THE INDEPENDENT VOICE OF TRUST

Modernização do Modelo Regulatório do Inmetro – O Modelo Americano

22 Outubro 2020

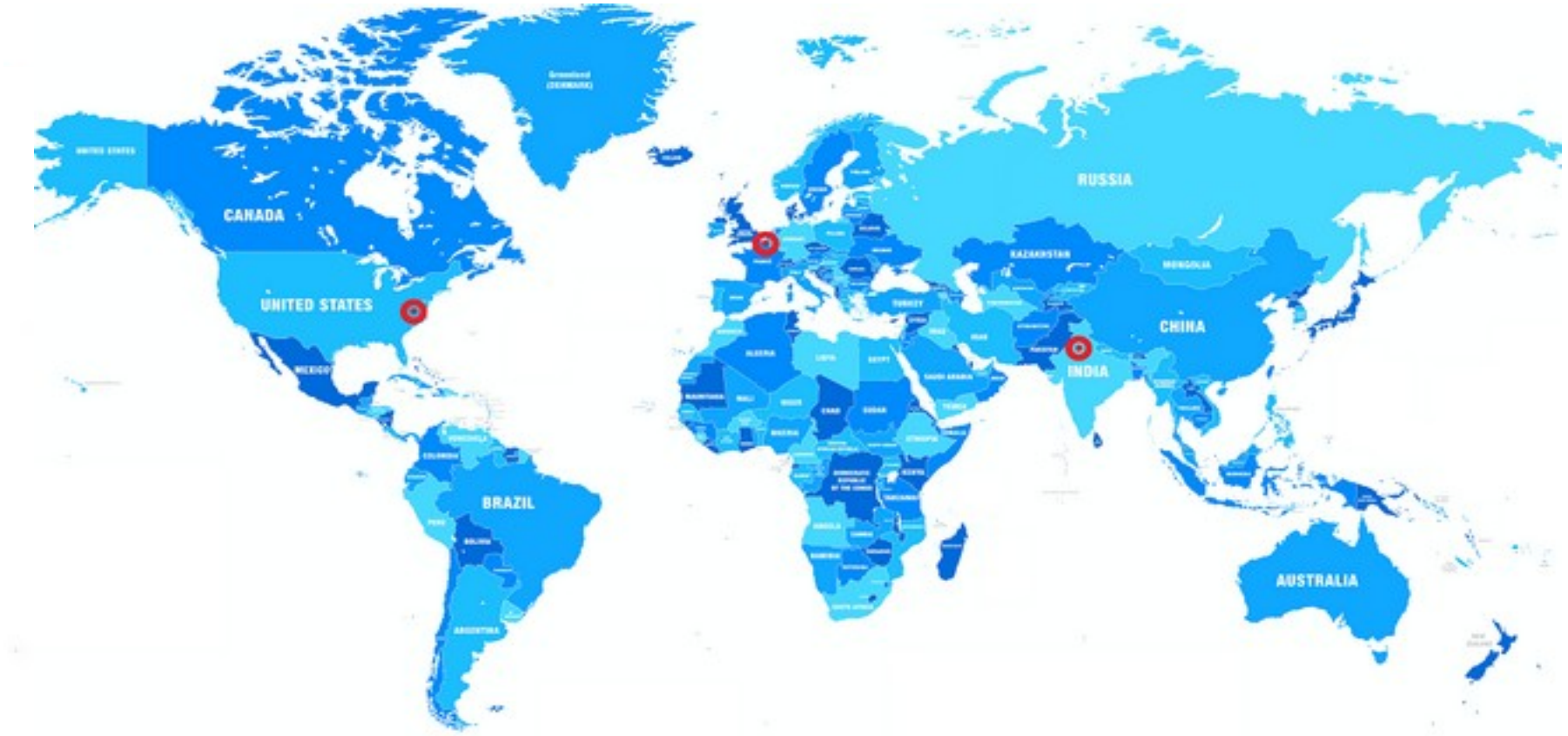
Agenda

- TIC Council
- Modelo regulatório dos EUA
- Avaliação da conformidade nos EUA
- Dados e estudos sobre diferentes modelos de avaliação da conformidade

