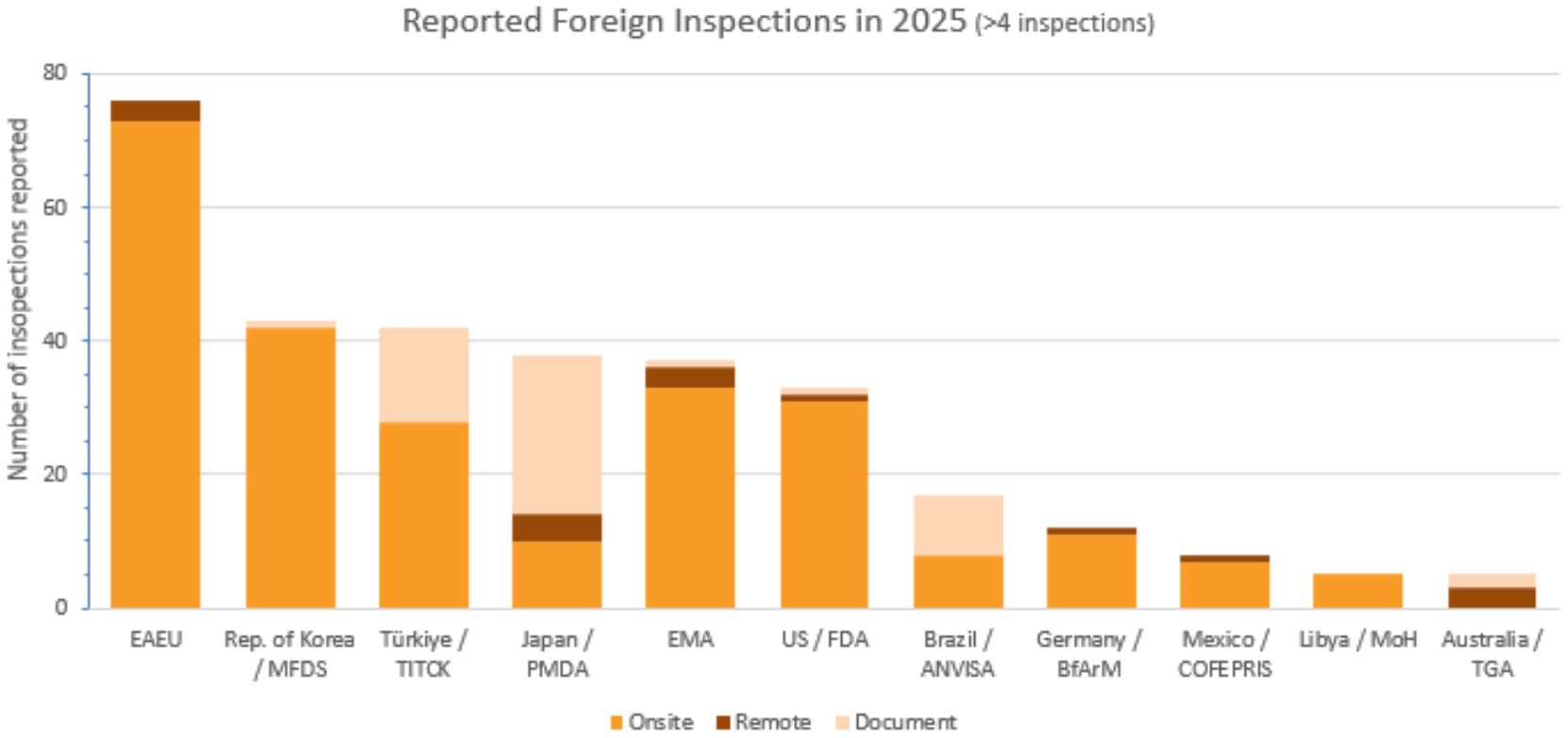



* **The number of foreign inspections reported to decline**



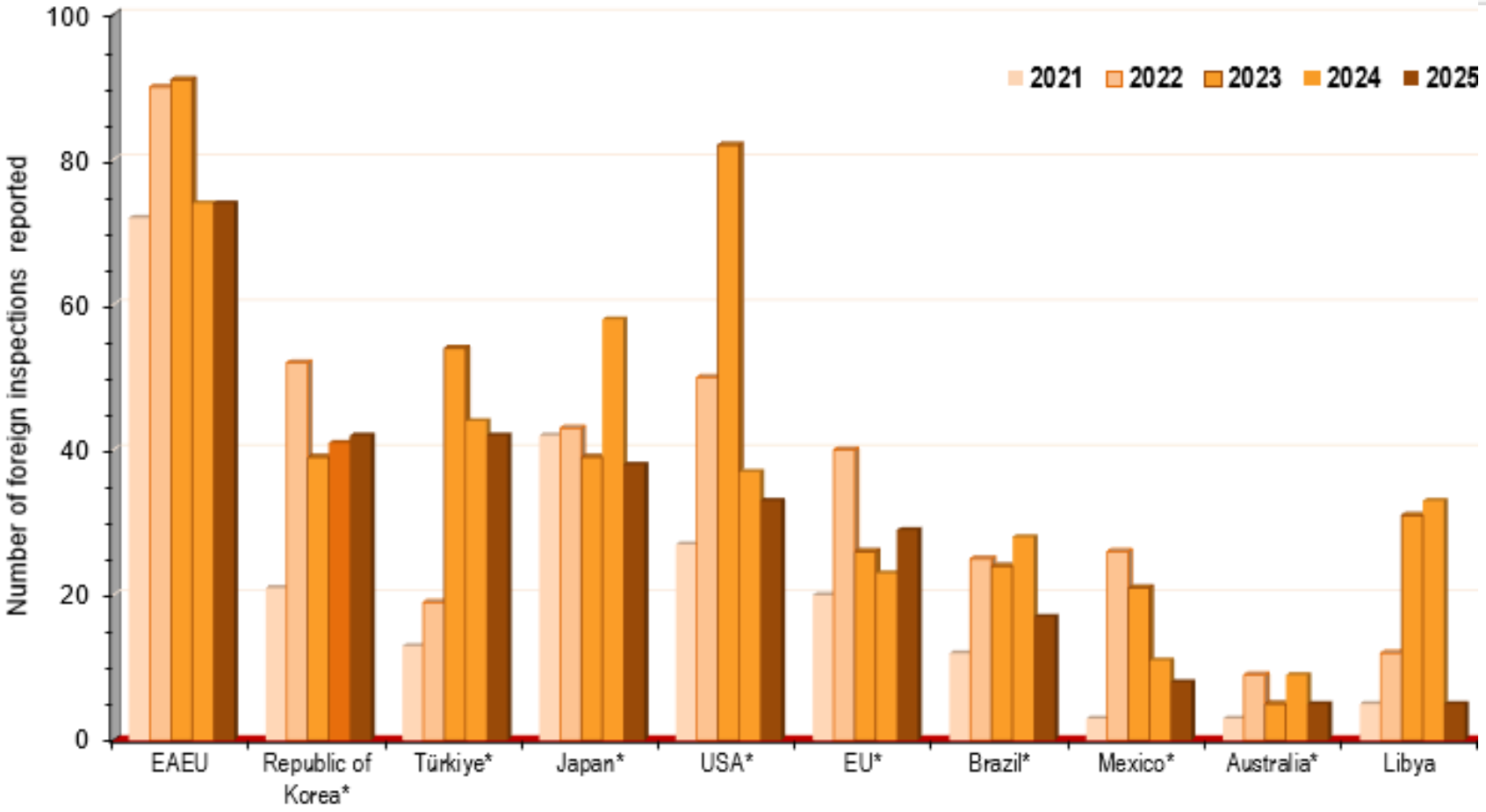
All inspections included independent of the mode used

