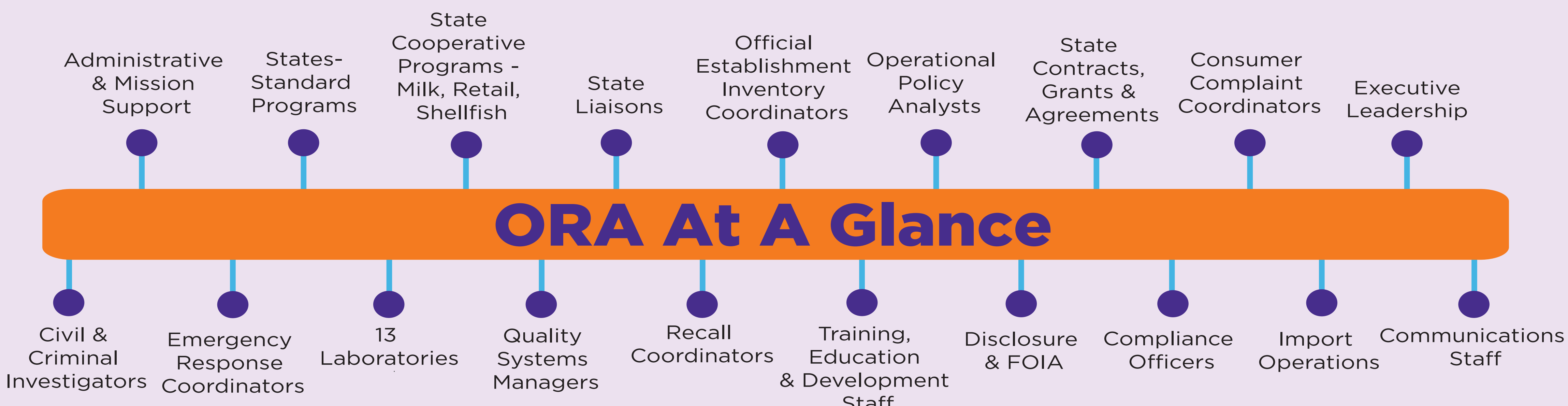


ORA Facts

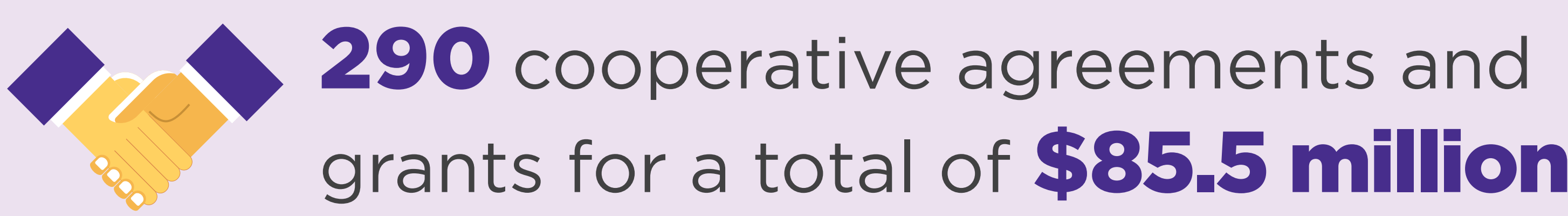
ORA Maximizes Compliance of FDA Regulated Products
and Minimizes Risks Associated with Those Products