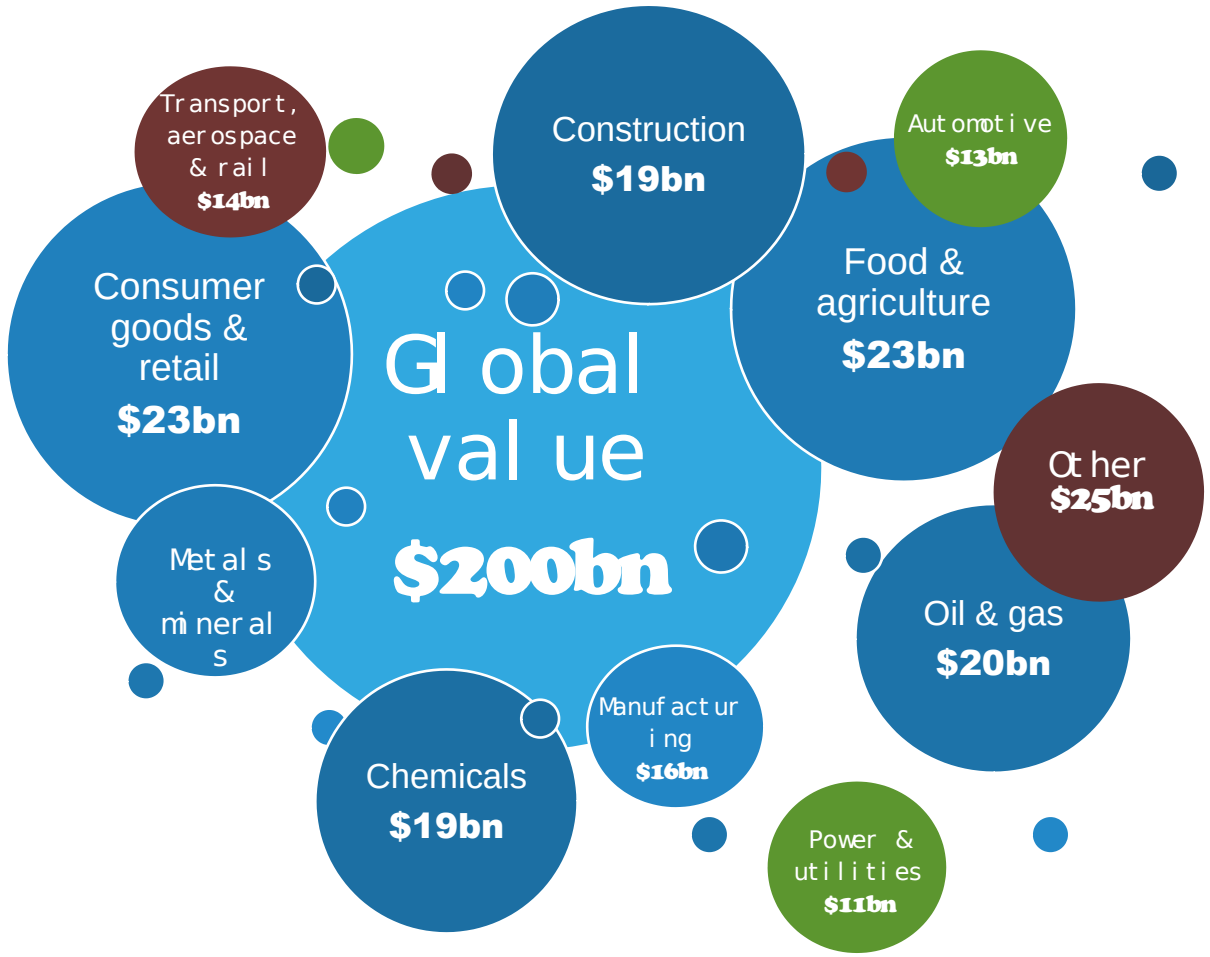
TIC Council

The Independent Voice of Trust

- Organização sem fins lucrativos
- ~90 associados em mais de 160 países
- Matriz em Bruxelas e presença nos Estados Unidos, Índia e em breve na China

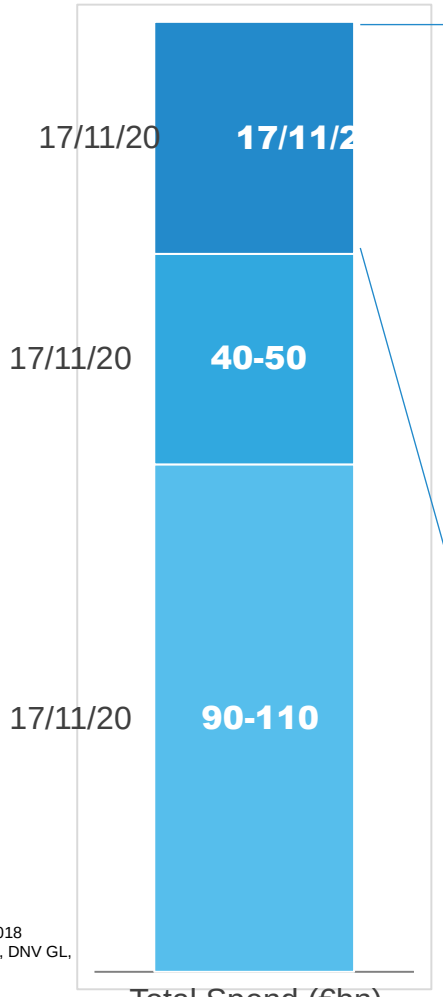


Mercado TIC - Testing Inspection & Certification

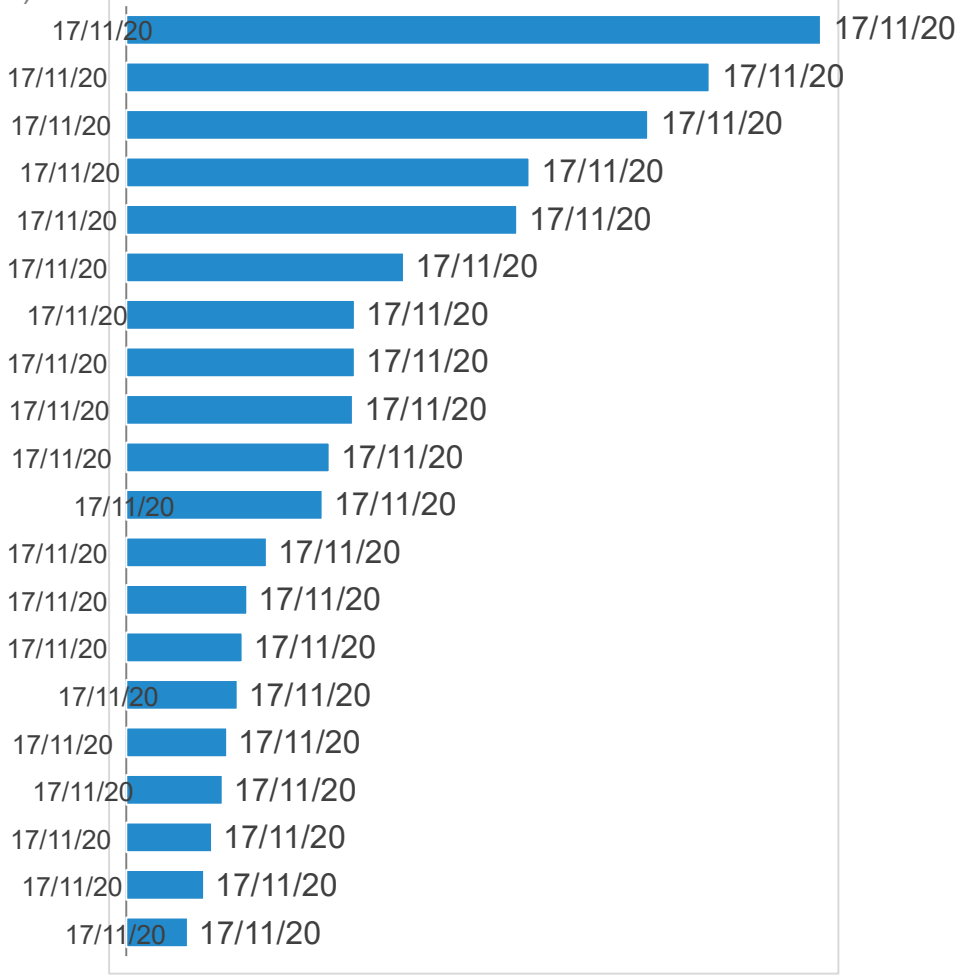


Source: Bureau Veritas (2020). "Other" includes Public authorities, Marine, Health, Banking & insurance, and Process (which may include TIC services applied to the conformity assessment of end-users' internal processes).