# Modes of the foreign inspections performed



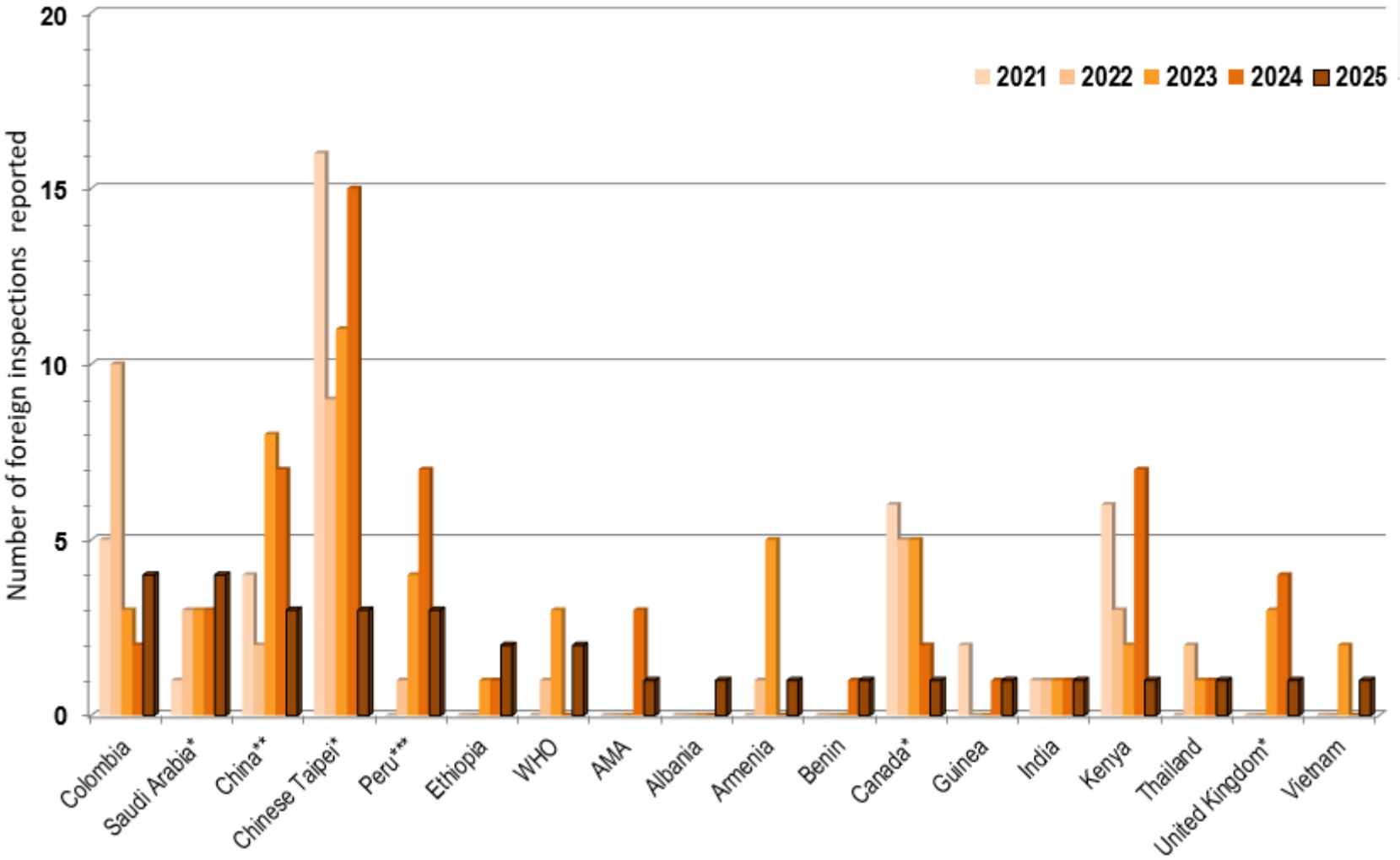

- **There is a trend to be back for onsite for foreign inspections; however**
  - Türkiye and Japan may not follow the above trend potentially driven by document request as part of submissions / license renewals
  - Australia may have implemented the reliance approach by getting additional information from individual inspections performed remotely and as document inspections

# Number of foreign inspections by country 1/2




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

# Number of foreign inspections by country 2/2




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

# Agencies performing foreign inspections

- **76 jurisdictions have performed foreign inspections from 2003 to 2024**
- **29 jurisdictions performed foreign inspections in 2025**

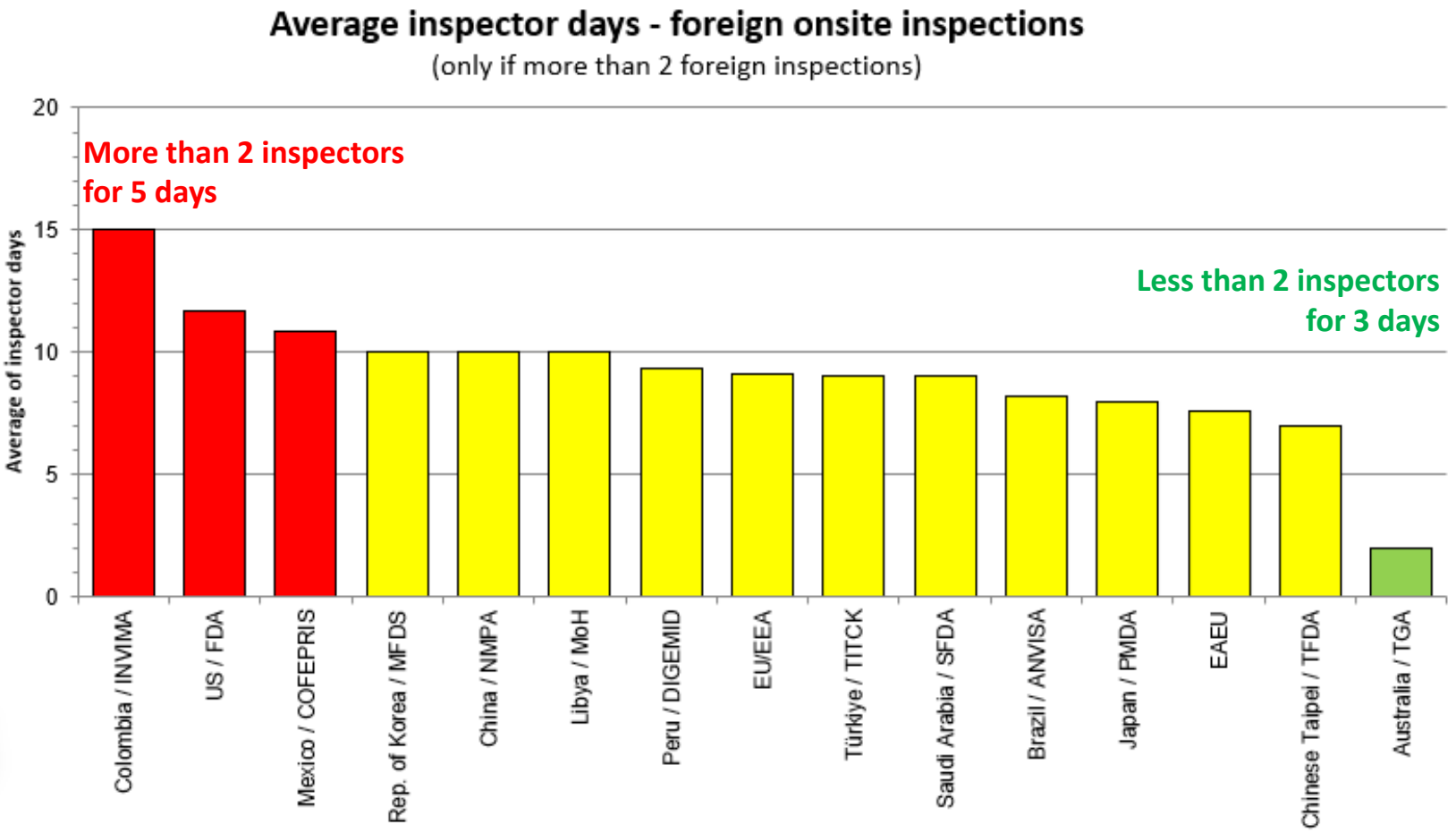
Albania
African Medicinal Agency
Argentina*
Australia*
Benin
Bosnia Herzegovina
Botswana
Brazil*
Burundi
Cambodia[1]
Canada*
Chile
China**
Chinese Taipei*
Colombia
Congo
Costa Rica
EAEU[a]
Ecuador
Egypt***
Ethiopia
EU/EEA*[a]
Ghana***
Gulf States (GCC)
Guinea
Honduras
Hong Kong China*
Iceland*
India
Indonesia*
Iran*
Iraq
Israel*
Ivory Coast
Japan*
Jordan*
Kenya
Lebanese
Libya
Malawi
Malaysia*
Malta
Mexico*
Nepal
New Zealand*
Nigeria***
Oman
Padua Neu Guinea
Pakistan
Panama
Peru***
Republic of Korea*
Rwanda***
Saudi Arabia*
Sierra Leone
Singapore*
South Africa*
Sri Lanka
Sudan
Switzerland*
Syria
Tansania***
Thailand*
Tukmenistan
Tunisia
Türkiye*
Uganda
Ukraine*
United Arab Emirates
United Kingdom*
USA*
Venezuela
Vietnam
WHO
Yemen
Zimbabwe***

- **No additional country performing foreign inspections in 2025!**

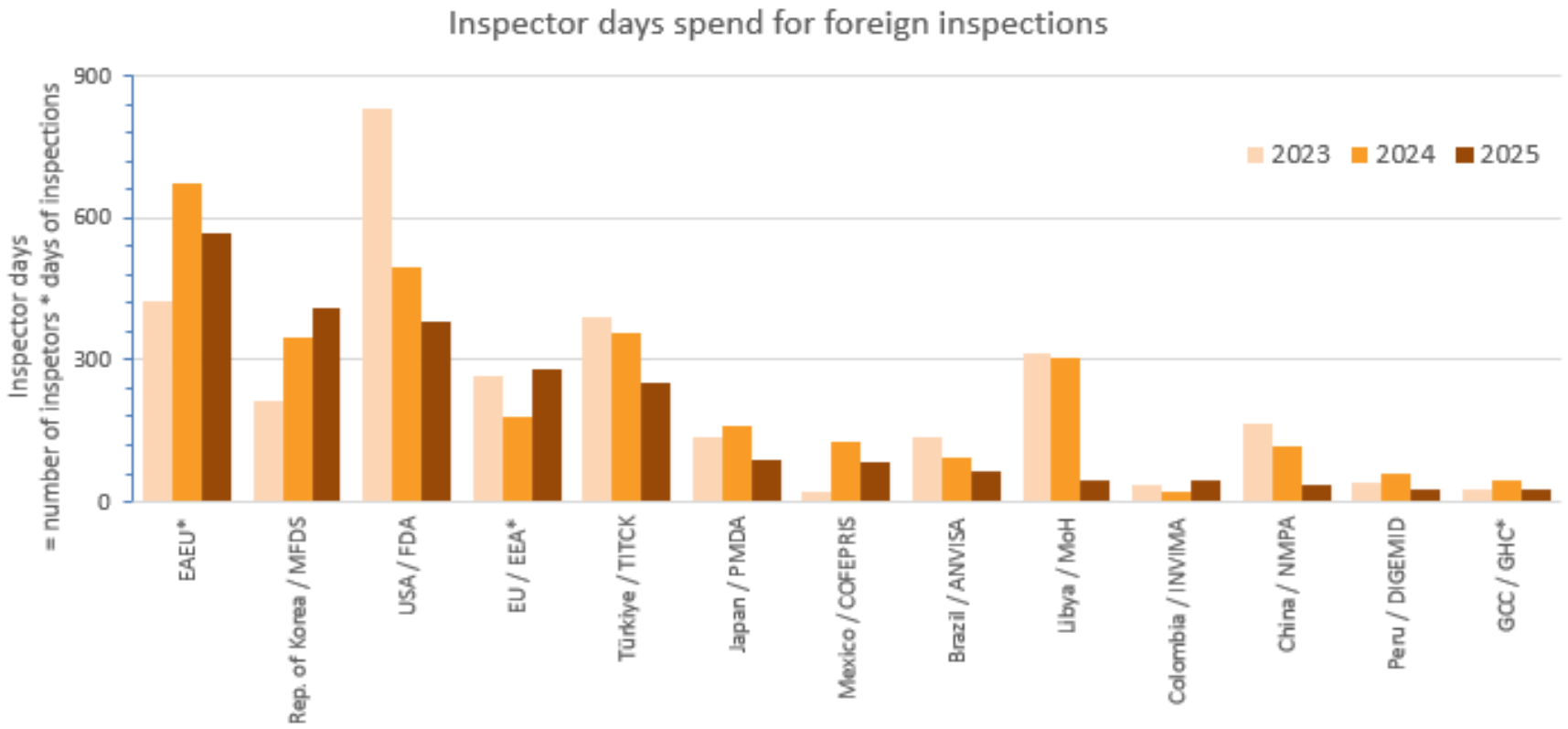
References:
a EU/EEA and EAEU countries as <u>one</u> inspectorate only
Orange: foreign inspection in 2024
Light blue: active in previous years; no reports in 2025
Green: no foreign inspection for the last 5 years

