

Developing a Risk-based Conformity Assessment System

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Innovation inherently creates risk



Services for today's challenges



Conformity Assessment Defined

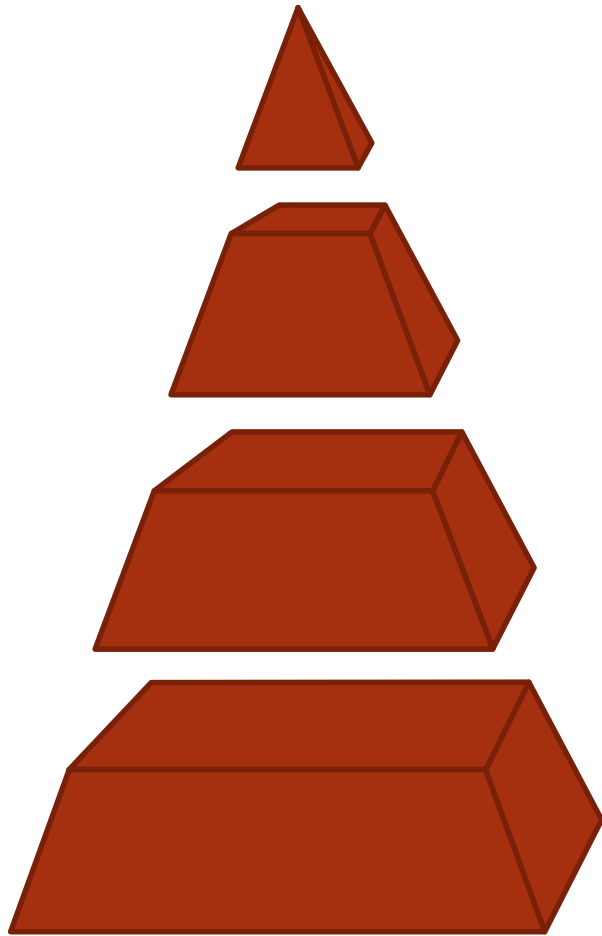
“demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”

- Includes activities such as:
 - Testing
 - Inspection
 - Certification

Source: ISO/IEC 17000



Key Elements of Compliance



Compliance Systems (Market Access)

Rules and Regulations that define a market

Conformity Assessment

Available paths which compliance can be verified
(design, production, documentation)