Mercado TIC - Testing Inspection & Certification



"Top 20" TIC Company Revenue[1], Latest Available Year
(€bn)



1. 2019 revenue shown for all, other than the following, where 2018 revenue figures are shown: TUV Sud, Synlab, TUV Rheinland, DNV GL, TUV Nord, Apave

Source: OC&C "TIC 101" database and analysis, May 2020

Atividades de Avaliação da Conformidade

Certificação:

Inclui inspeções, ensaios e auditorias periódicas pela certificadora após a entrada do produto no mercado

- ✓ Cumprimento com normas
- ✓ Melhoria da qualidade, segurança e desempenho
- ✓ Mitigação de riscos regulatórios
- ✓ Acesso a mercados globais
- ✓ Proteção da reputação
- ✓ Redução de custos para

6

Modelo Regulatório dos EUA

1. Sistema descentralizado e complexo

2. Agências reguladoras: algumas fazem parte do Executivo outras são independentes e supervisionadas pelo Congresso

3. OMB/OIRA – supervisão

4. Boas Praticas Regulatórias:

- ✓ Transparência
- ✓ Participação da sociedade
- ✓ Baseada em riscos
- ✓ Avaliação de impacto
- ✓ Dados e ciência
- ✓ Revisão retrospectiva
- ✓ Supervisão
- ✓ Cooperação internacional

The Reg Map® Informal Rulemaking

ICF staff are experts in drafting rulemaking documents and preparing supporting analyses | Visit us at icf.com/regsupport. Also check out icf.com/commentworks for a faster, cheaper, and better way to respond to public comments on proposed rules. To request a copy of the Reg Map, please email us at RegMap@icf.com

ICF

What is the Reg Map?
This Reg Map is a primer on the federal government agency "informal" rulemaking process. The Reg Map reflects general requirements that apply to most federal agency rulemakings. In rare cases, the APA requires trial-type, or "formal," procedures to develop a rule. Other statutes that apply to a specific agency, program, or subject may impose or permit different procedural steps (e.g., mandating negotiated rulemaking to develop a proposed rule).

Must all rulemakings follow all Reg Map steps?
In a typical case, a rulemaking action would proceed from Step 1 to Step 9, including OMB review at the proposed and final stages for certain kinds of significant regulatory actions, per E.O. 12866. As the Reg Map shows, however, Congress has exempted some rulemaking actions from APA notice requirements. In addition, when stakeholders have challenged regulatory actions, courts have interpreted APA requirements over time, influencing how agencies carry out "informal" rulemaking procedures at a practical level, some of which is explained in the Reg Map.

Are the requirements described in the Reg Map applicable to all federal agencies?
Some of the procedures described in the Reg Map, such as OMB review, only apply to executive agencies (i.e., Cabinet departments and independent agencies that answer directly to the President), while others, such as APA public notice-and-comment requirements and the PRA, also apply to independent regulatory agencies (i.e., boards and commissions listed in 44 U.S.C. 3502(5)). Following APA requirements and other applicable authorities that affect the rulemaking process is the best way for all agencies to develop final rules that will meet regulatory objectives and survive judicial review.

Step 1

Consider Initiating Events

- **Laws enacted by Congress**
- **Court decisions**
- **Agency initiatives from various sources, including:**
  - Agency plans and priorities
  - New data, technologies, or research
  - Patterns of accidents or violations
  - Public comments on RFIs
  - Retrospective analyses of existing regulations
  - Recommendations from the President, OMB, other agencies, congressional committees, federal advisory committees, states, or external groups
  - Changes in the regulated community
  - Petitions for rulemaking, including petitions for reconsideration

See www.regulations.gov and www.reginfo.gov for intended regulatory and deregulatory actions and for other resources.

Revising or Rescinding an Existing Rule

Agencies seeking to modify or repeal a rule must follow the same informal rulemaking process requirements as they would for promulgating a new rule. See APA sec. 551(5) (5 U.S.C. 551(5)).

Reducing Regulatory Burden

Several administrations have undertaken efforts to reduce regulatory burdens by identifying and eliminating regulations that no longer serve their intended purposes or impose costs that cannot be justified. As reducing regulatory burden is an evolving topic, those interested should monitor the FAQs/Related Resources page of OMB's website, as additional executive directives on this subject are likely in the future.

Step 2

Decide Whether Public Notice Is Needed

Unless other exemptions apply, APA sec. 553 requires public notice and comment to propose a rule or a showing of "good cause"—an agency demonstration that notice and comment are "impracticable, unnecessary, or contrary to the public interest" (omit Steps 3 through 6). Generally, this exemption applies only to cases where: the rule is a minor determination in which the public is not interested or that involves little to no agency discretion; advance notice would defeat the regulatory objective; immediate action is necessary to reduce imminent harm to people or property; or Congress implicitly waives notice-and-comment requirements.

"Good cause" options:
- Emergency rules
- Interim final rules (omit Steps 3 through 6 but provide comment period and final rule after Step 9)
- Rules that codify statutory language where agency has no discretion to change the provision
- Direct final rules (streamlined process for non-controversial rules; must be withdrawn if opposed)
- Technical corrections

Other exemptions include interpretive rules; general policy statements; agency rules of procedure, organization, or practice; rules involving a military or foreign-affairs function of the United States; or matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts (omit Steps 3 through 6).