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

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

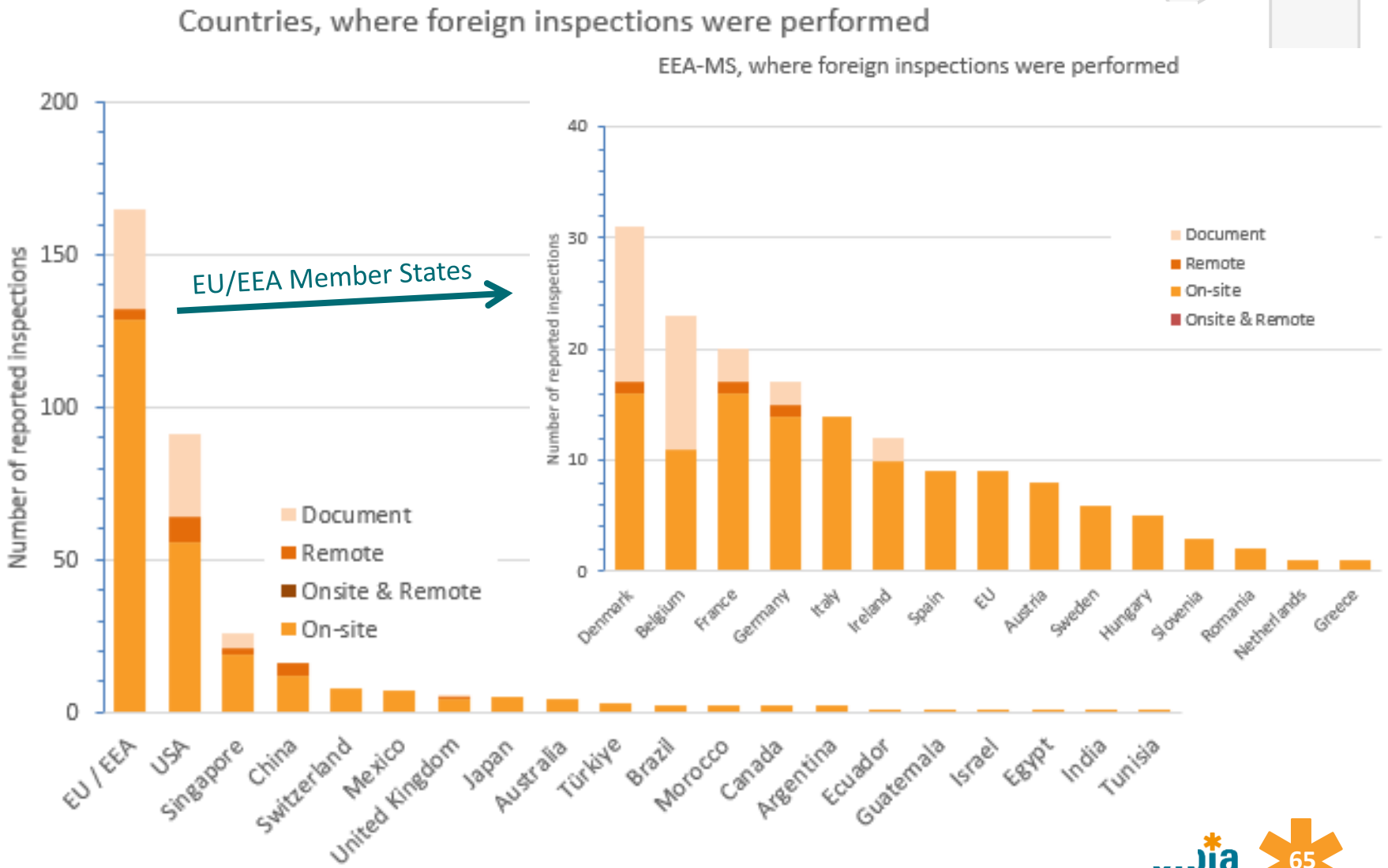


# Inspector days spent on foreign inspections at manufacturing sites (onsite only)




* Sum of all counties in this region

# Locations of Manufacturing Sites Hosting Foreign Inspections

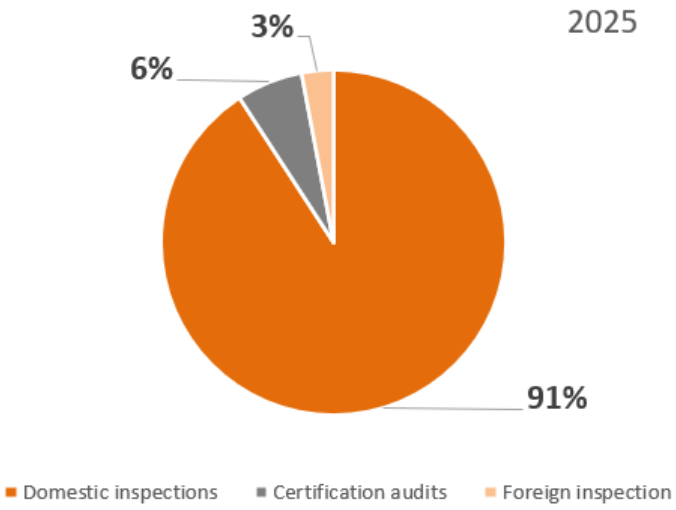


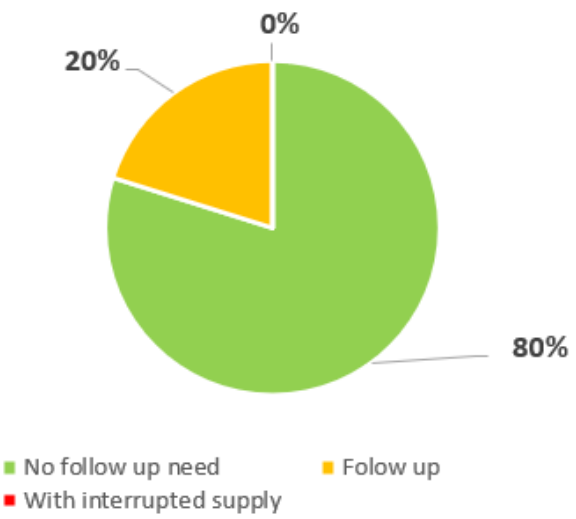



No Onsite & Remote inspection reported

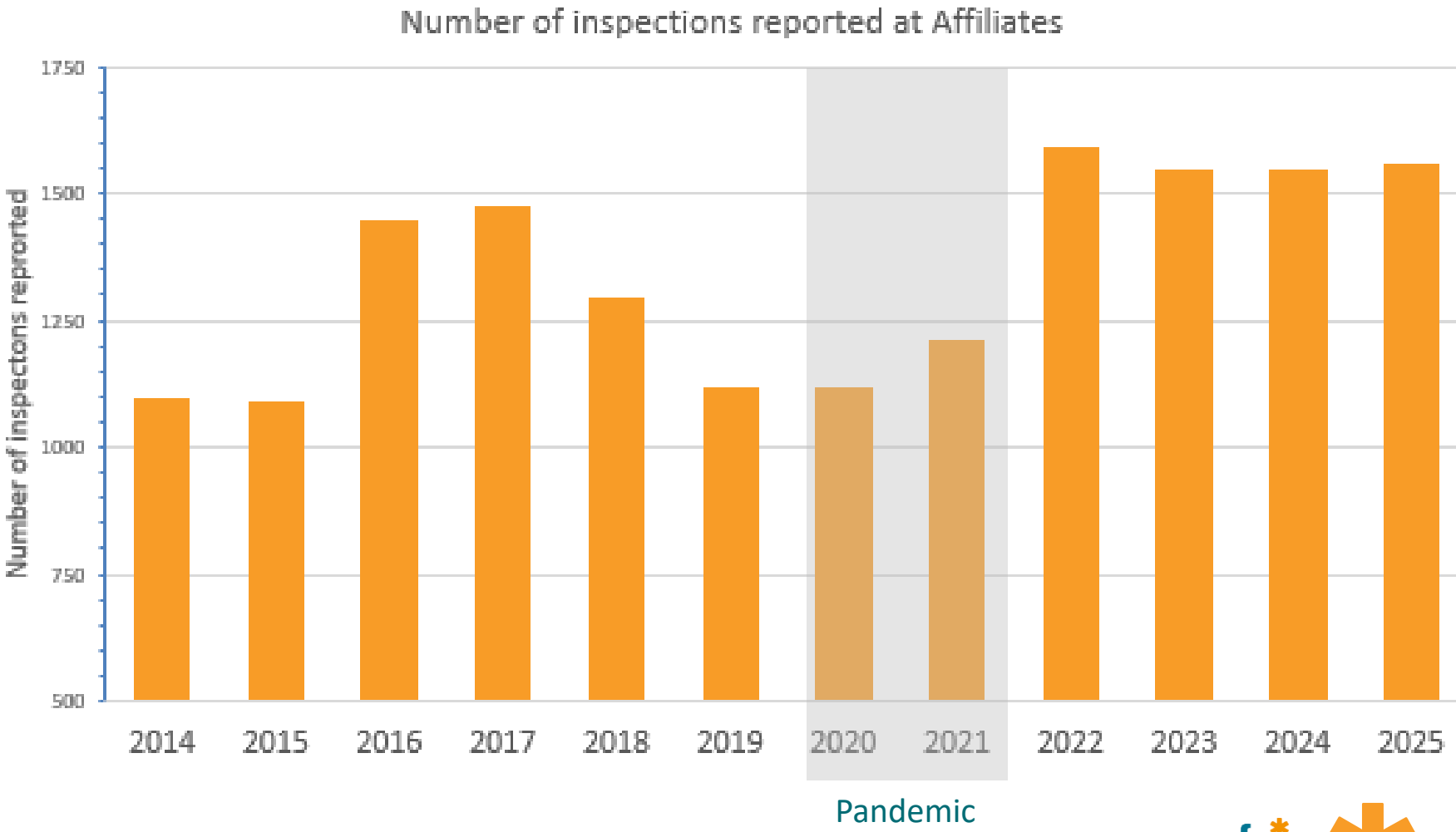
'EU': companies did not disclose the Member State, where the site is located