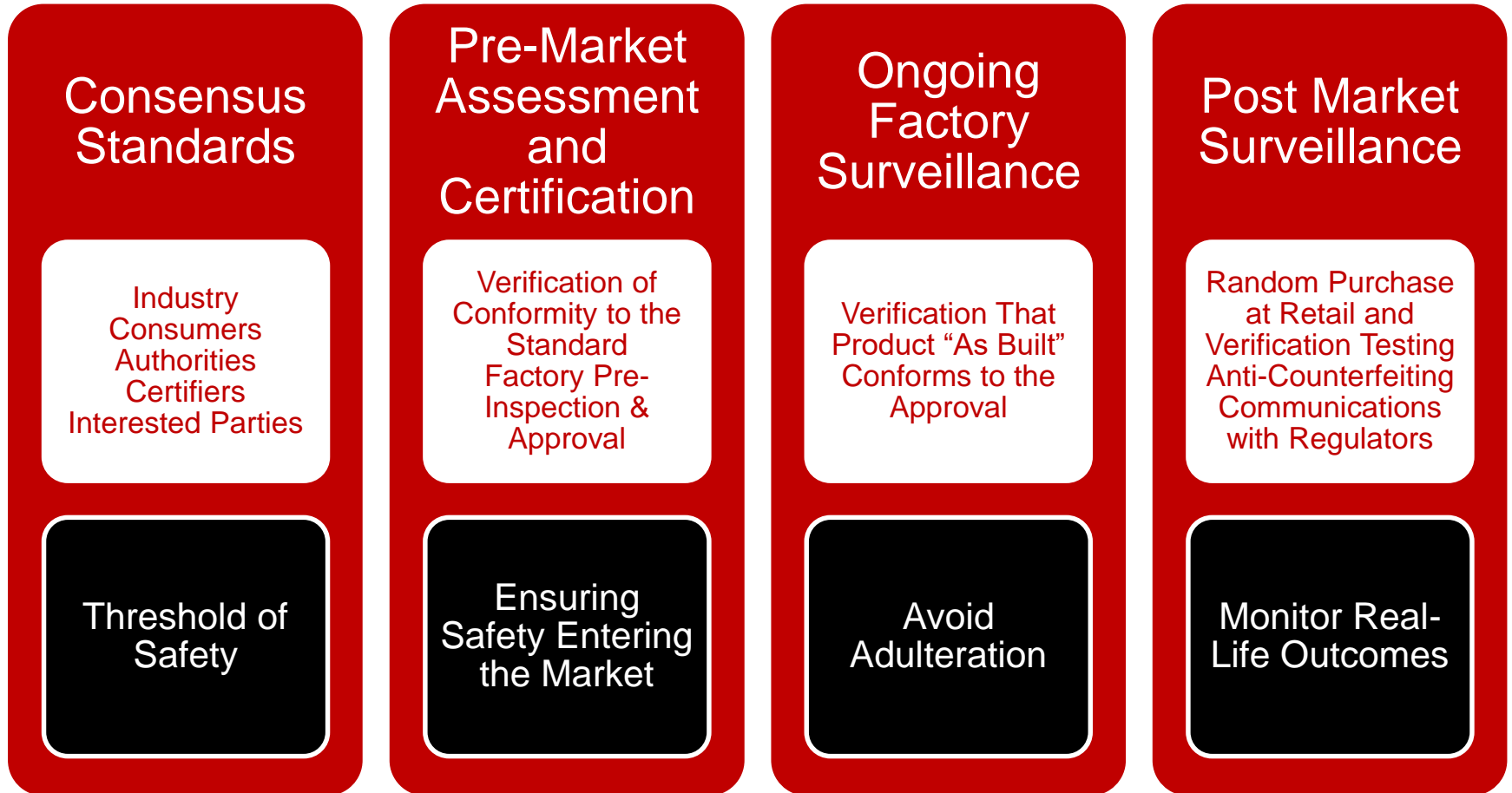
Technical Requirements / Standards

Minimum requirements used for evaluating compliance
(may be mandatory or voluntary)

Market Requirements (Market Acceptance)

Additional requirements to those of the compliance system
to establish confidence in the marketplace

A Balanced Approach to Conformity Assessment



Recipe for maintaining "Integrity & Trust" while balancing "Safety & Time-to-Market"



Table 1 — Building a product certification scheme

Conformity assessment functions and activities ^a within product certification schemes		Types of product certification schemes ^b							
		1a	1b	2	3	4	5	6	N ^{c,d}
I	Selection, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II	Determination of characteristics, as applicable, by: a) testing b) inspection c) design appraisal d) assessment of services or processes e) other determination activities, e.g. verification	x	x	x	x	x	x	x	x
III	Review Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	x
IV	Decision on certification Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V	Attestation, licensing								
	a) issuing a certificate of conformity or other statement of conformity (attestation)	x	x	x	x	x	x	x	x
	b) granting the right to use certificates or other statements of conformity	x	x	x	x	x	x	x	
	c) issuing a certificate of conformity for a batch of products		x						
	d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.		x	x	x	x	x	x	
VI	Surveillance, as applicable (see 5.3.4 to 5.3.8), by:								
	a) testing or inspection of samples from the open market			x		x	x		
	b) testing or inspection of samples from the factory				x	x	x		
	c) assessment of the production, the delivery of the service or the operation of the process				x	x	x	x	
	d) management system audits combined with random tests or inspections						x	x	

^a Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.

^b An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.

^c A product certification scheme includes at least the activities I, II, III, IV and V a).

^d The symbol N has been added to show an undefined number of possible other schemes, which can be based on different activities.