ORA Employees



Regulatory and Public Health Partnerships

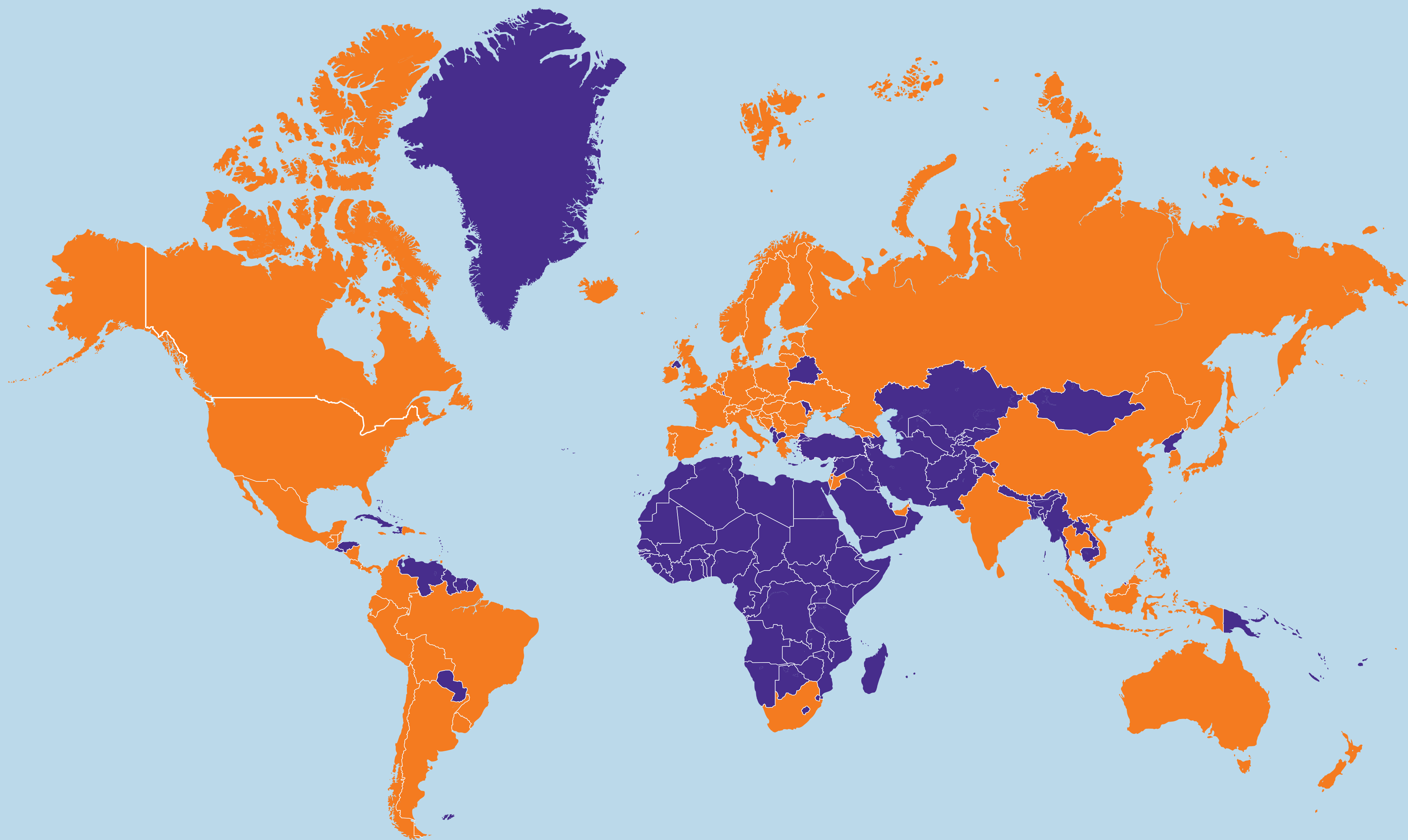
Expanded our federal, state, local, tribal and territorial regulatory and public health partnership efforts