# Inspections at Affiliates

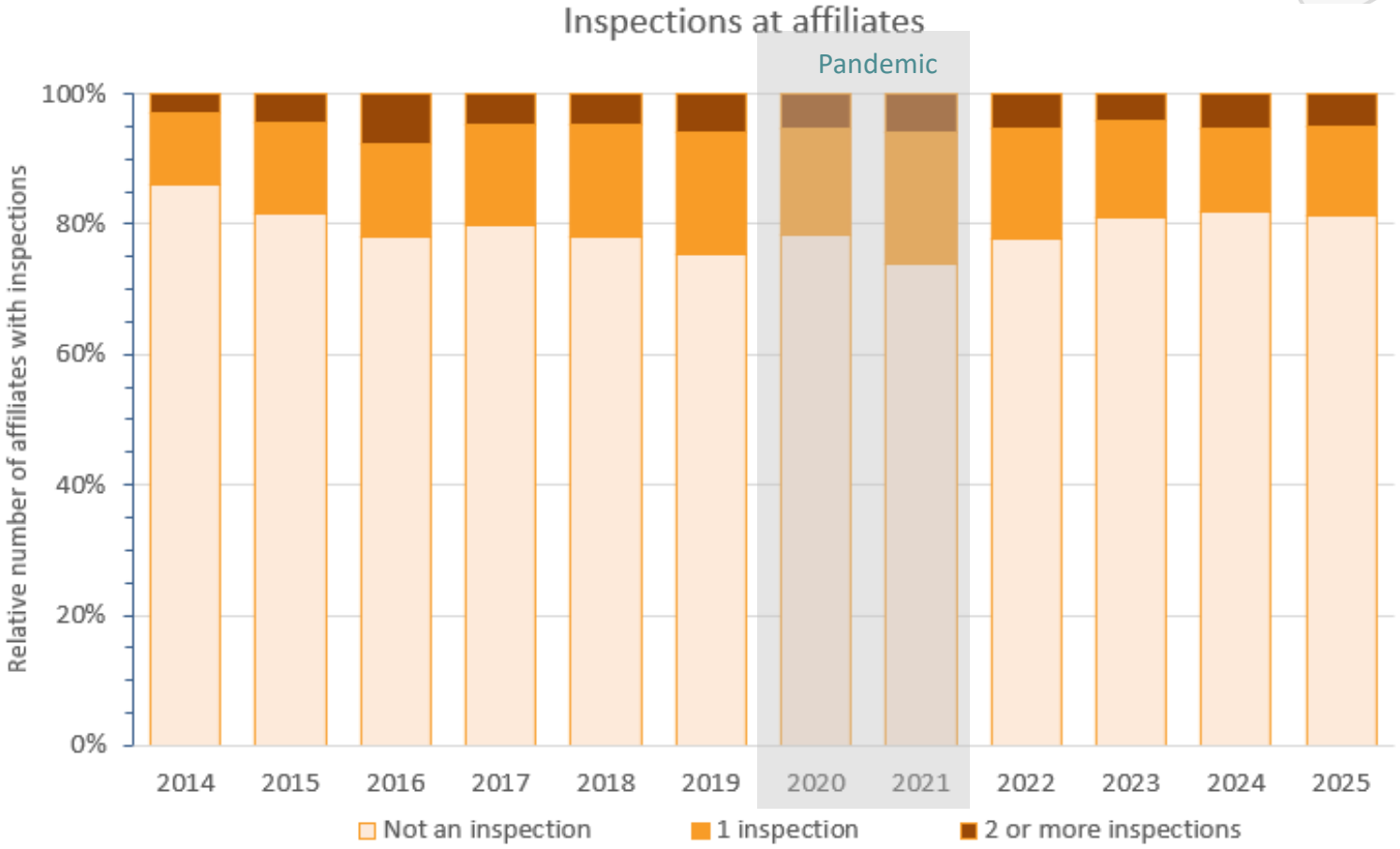


# Constant level of inspections at affiliates with very limited influence by the pandemic



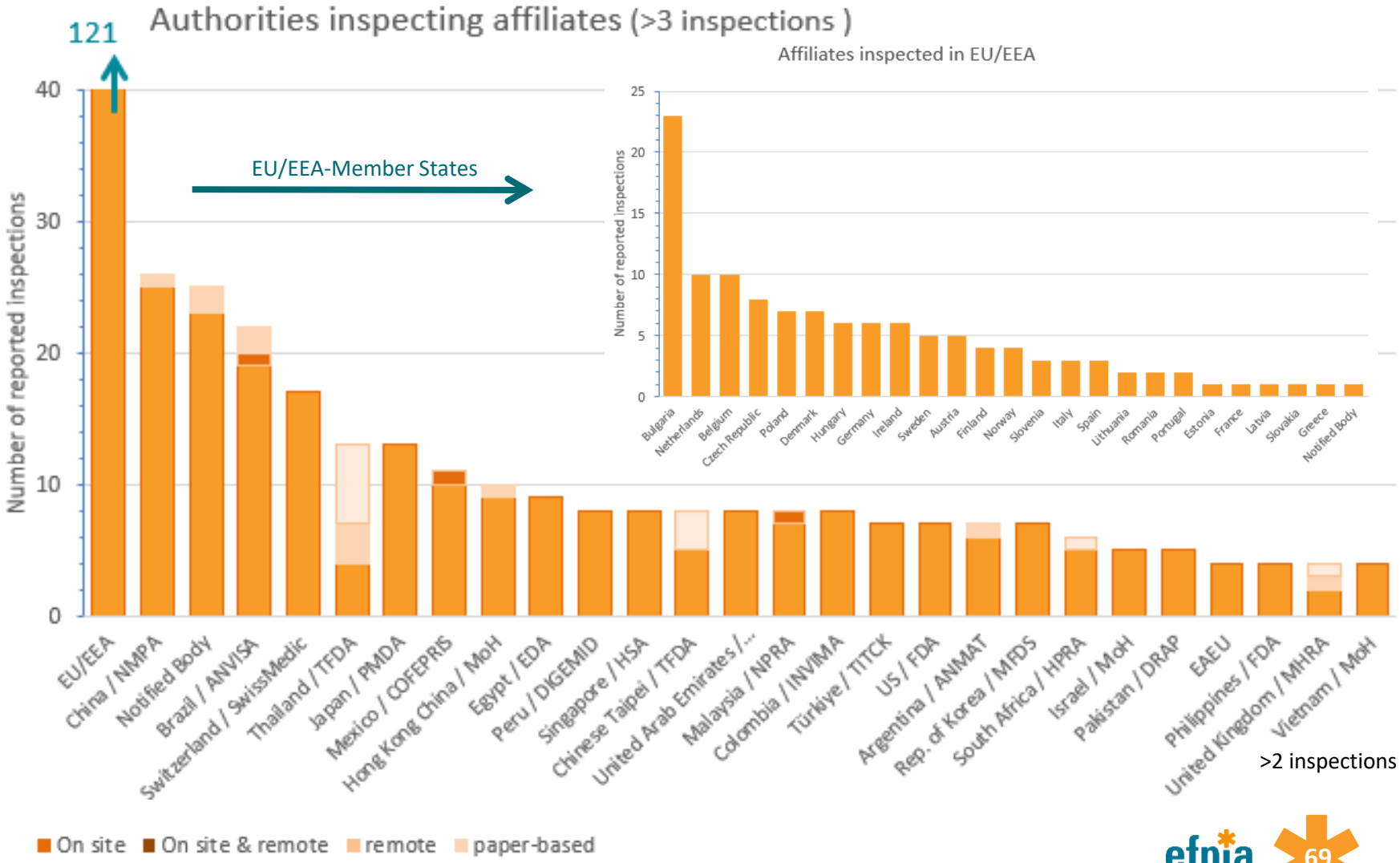
# Number of affiliates inspected




- **Facts**
  - The inspection oversight is constant
  - 80% without inspections – assumption: inspections every 5 years?