WTO Approach

Technical Barriers to Trade (TBT) Agreement references various mechanisms for demonstrating a product's compliance with requirements

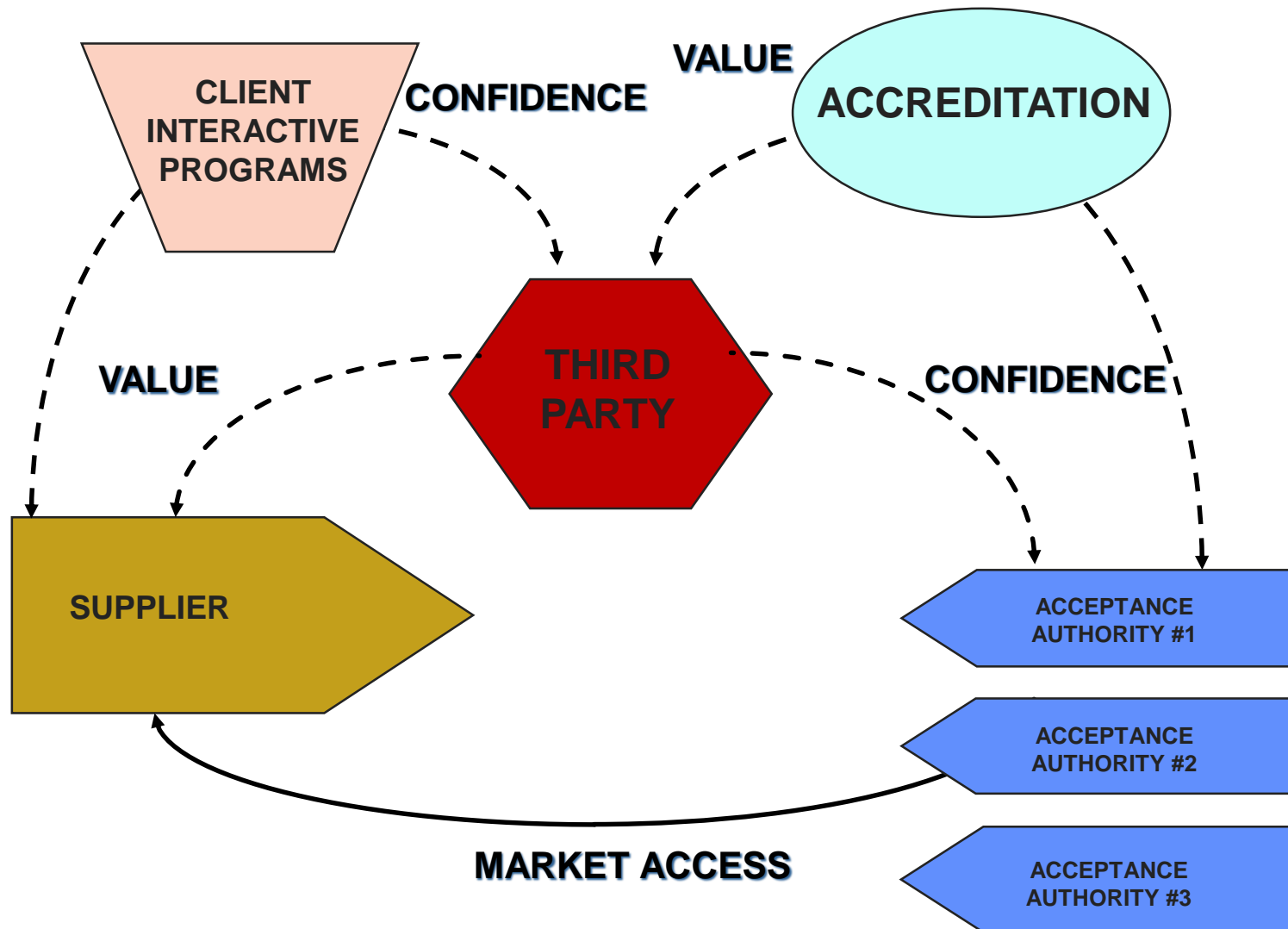
Third party Conformity Assessment and SDoC are listed as valid options, among others

Stipulates that governments have the right to choose the method of conformity that meets their confidence needs

Article 5 states that Members must ensure that conformity assessment measures do not create unnecessary barriers to trade



3rd Party Conformity Assessment Value Chain



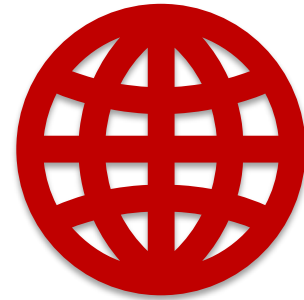
The NRTL Program and Benefits of Relying on Private Sector Organizations

OSHA's Nationally Recognized Testing Laboratory (NRTL) Program recognizes private sector organizations as NRTLs to determine that specific products meet consensus-based safety standards to provide the assurance that these products are safe for use in the US workplace.