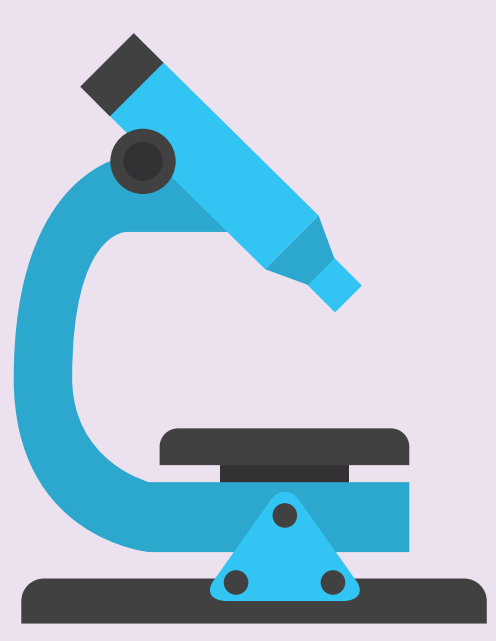
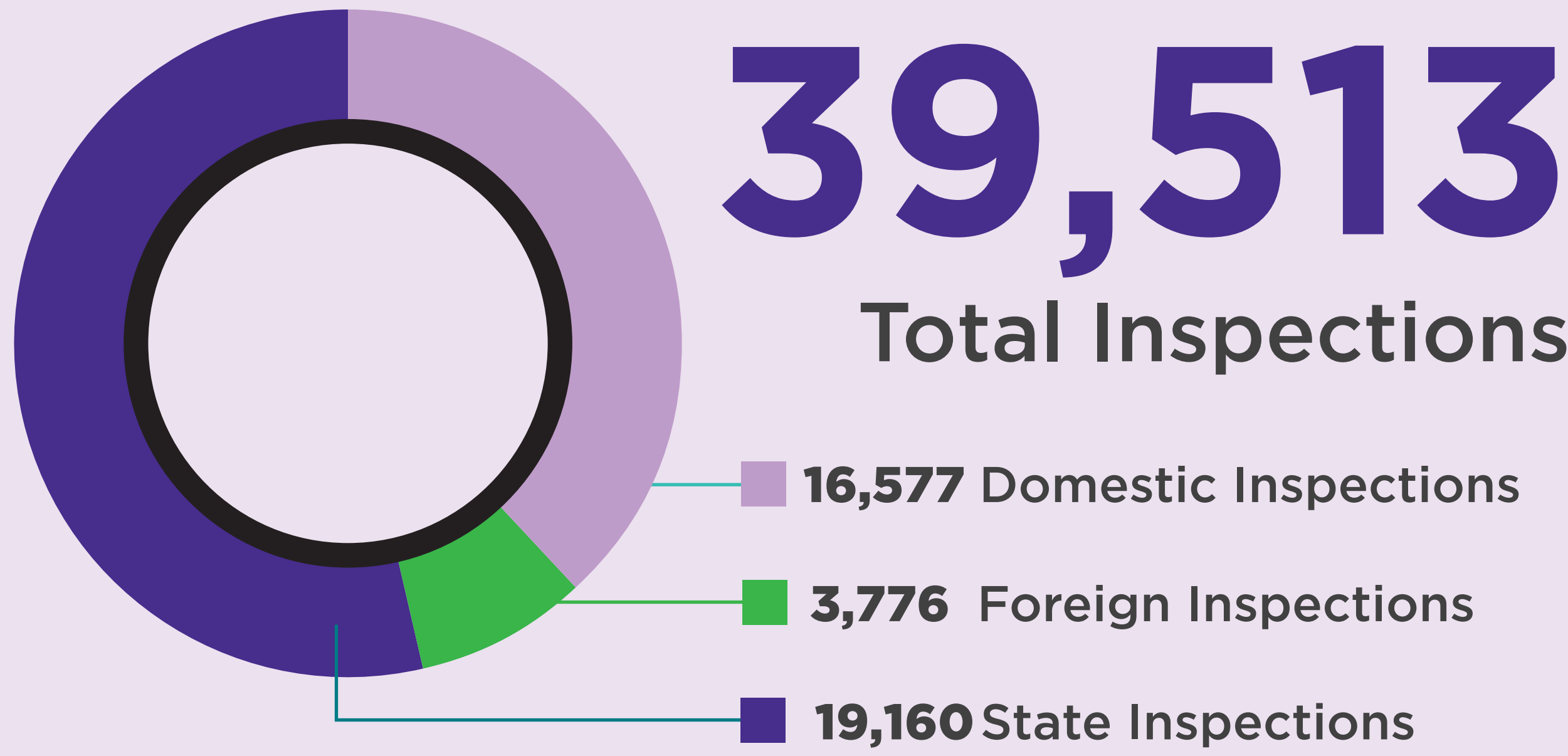
Inspections: ORA's Global Reach