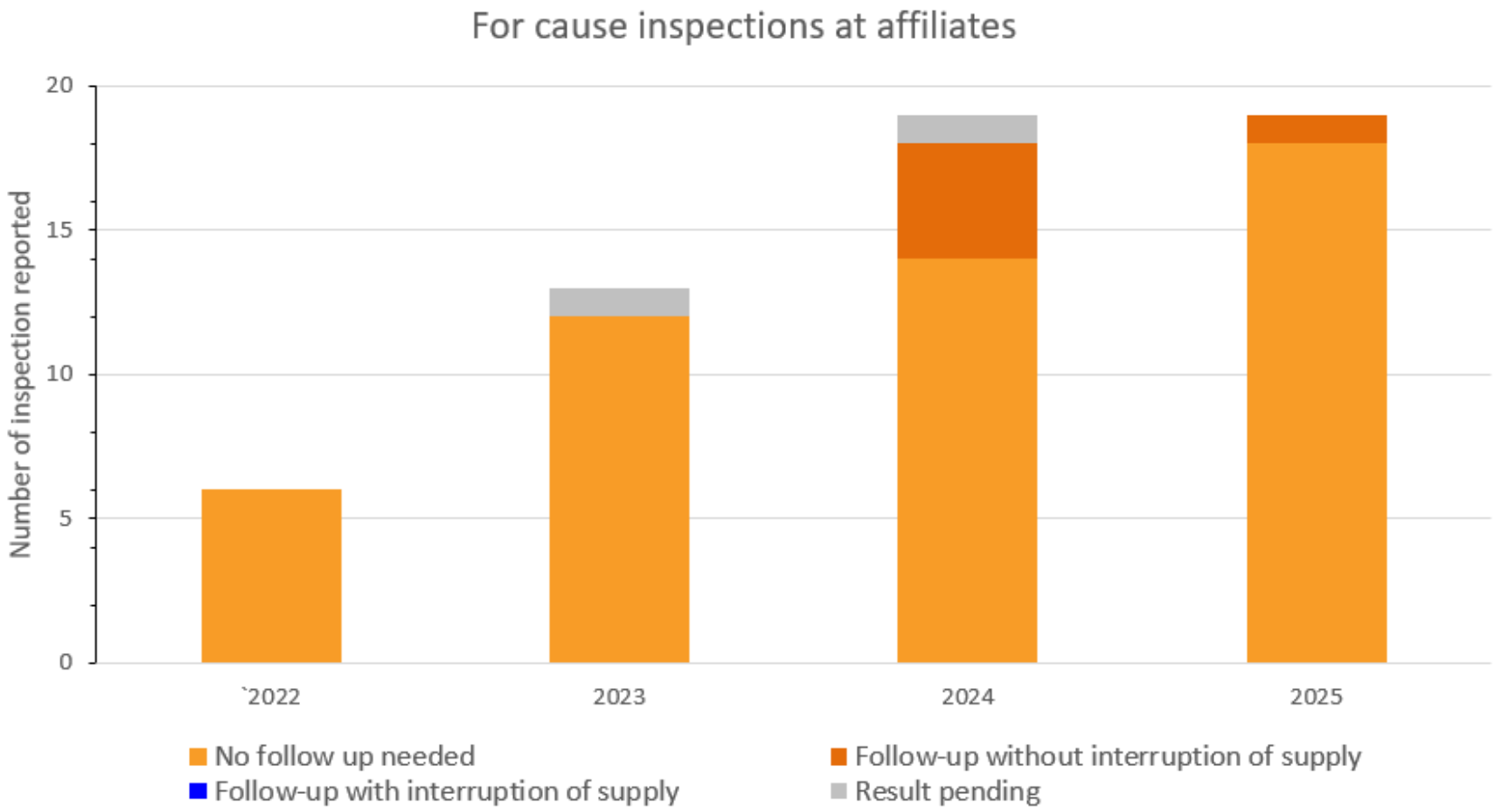
## INSPECTIONS AT AFFILIATES

# Local affiliates have received inspections - no trend by region



## INSPECTIONS AT AFFILIATES

# For cause inspections do not result in interrupted supply



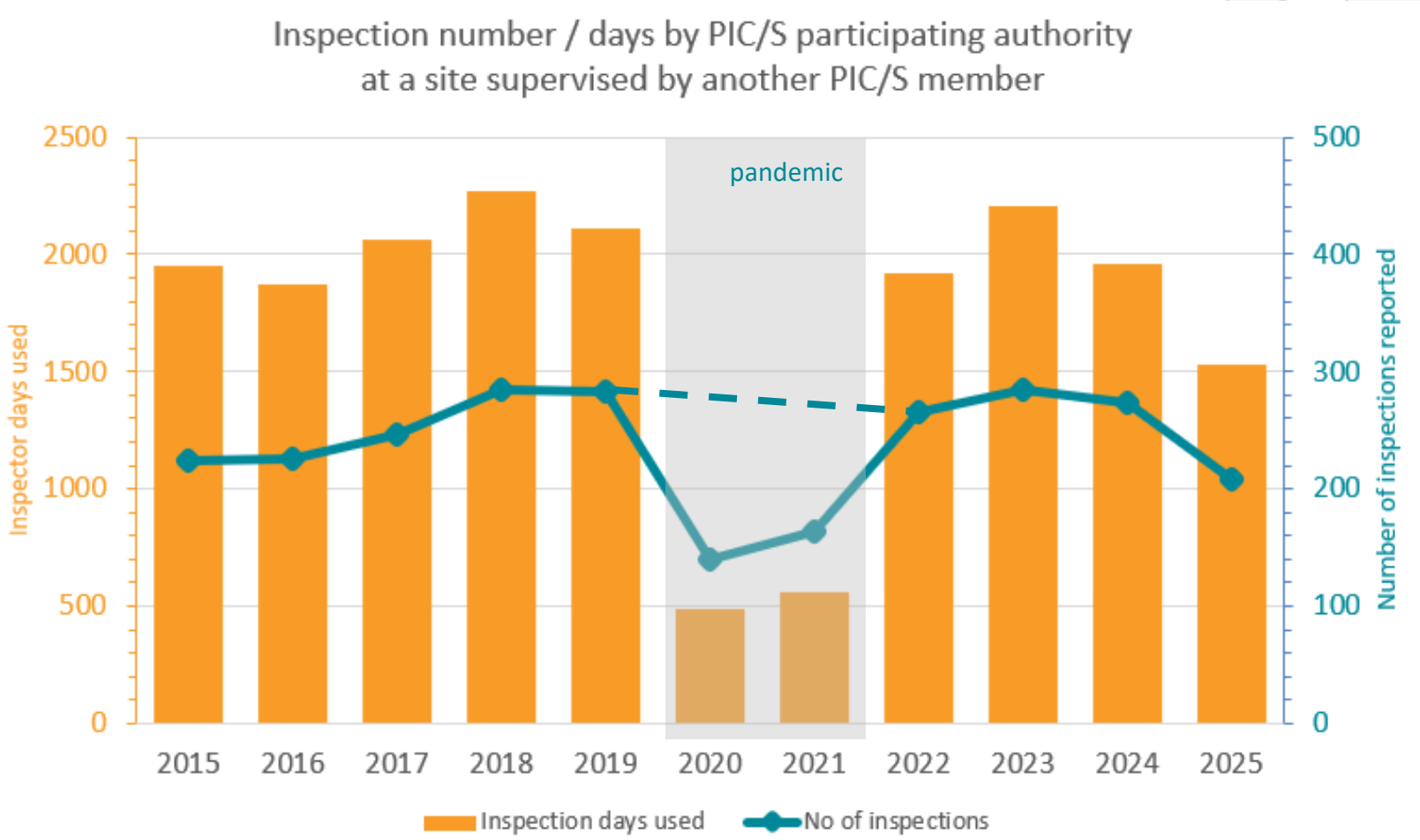

* **The number nearly doubled 2022 to 2023 and again to 2024; it's now stabilised**

# PIC/S

**LEVERAGE TOOLS e.g.,**

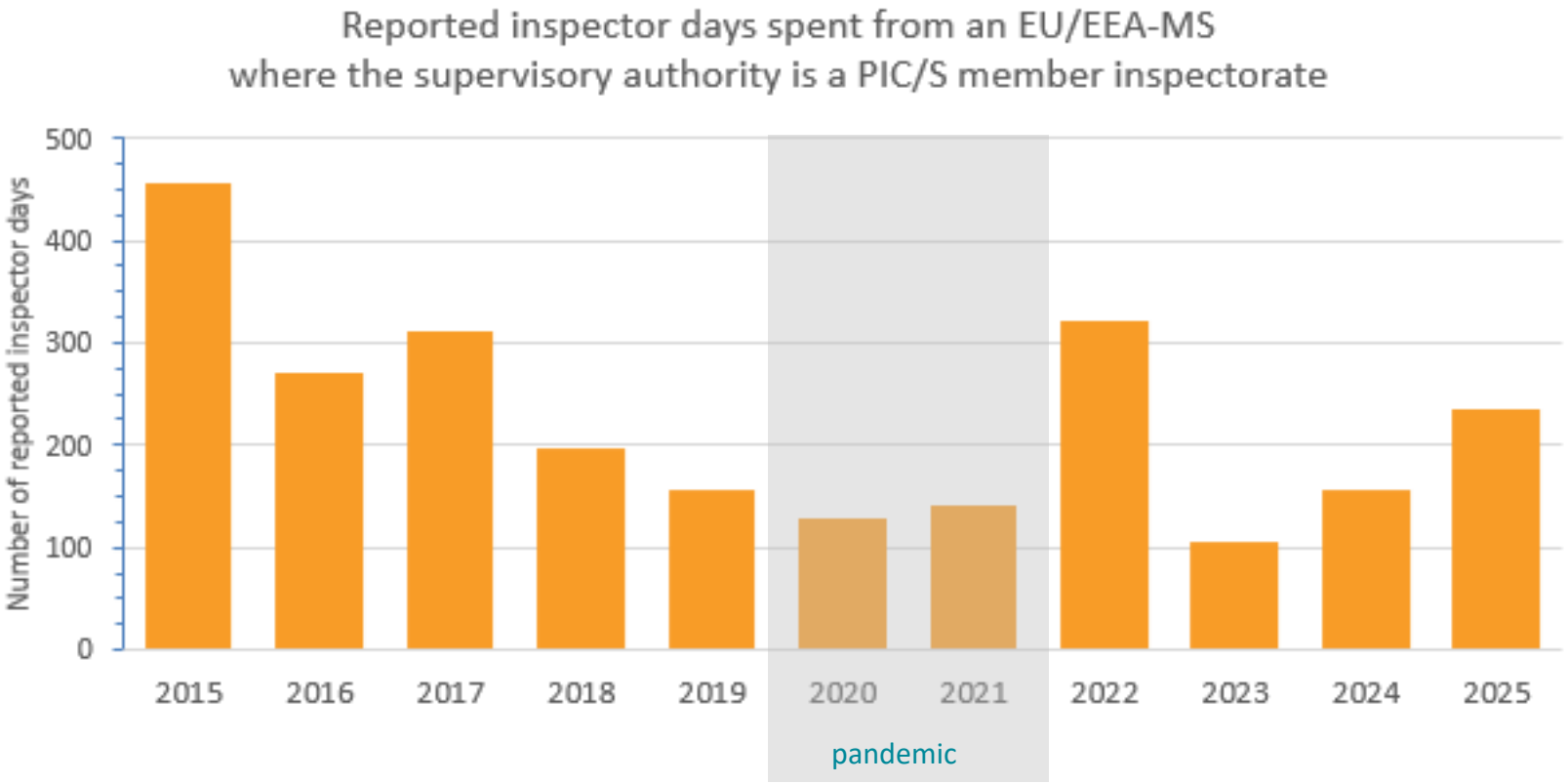
- **Risk-based inspection planning**,
  PIC/S guideline PI 037-1, 1 January 2012
- **GMP-Inspection reliance**,
  PIC/S guideline PI 048-1, 01 June 2018