If no exemptions apply,
options for notice and comment include:
- NPRM (proposes specific provisions with rationale and seeks comment)
- ANPRM (seeks comments and data to help develop a proposed rule)

Step 3

Develop a Proposed Rule

An NPRM proposes to add, revise, remove, or re-designate CFR provisions, and it must consist of a description or statement of the proposed regulatory text and a preamble to inform a non-expert reader of the proposal's basis and purpose. See 1 CFR 18.12.

The NPRM must explain:
- Legal basis: The statutory authority to issue rules for the regulated entities and the subject area
- Proposed provisions: A presentation of the proposed rule text or a description of the issues
- Rationale for each proposed provision: An explanation of why a rule is needed; what it would accomplish; and what data, research, analyses, and assumptions were used to develop the rule

Rule preamble should discuss:
- Regulatory background and history
- Alternatives the agency is considering
- Analyses describing compliance with applicable statutes or executive orders

Analyses begun in Step 3 must be finalized in Step 7.

What Is Negotiated Rulemaking?

A negotiated rulemaking allows agency staff and stakeholders, or interested and affected parties, to develop a proposed rule together, facilitated by a mediator. See 5 U.S.C. 561-570.

Step 4

Send Proposed Rule to OMB for Review

OMB will review any rule an agency or ORIA considers "significant" under E.O. 12866. See E.O. 12866 sec. 6. (ORIA is the OMB office responsible for coordinating executive branch review of agency rulemaking documents and reviewing agency ICRs under the PRA.)
- 10-day OMB review for agency's preliminary "significant" determination
- 90-day OMB review for rule, assessments, and analyses (120 days if director of OMB grants extension)
- ORIA may waive review
- Agency head may request extension

An agency must submit with the rule an RIA (i.e., cost-benefit assessment) for any significant regulatory action.

Interagency review coordination: OMB may circulate an NPRM to other agencies interested in the content.

OMB will invite the issuing agency to meetings requested by the public to discuss regulatory actions under review per E.O. 12866 sec. 6(b)(4).

E.O. 12866 does not subject independent regulatory agencies to OMB rule review requirements.

See www.reginfo.gov/public to keep up with OMB review actions and for other resources.

Step 5

Publish the NPRM

An agency must publish "either the terms or substance of the proposed rule or a description of the subjects and issues involved" in the Federal Register, the official daily publication for federal agency actions. See APA sec. 553(b).

The NPRM also must include:
- Statement of the time, place, and nature of public rulemaking proceedings
- Reference to the legal authority under which the rule is proposed
- Regulation Identifier Number

See www.federalregister.gov for the daily Federal Register and for other resources.

What Is Incorporation by Reference?

With the approval of the Director of the Federal Register, an agency may incorporate material into rules by simply referencing it. Such material must be:
- Published
- Reasonably available to and usable by affected individuals
- Not produced by the agency

Congress authorized this process to reduce the volume of language published in the Federal Register and CFR. The legal effect is that the referenced material is treated as if it were newly published in the Federal Register.

Step 6

Analyze Public Comments

An agency must give the public a meaningful opportunity to submit written comments, in paper or electronic form, and it must consider all "relevant matter presented." See APA sec. 553(c). E.O. 12866 recommends a comment period of at least 60 days.

The E-Government Act of 2002 requires agencies to provide for electronic filing of public comments and make dockets available online (Pub. L. 107-347 sec. 206(d)). See www.regulations.gov, the online portal for submitting public comments.

Courts have interpreted the APA requirements noted above to mean that **agencies must provide responses to significant issues raised in the comments.** Significant issues are relevant points that, if adopted, would require a change to the agency's proposed rule.

Step 7

Develop a Final Rule

A final rule presents the CFR provisions adopted and must incorporate into the preamble a concise general statement of the basis and purpose for the agency decision. See APA sec. 553(c). **final rule choices must not be "arbitrary and capricious" (i.e., fail to provide a rational basis for the decision).** See 5 U.S.C. 706.

A final rule must be within the scope and a "logical outgrowth" of the proposed rule. A final rule can be substantially different from the NPRM so long as the agency provided adequate notice to the public of the possibility for changes of the type that were adopted.

Final rule documents:
- Explain the provisions adopted and the reasons for the agency's decisions, including a discussion of changes from the NPRM
- Discuss and respond to significant public comments
- Update and finalize analyses begun in Step 3
- Set an effective date and any applicable compliance date (see Step 9)

Step 8

Send Final Rule to OMB for Review

OMB will review any rule deemed "significant" under E.O. 12866. Agencies must ensure that a rulemaking schedule accounts for at least a 90-day OMB review period for significant rules. ORIA may permit a shorter period of review in exigent circumstances. **The agency must revise the regulatory package to address OMB concerns and respond to any interagency review comments.** E.O. 12866 also includes requirements relating to ORIA communications with individuals outside the executive branch about the substance of a regulatory action under review. After publication of the regulatory action in the Federal Register, an agency must identify for the public the substantive changes between the draft submitted to ORIA for review and the action subsequently announced plus the changes it made at OMB's recommendation or suggestion (E.O. 12866 sec. 6(a)(3)(E)).

Step 9

Publish Final Rule

Effective date: The APA specifies that agency rules generally may not take effect until at least 30 days after publication in the Federal Register, except for a substantive rule that grants an exemption or relieves a restriction or for other "good cause." See APA sec. 553(d). Agencies can set a more delayed effective date (date on which regulatory changes are implemented in CFR) for some or all rule provisions and can set an even more delayed compliance date (date by which regulated persons must comply) for some or all of the rule requirements.

Congressional Review Act (5 U.S.C. ch. 8): Under the CRA, before most final rules can take effect, an agency must submit them and supporting information to the House, the Senate, and the GAO. Rules defined as "major" under the CRA may not take effect for at least 60 days (30 days for non-major rules), with exceptions in some cases.