ORA's Global Inspections:

| | | | |
|--------------------------|-------------------------|------------------|----------------------|
| Argentina | Estonia | Lithuania | Spain |
| Aruba | Finland | Malaysia | Sri Lanka |
| Australia | France | Malta | Sweden |
| Austria | Georgia | Marshall Islands | Switzerland |
| Belgium | Germany | Mexico | Taiwan |
| Belize | Greece | Netherlands | Thailand |
| Bolivia | Grenada | New Zealand | Trinidad & Tobago |
| Bosnia-Herzegovina | Guatemala | Nicaragua | Ukraine |
| Brazil | Hong Kong SAR | Norway | United Arab Emirates |
| Bulgaria | Hungary | Panama | United Kingdom |
| Canada | Iceland | Peru | United States |
| Cayman Islands | India | Philippines | Uruguay |
| Chile | Indonesia | Poland | Vietnam |
| China | Ireland | Portugal | |
| Colombia | Israel | Romania | |
| Costa Rica | Italy | Russia | |
| Croatia | Jamaica | Serbia | |
| Czech Republic | Japan | Singapore | |
| Denmark | Jordan | Slovakia | |
| Dominican Republic (the) | Korea (the Republic of) | Slovenia | |
| Ecuador | Latvia | South Africa | |



Inspections



45,002

Samples Collected & Analyzed

IMPORTS

A line is a distinct product within a shipment. A single shipment may include multiple lines.

40,018,795

Import Lines

Criminal Investigations

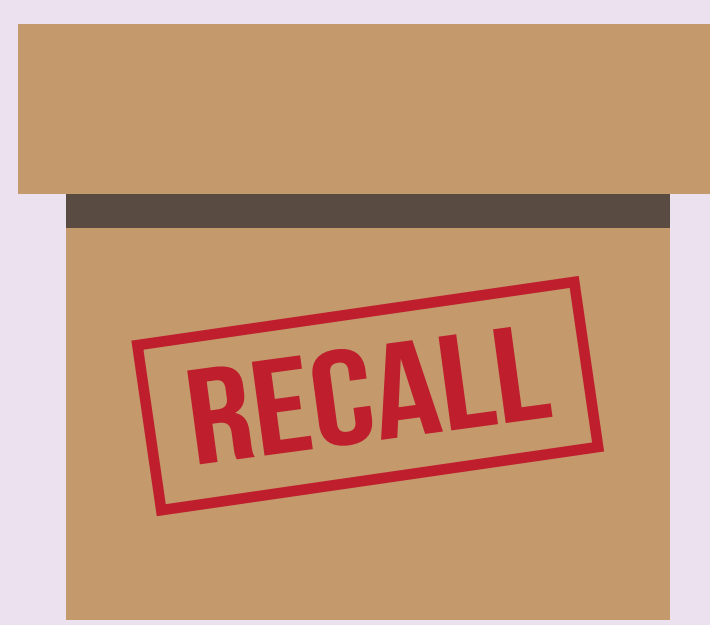
Enforcement



15,318

Warning Letters Issued

*Includes 14,875 warning letters issued by the Center for Tobacco Products



9,199

Recalled Products



12

Injunctions



3

Seizures



243

Import Alerts

Allow FDA to detain future shipments of potentially violative products without testing or examination



283

OCI Arrests



\$205,048,648

OCI Assets Forfeited and Seized



226

OCI Convictions



\$461,432,091

OCI Fines and Restitution