# Foreign inspections between PIC/S Participating Authorities



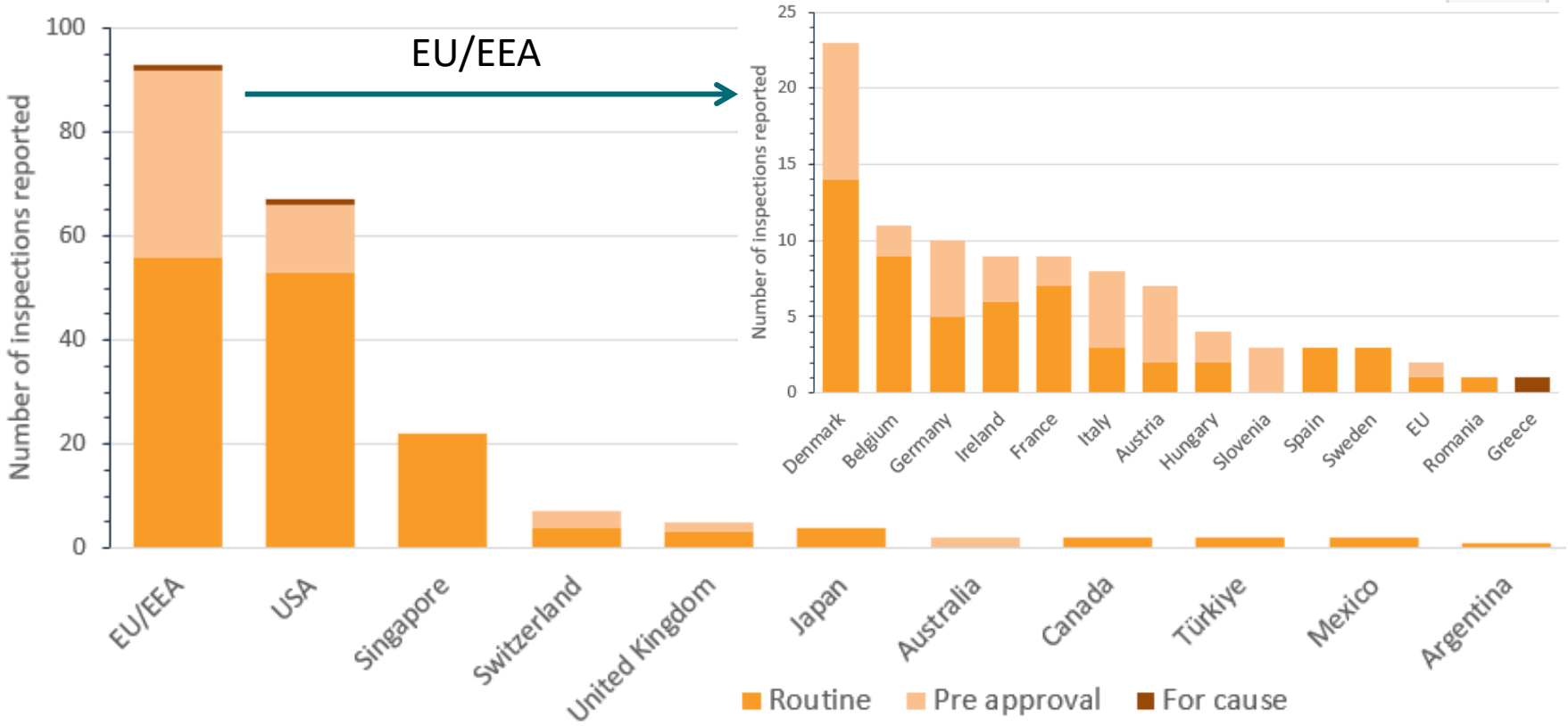

* Lowest number of inspections since 2015 (pandemic excluded)

# Foreign inspections between PIC/S Participating Authorities – by EU/EEA based authorities




* For EU/EEA inspectors we note inspections having 2.4 inspectors over 4.2 days in average in 2025

# Sites in a country with a PIC/S participating authority receiving inspections from a PIC/S participating authority

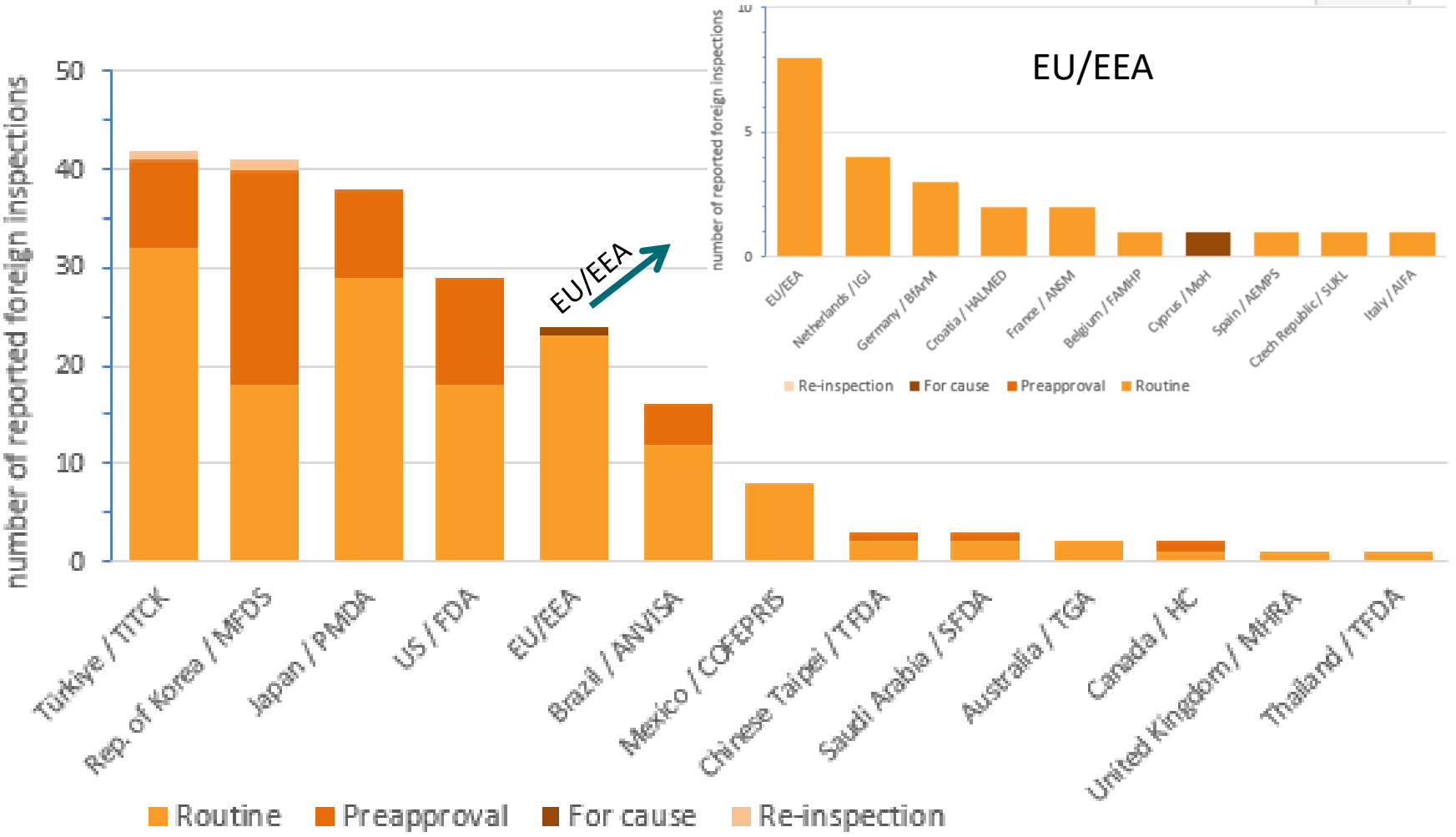



* **Countries receiving most often the inspections from PIC/S participating authorities are in EU (Denmark, Belgium, Germany, France) and US**