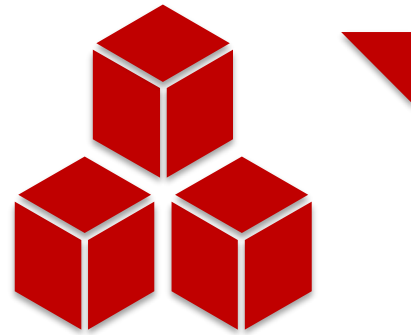
How does OSHA benefit from reliance on private sector NRTLs?

- Recognition Process that Preserves Confidence
- Reduces Government Costs
- Lessens OSHA's Market Surveillance Burdens
- Positively Affects the Development of Standards
- Promotes International Trade





MARKETS



PRODUCTS

IFIA Study: Purpose

Purpose: To gauge the effectiveness of ensuring safety of consumer products, comparing self declaration system and 3rd party testing and certifications



IFIA Study: Methodology

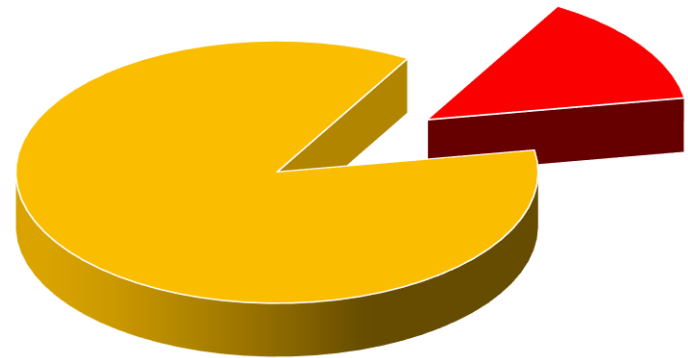
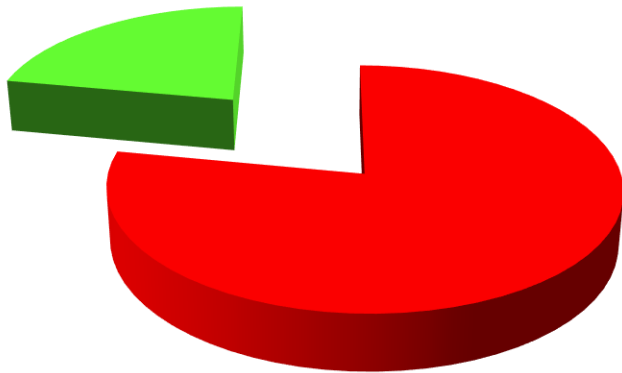
Purchase products from the market and send to an independent laboratory not affiliated with IFIA.

- Electric Fans
- Toasters
- Heating Devices
- Luminaires
- Chargers for IT products
- Room heaters
- Hair dryers
- Hair curlers, straighteners
- Irons
- Small power tools

IFIA Study: Results #1 – EU SDoC Products

Of the 319 samples submitted, **77%** were **NOT** in compliance with EU standards and regulations

Safety-critical failures were found in 1 out of every 7 products tested were of (i.e. high risk of fire, permanent injury, etc) which were reported to local authorities (**48 instances [15%]**)



IFIA Study: Results #2 – EU Certified Products

Of the 139 samples submitted, there was only **1 instance (0.7%)** of *safety-critical* failures, which was immediately reported to the certifier, and then to the manufacturer



IFIA Study: Results #3 – US & Canada Certified Products

Of the 185 samples submitted, there were **2 instances (1%)** of *safety-critical* failures, also immediately reported to the certifier, and then to the manufacturer



IFIA Study: Other EU Data

Online purchasing results (2015 survey) did not change in any significant manner from the past

Percentage of products actually inspected by market surveillance authorities = 0.3%

Percentage of domestic accidents due to faulty products that are reported by EU consumers = 1%

Rate of success for first-time product submittals: 50%

Percentage of periodic factory inspections that yield:

- Safety-critical issues: 10%
- Non-compliant findings: 15%

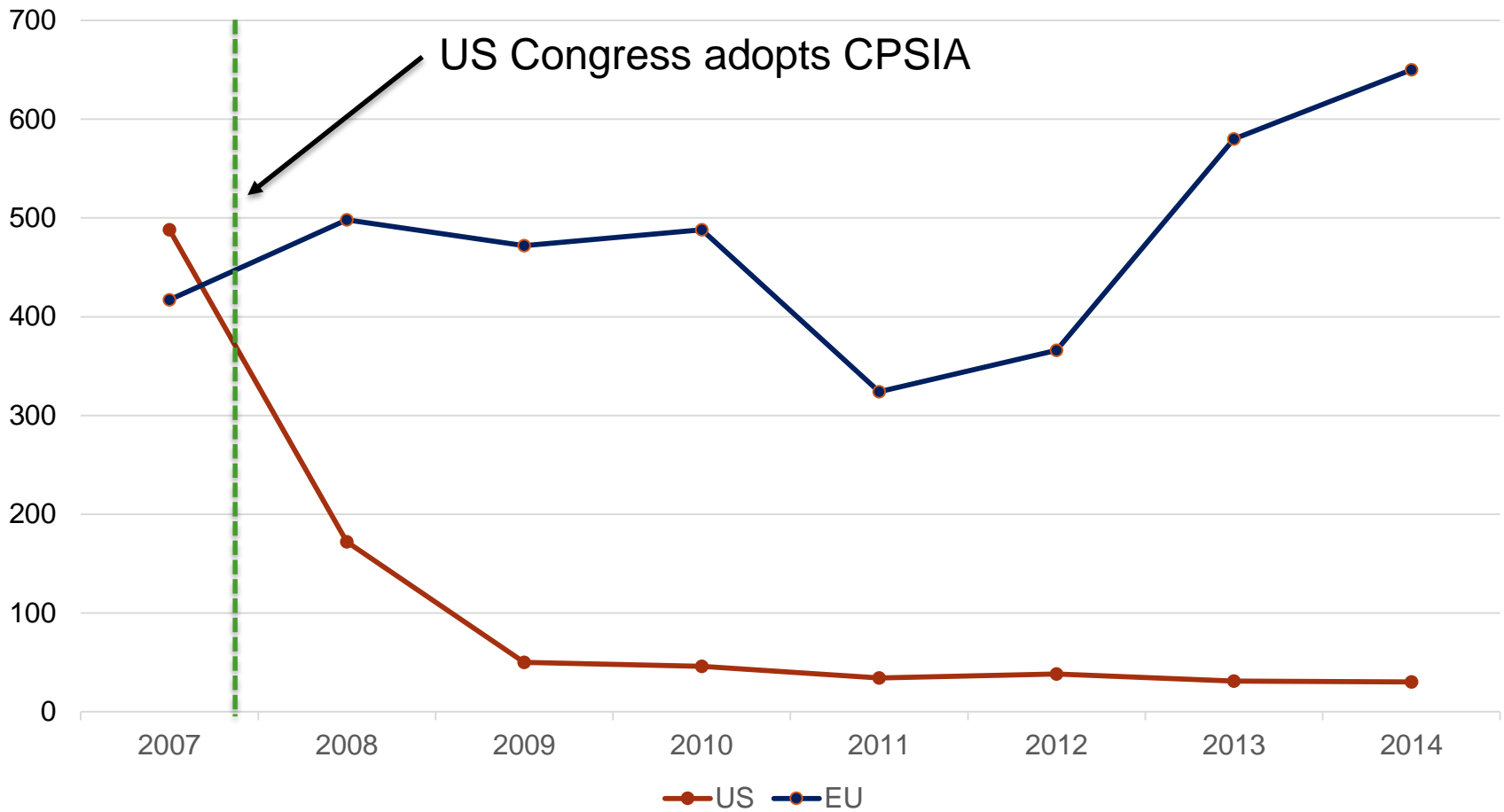
Other directives (R&TTE): 69% of products 2014 not in compliance. Drones (remotely piloted aircraft systems): 92% not in compliance

13% of tablet PCs pulled from Germany and Netherlands' markets in 2012 were 'in compliance'.

UK: 2011-2014 ~12,000 house fires were caused by faulty white good appliances. Recalls success < 20%.