Bases for legal challenges include claims that the agency:
- Had no statutory authority to issue the rule
- Failed to address statutory criteria for issuing rules or considered factors not allowed by the statute
- Provided inadequate notice (e.g., final rule not a "logical outgrowth" of the proposal, no NPRM with inadequate "good cause")
- Failed to consider public comments
- Reached an "arbitrary and capricious" decision (i.e., provided no rational basis for the action) (see 5 U.S.C. 706)

See www.ecfr.gov for the latest unofficial version of the CFR.

Regulations with Legal Effect Must Be Published in CFR

The Federal Register Act at 44 U.S.C. 1510 (implemented at 1 CFR 8.1) requires regulations that have general applicability and legal effect to be published in the CFR.

Specific Analyses for Steps 3 and 7

Most Frequent Analyses

E.O. 12866 and E.O. 13563, Regulatory Review

RIA required for "significant regulatory actions," which include those that would:
- Have a $100 million or more annual effect on the economy (in current dollars)
- Raise novel legal or policy issues
- Have other significant impacts

If the annual effect is $100 million or more, the rule is "economically significant" and requires:
- Cost-benefit analysis of policy alternatives
- Quantified and monetized costs and benefits

If a rule is significant but the annual effect is less than $100 million, an agency must analyze costs and benefits of the selected approach. ORIA may also require assessment of policy alternatives.

Regulatory Flexibility Act (5 U.S.C. ch. 6)

Applies to rules that may have a "significant economic impact on a substantial number of small entities" (SISNOSE), if APA or other statutory notice and comment is required.

An agency must analyze small-entity impacts and mitigate them if possible.
- If there is a SISNOSE, an agency must estimate the number of small entities affected and the potential effects on them and consider alternatives to reduce the impacts.
- If there is no SISNOSE, the agency may certify as such and provide the basis for the certification – this certification is subject to judicial review.

Paperwork Reduction Act

Applies to any agency "collection of information" imposed on 10 or more people and requires submitting an ICR to OMB for approval, which must detail the need for, use, burdens (time and costs), and methodology of the information collection. An RIA must reflect any changing information collection burdens in the rule.
- A collection of information occurs when an agency requires recordkeeping or obtains, solicits, or requires the disclosure to third parties of information, regardless of form or format (e.g., reporting requirements, application forms, surveys)
- Public meetings and Federal Register solicitations for public comment are not collections of information under the PRA (see 5 CFR 1320.3(h))
- The PRA applies broadly and is not limited to information collections in regulatory provisions – non-rule collections of information also must receive approval
- At least every 3 years, an agency must update, and OMB must approve, any collection of information

Less Frequent Analyses

National Environmental Policy Act (42 U.S.C. 4321-4347)

E.O. 13132, Federalism

Impact statement required if the rule has

Frequently Asked Questions

How Should Agencies Draft Rulemaking Documents?

E.O. 12866 (Regulatory Planning and Review), E.O. 12988 (Civil Justice Reform), and the Presidential Memorandum on Plain Language (63 FR 31885) all direct agencies to use plain language in drafting rulemaking documents. Rulemaking documents also must conform to publication requirements in the CFR regulations (1 CFR chs. I and II). The OFR provides additional drafting guidance in its Document Drafting Handbook.

What Rules Are Agencies Planning to Issue?

A Unified Agenda (formally the Unified Agenda of Federal Regulatory and Deregulatory Actions) is published in the Federal Register in the spring and fall of each year, as required by E.O. 12866. The Unified Agenda provides information concerning agency rules under development and review, including the Regulatory Plan (showing the most important significant regulatory actions agencies plan to take – fall only) and the Regulatory Flexibility Agenda (describing actions likely to result in SISNOSE – spring and fall). The most recent Unified Agenda can be accessed on www.reginfo.gov. The E.O. 12866 requirements to list regulatory actions in the Unified Agenda apply to independent agencies as well as executive agencies.

What Is in a Rulemaking Record?

What Is the Difference Between a Rule and a

Frequently Used Rulemaking Terms and Abbreviations

ANPRM	Advance Notice of Proposed Rulemaking
APA	Administrative Procedure Act
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CRA	Congressional Review Act
DDH	Document Drafting Handbook
E.O.	Executive Order
FDMS	Federal Docket Management System
FOIA	Freedom of Information Act
FR	Federal Register
GAO	Government Accountability Office
IBR	Incorporation by Reference
ICR	Information Collection Request
IFR	Interim Final Rule

Modelo Regulatório dos EUA *(cont.)*

- Órgãos reguladores devem utilizar, sempre que possível:
  - Normas internacionais voluntárias
  - Avaliação da conformidade (AC) do setor privado
  - Esquemas internacionais de AC

NIST provê diretrizes, treinamento e apoio técnico aos órgãos reguladores no desenvolvimento de programas de AC