'EU': companies did not disclose the Member State, where the site is located

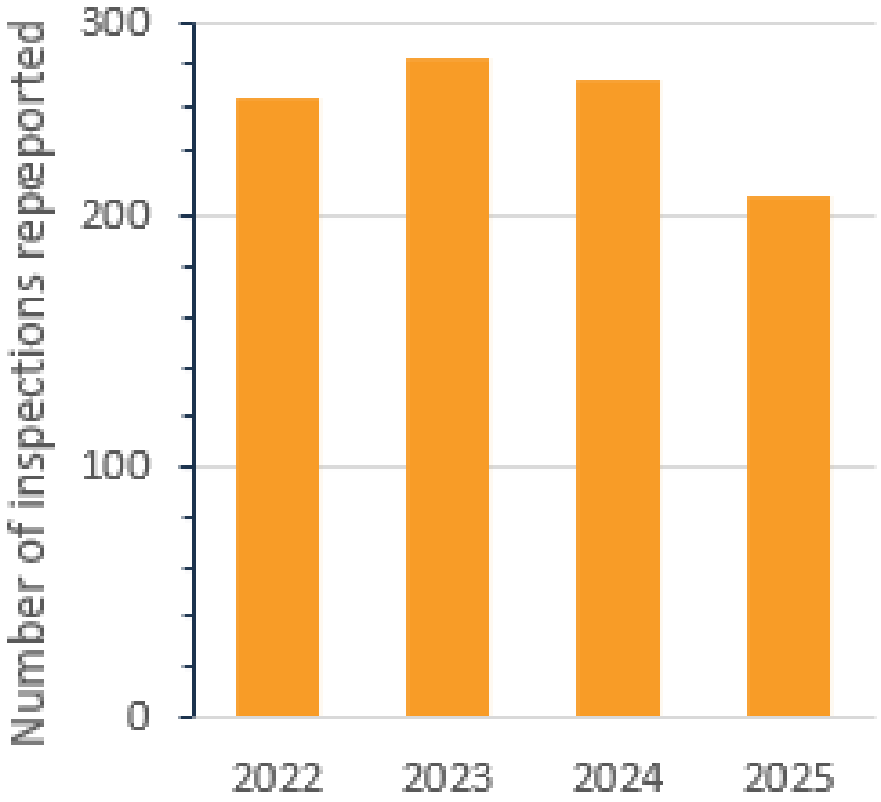
**1’514**
**inspector days used**
**(1’976 in 2024)**
**(2’500 days in 2023)**

# Foreign inspections between PIC/S Participating Authorities



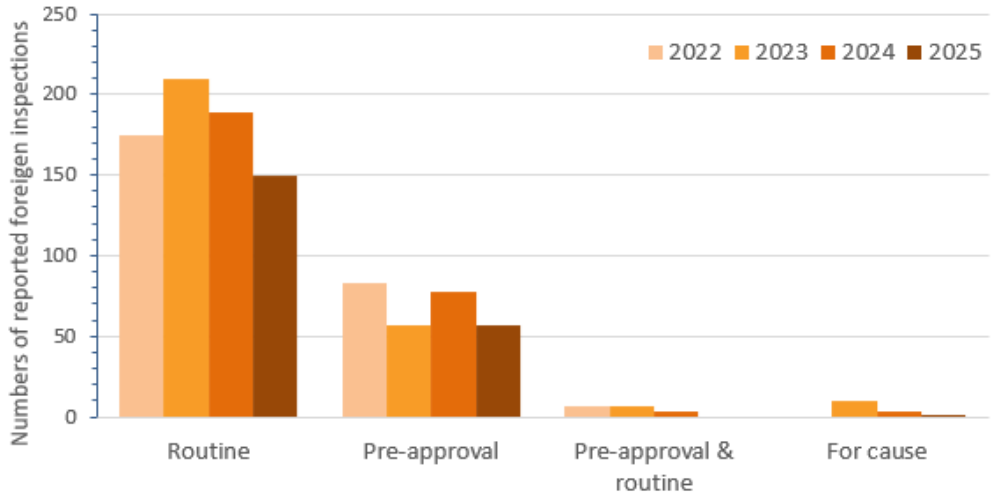

‘EU/EMA’: companies did not disclose the Member State, where the site is located

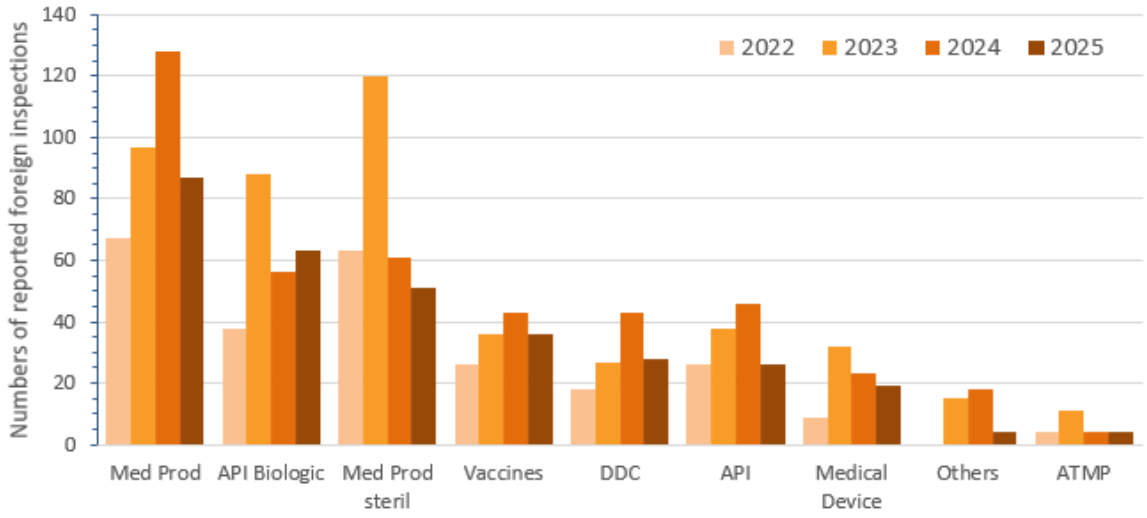
# Inspection within PIC/S Participating Authorities




- **Reliance is progressing**
  - Among PIC/S participating authorities' inspections in each other country is slowly decreasing