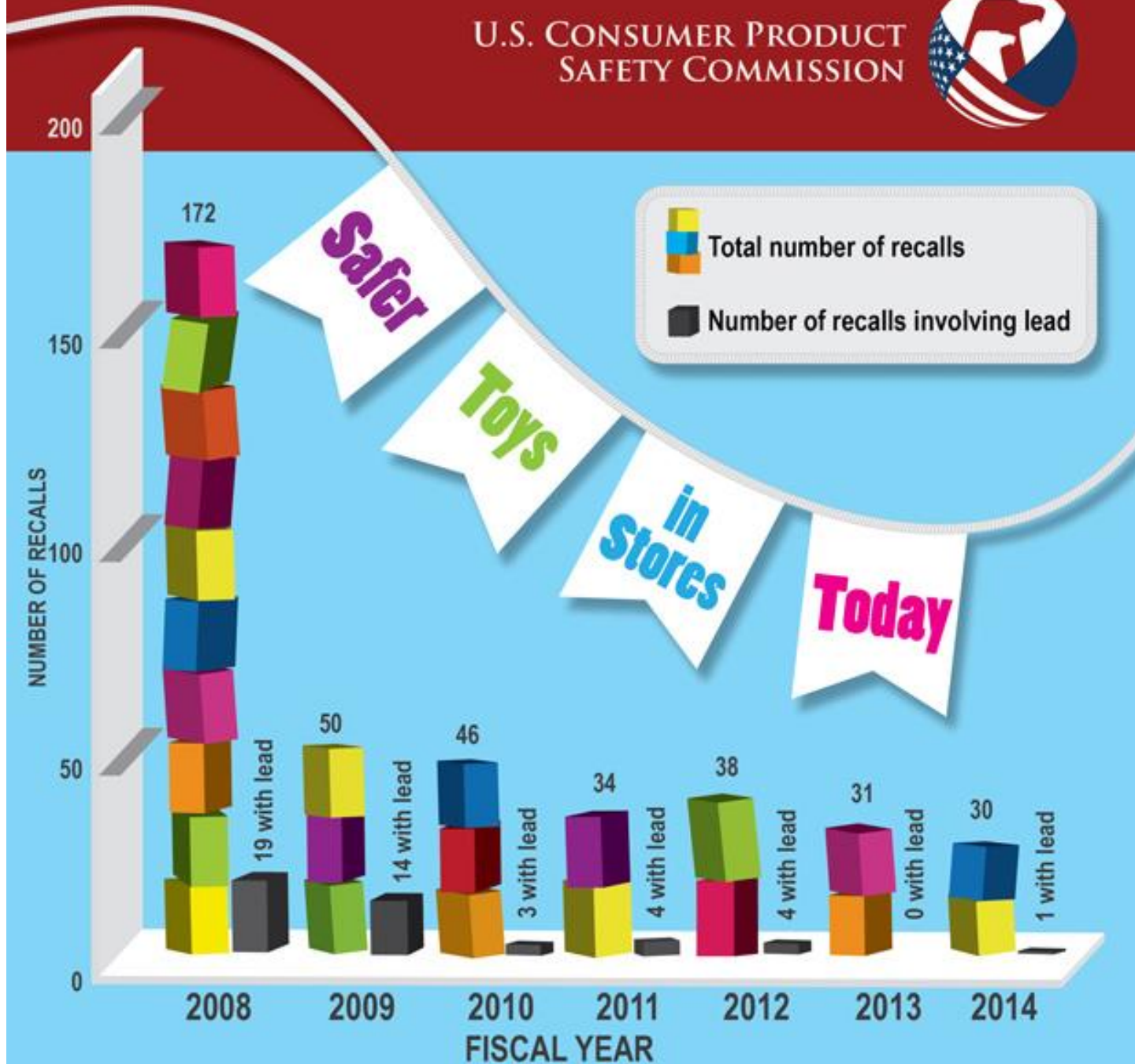


Toy recalls/notifications in the EU and US





Case Study: Impact of Third Party Testing on Toy Recalls in the US



Best Practices

- National Treatment
- Use of Independent Third Parties
- International Harmonization of Requirements
- Conformity Assessment Selection Based on Risk Level
- Public-Private Partnerships
- Private Sector, Consensus Based Standards
- Intellectual Property Protections
- Standards & Conformity Assessment in Government Procurement
- Science Based Risk Assessment

Asante Sana!



Transportable Conformity AssessmentSM

Case: Flow of a CB Test Report (CBTR)/CB Test Certificate (CBTC)