Avaliação da Conformidade nos EUA

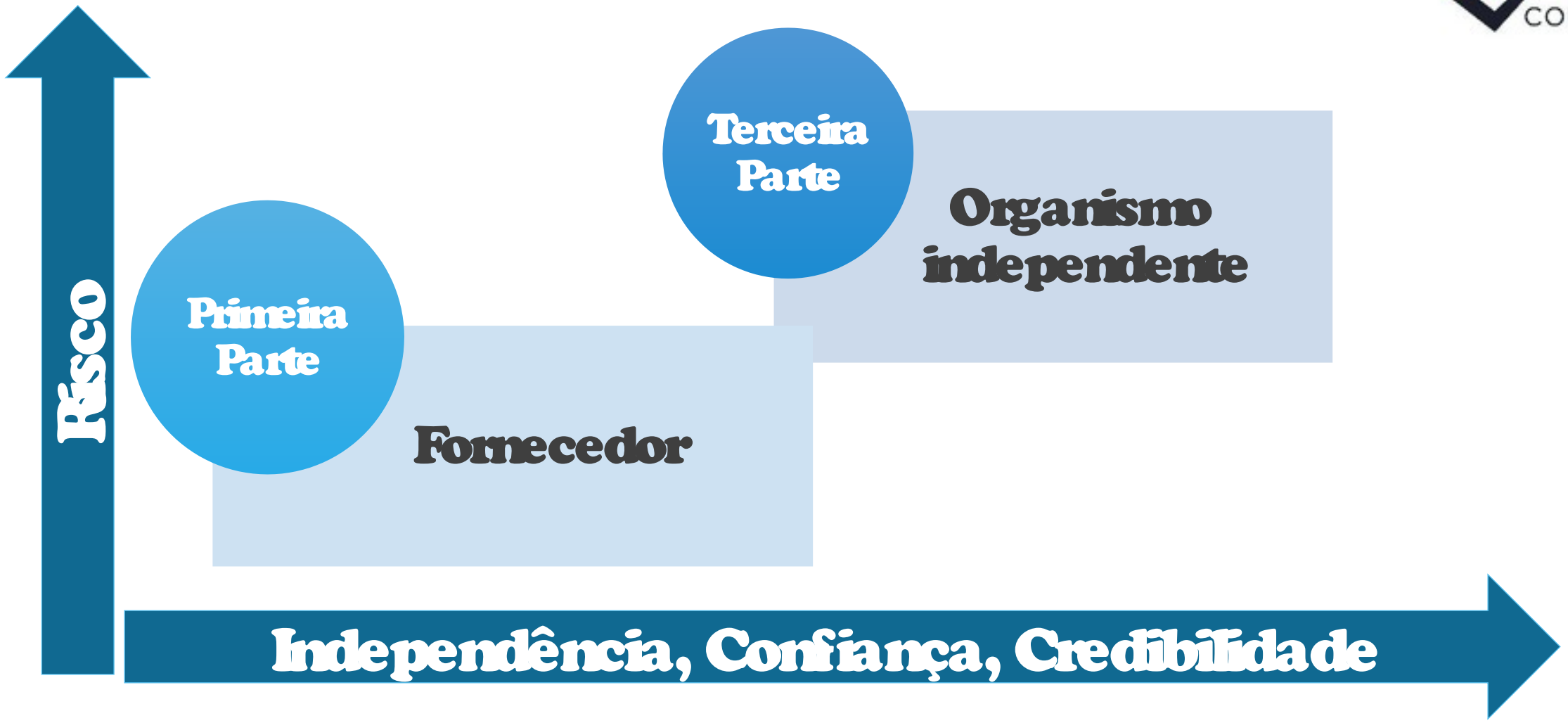
Programas Regulatórios Compulsórios

Programas Governamentais Voluntários

Programas do Setor Privado

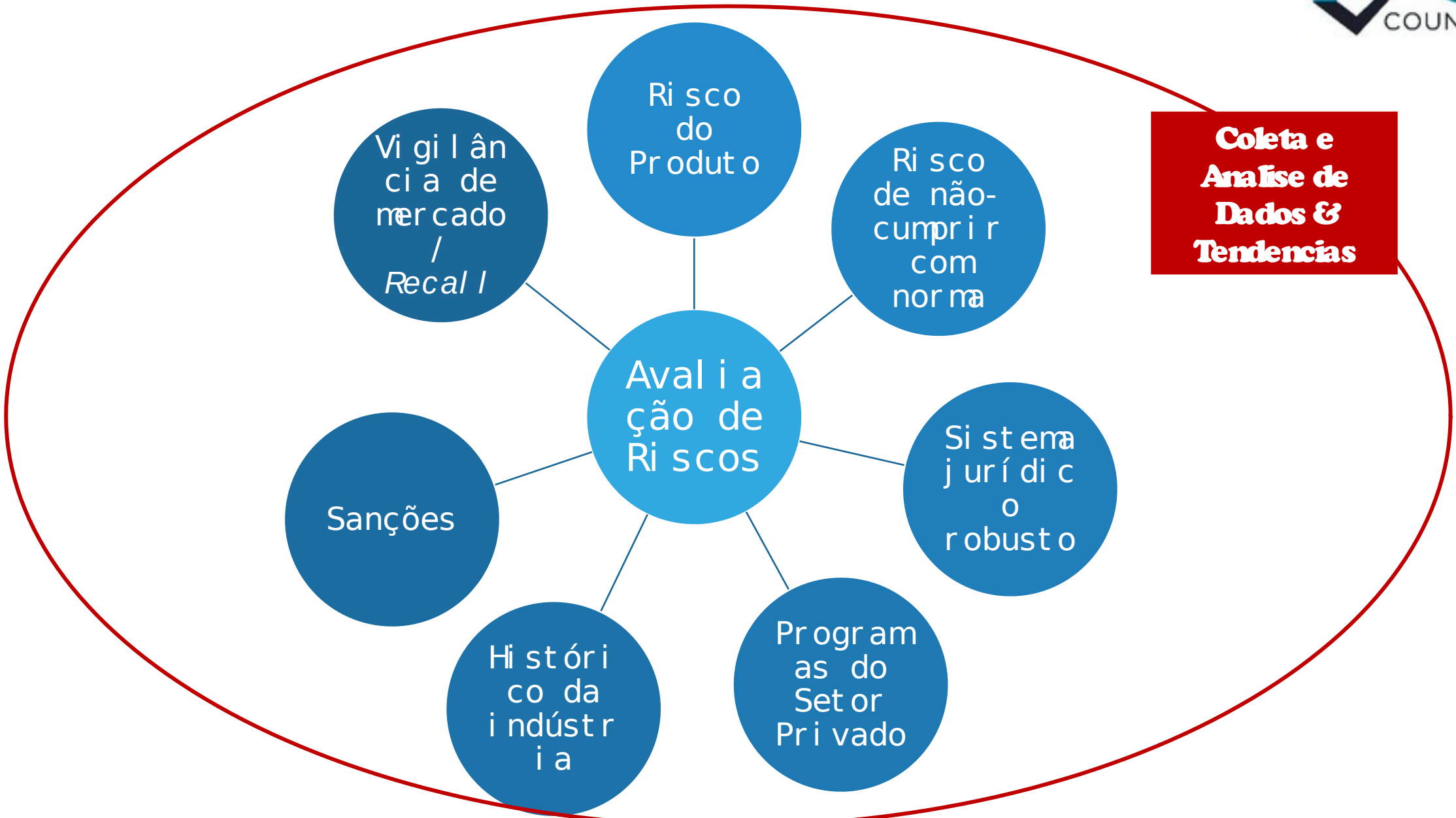
Governo intervém apenas quando o mercado não funciona