# PIC/S Participating Authorities – Inspection / product type



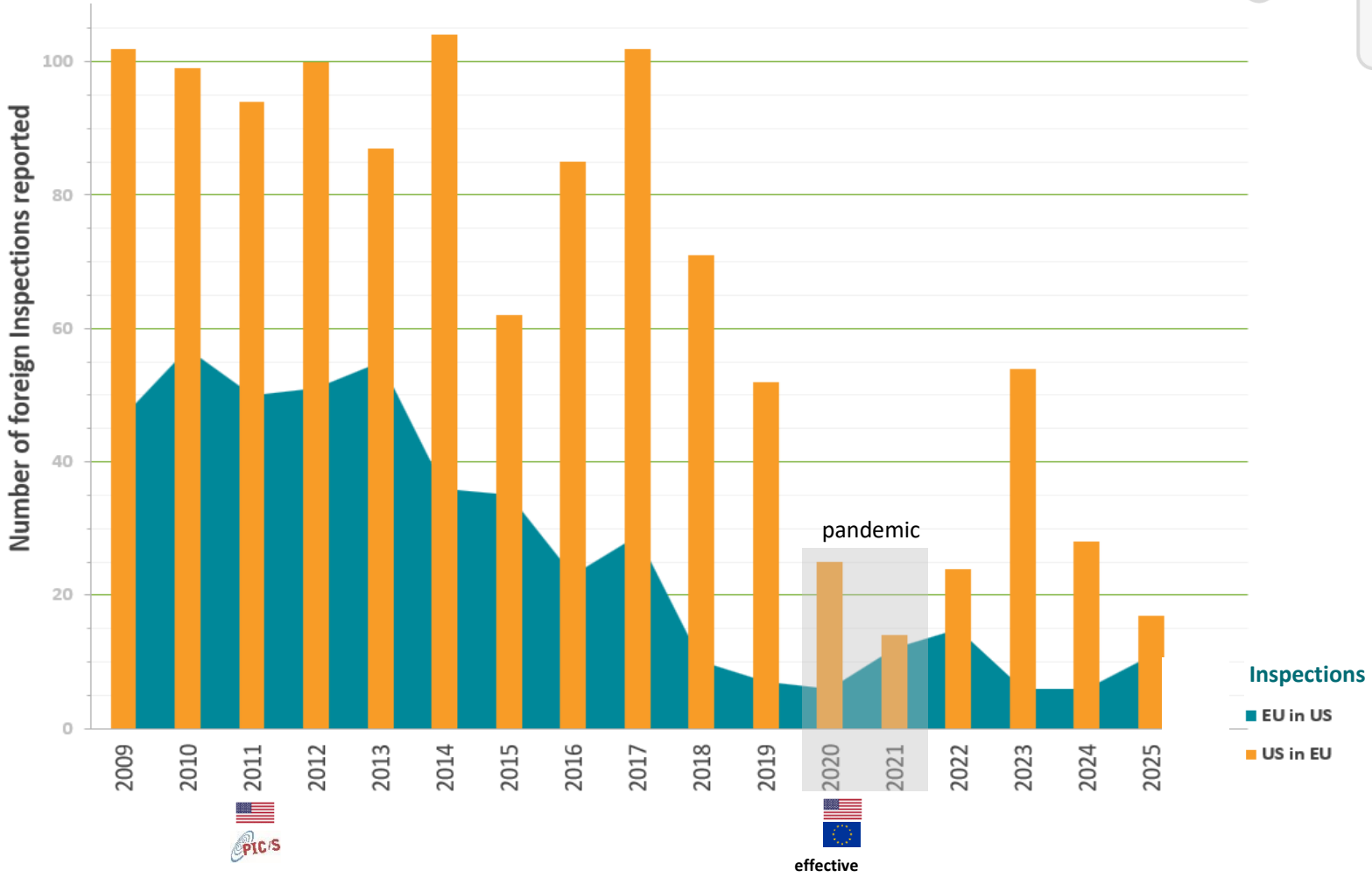
# MRAs

# Implementation of MRAs with the EU

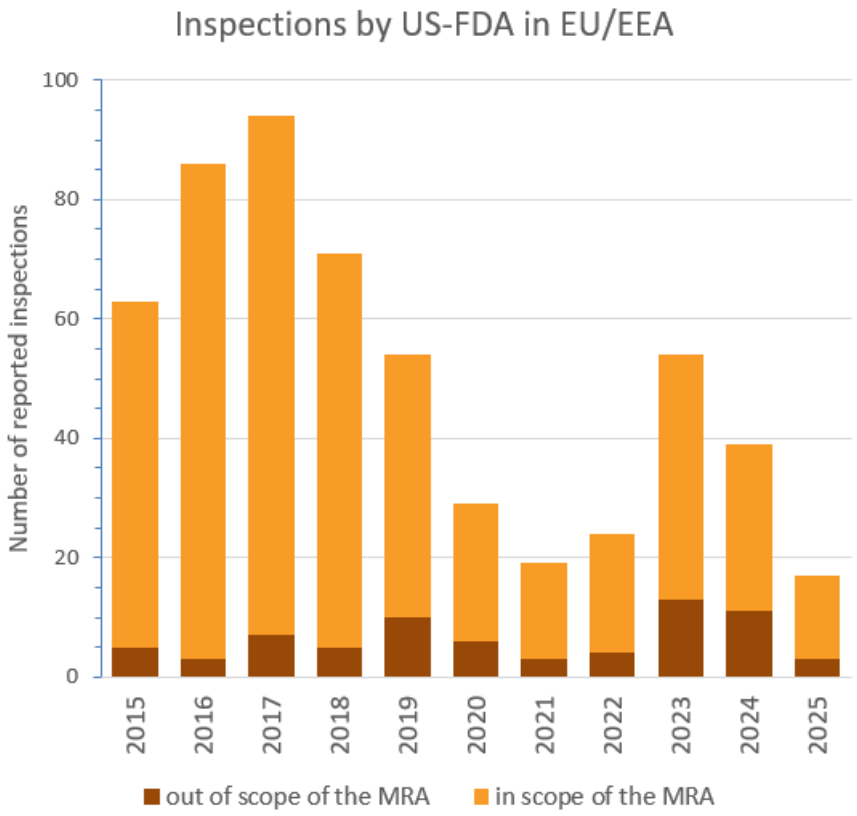
- **Positive impact of implemented leading to**
  - Less duplicative inspections
  - Reduced number of inspections
  - Inspections on behalf of the local agency in case of resource issues
- **MRAs are used - challenges remain**
  - Expanding scope to other modalities incl. vaccines/plasma derived, ATMPs, radiopharmaceuticals, as applicable
  - Consistent interpretation of modalities
    - Oligonucleotides may be seen as ATMPs
  - Legal interpretations of terminologies
    - 'Pre-approval inspection', 'GMP-certificate'
    - ATMPs / CGTs
  - Forms/documents as part of the regulatory submission are interpreted as 'Inspections'
  - Japan (drug product), Switzerland (medical device)
- **We see opportunities for unilateral reliance approaches**
  - PIC/S membership to facilitate recognition

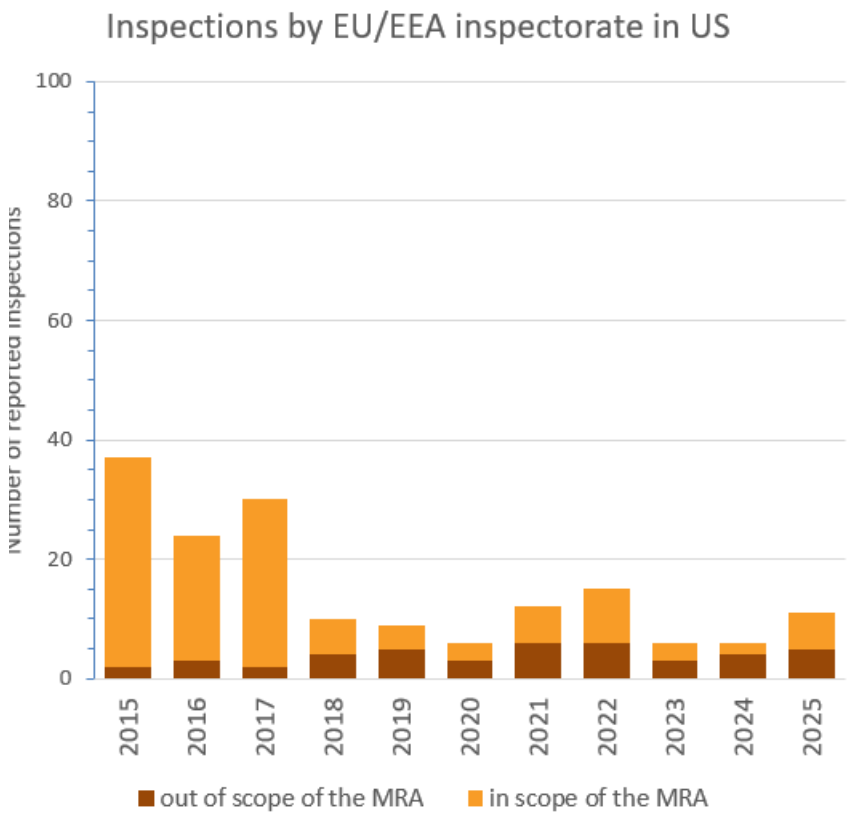
# ANNUAL EFPIA INSPECTION SURVEY – US/EU MRA

## Full EU / US MRA implementation could leverage further benefits

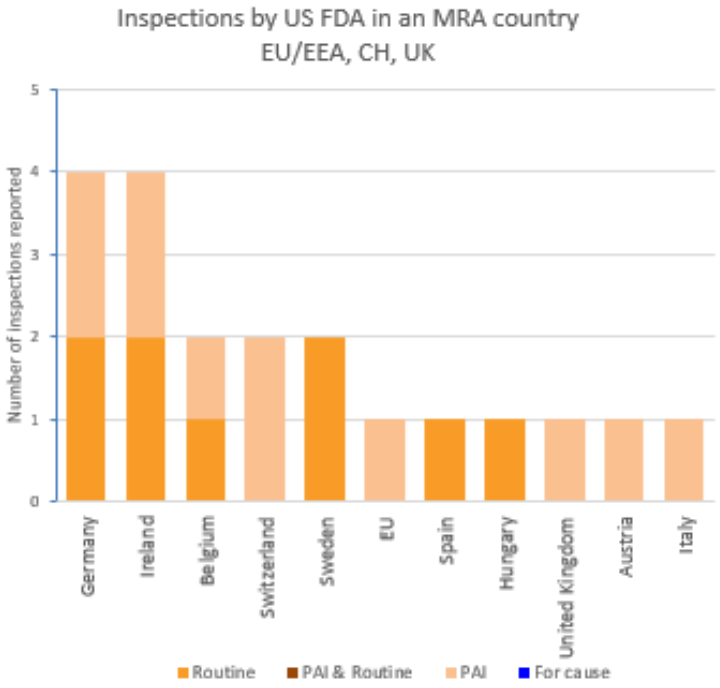


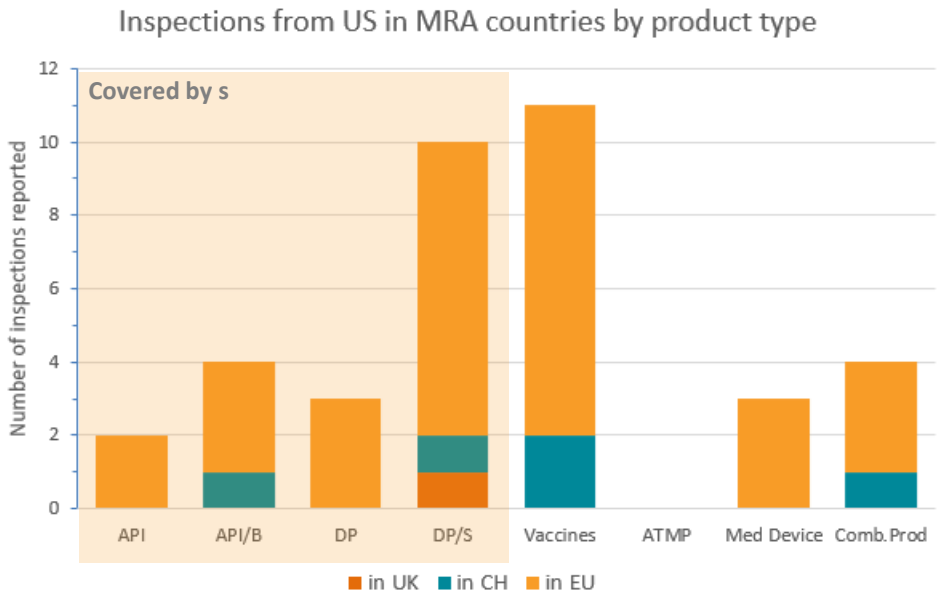
# Inspections in each other territory as of scope



# Full implementation could leverage further benefits




- **Opportunity: about 60% of the FDA inspections are within scope of an**
  - 11 out of 28 inspections from the US in EU had been reported to be for vaccines, combination products or ATMP

'EU': companies did not disclose the Member State, where the site is located

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