Avaliação da Conformidade nos EUA



Avaliação de Riscos -> Nível de

Avaliação da Conformidade nos EUA



Exemplos de Agencias Reguladoras

U.S. Consumer Product Safety Commission (CPSC)

Regulamenta a segurança de produtos de consumo

Agencia regulador a independente

Orçamento de ~ US$132 milhões

Uso de normas voluntarias sempre que possível

CPSC: Responsabilização

Responsabilidade de Cumprir com Regulamentações Técnicas e Normas Voluntárias

Todos igualmente responsáveis

Fabricantes

Importadores

Distribuidores

Varejistas

CPSC: Responsabilização *(cont.)*

Obrigatório reportar a CPSC imediatamente produtos que possam gerar riscos de ferimento grave ou morte entre outros requisitos...

Falha em reportar pode levar a multas e penalidades civil e criminal

CPSC: Prevenção de Acidentes e Mortes

Regulamentos

Normas voluntárias

Vigilância pós-mercado

Recall e sanções civil e criminal

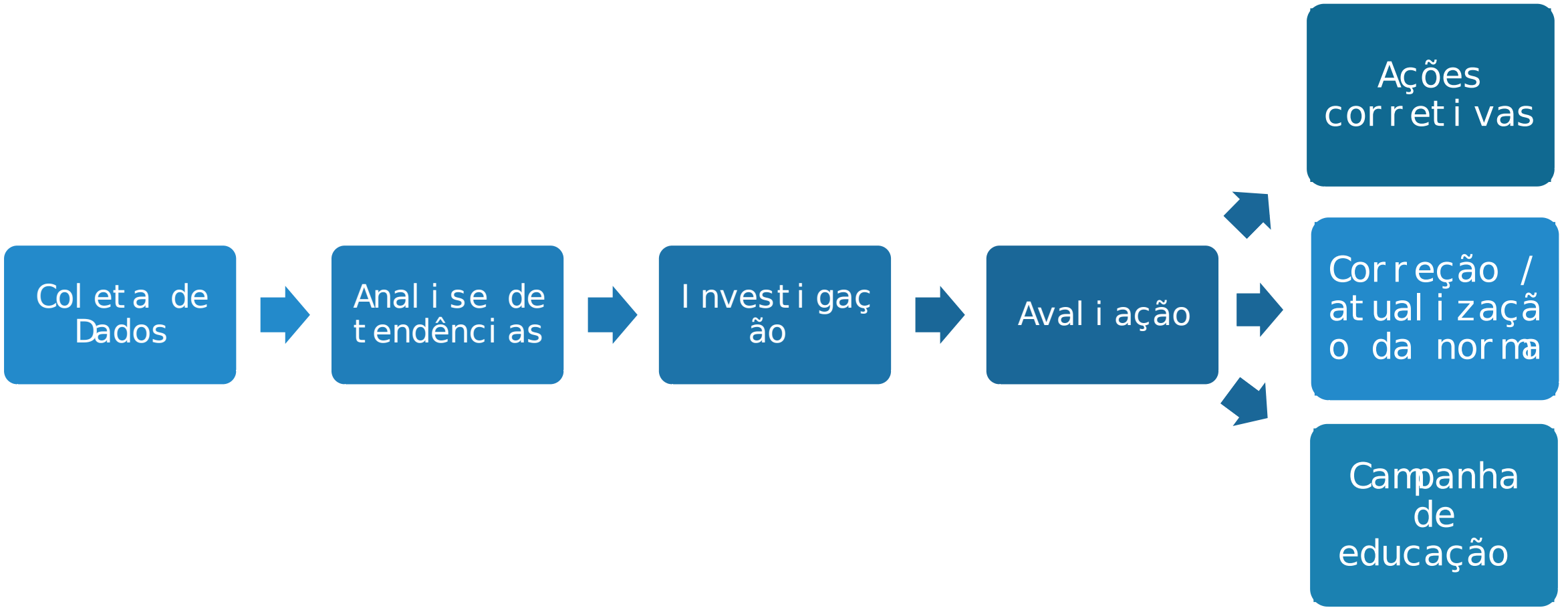
AC de terceira-parte para produtos infantis

Educa consumidores e indústria

Coleta de dados

Analise & monitoramento tendências

CPSC: Coleta e Analises de Dados



Sistema Jurídico e Segurança de Produtos nos EUA

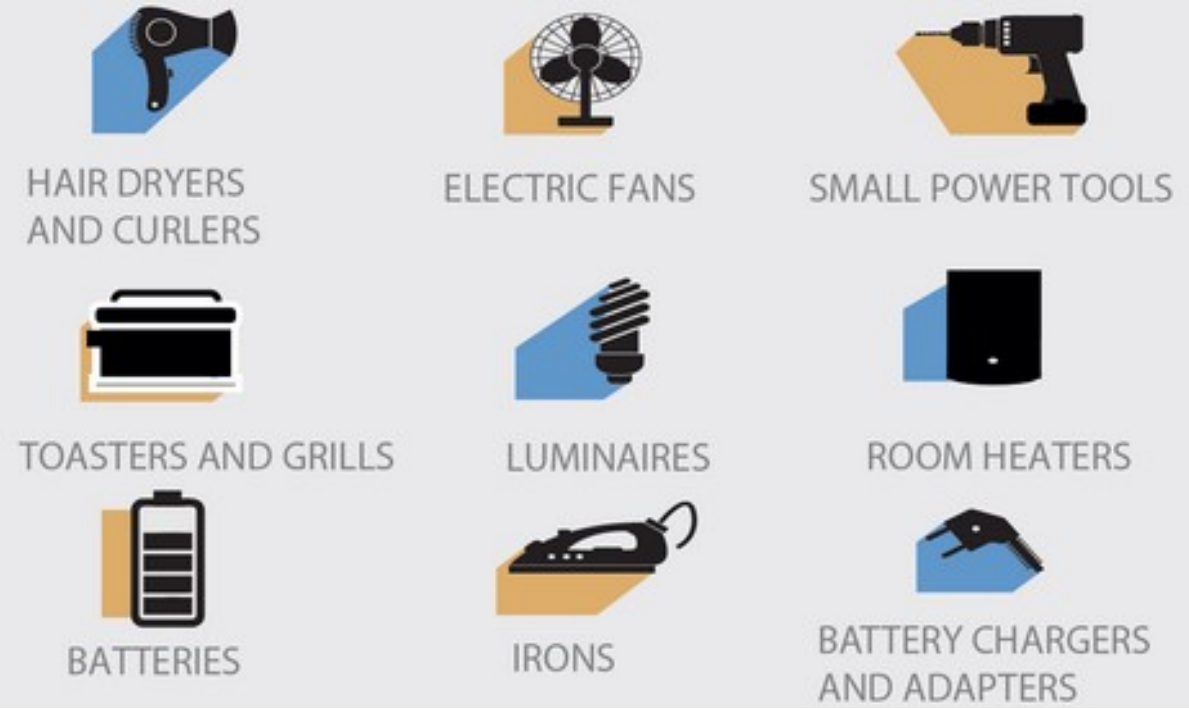
Programas de AC do Setor Privado

- Varejistas e varias associações de indústria possui programas que requer uso de AC de terceira parte:

Estudo de Mercado da IFIA

Taxa de cumprimento nos EUA e Europa

Comparação de produtos com declaração do fornecedor e produtos com certificação



* Consumer Product Market Survey 2014-2016:
https://www.tic-council.org/application/files/1415/5903/8639/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

Estudo de Mercado da IFIA *(cont.)*

Taxa de Cumprimento com Normas

Declaração do Fornecedor	Certificação
17% falhas críticas de segurança	**<1%** falhas críticas de segurança

Falhas críticas de segurança = **alto risco de incêndio e ferimento permanente**

* Consumer Product Market Survey 2014-2016:
https://www.tic-council.org/application/files/1415/5903/8639/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

Estudo da Comissão Europeia

Alto nível de não cumprimento no mercado Europeu*

- 32% Brinquedos
- 58% Eletrônicos
- 47% Produtos de Construção
- 40% Equipamentos de Proteção Individual

Desafio: recursos públicos insuficientes para financiar vigilância de mercado

*Safe products in the EU Single Market: Commission acts to reinforce trust:

Estudo OSHA nos EUA

Occupational Safety and Health Administration

TIC COUNCIL

Comparação de custos para OSHA entre modelo atual de certificação compulsória e modelo de declaração do fornecedor

US$1,000,000

US$360,000,000

*OSHA: : https://www.regulations.gov/document?D=OSHA-2008-0032-0099

Conclusão – Modelo Americano

- Regulamentação e AC baseado em riscos
- Assegura o cumprimento com normas e leis
- Penalidades civil e criminal
- Sistema jurídico litigioso
- Programas voluntários de AC do setor privado
- Programas efetivos de vigilância de mercado
- Programas de AC de terceira parte compulsório e voluntario dependendo do riscos e contexto

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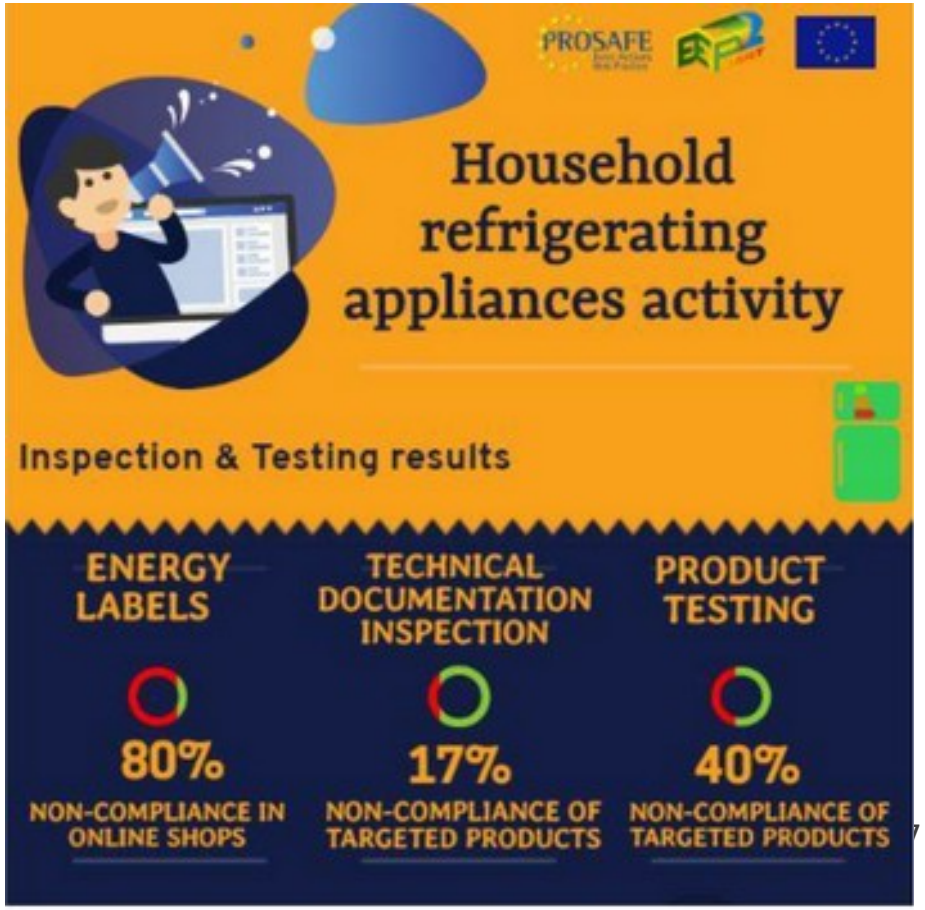
Wikipedia page:
Testing, inspection and certification

TIC-Council.org

What Does the Data Say?

Surveillance actions targeted at EU eco-design and energy labelling fou high levels of **non-compliance**:

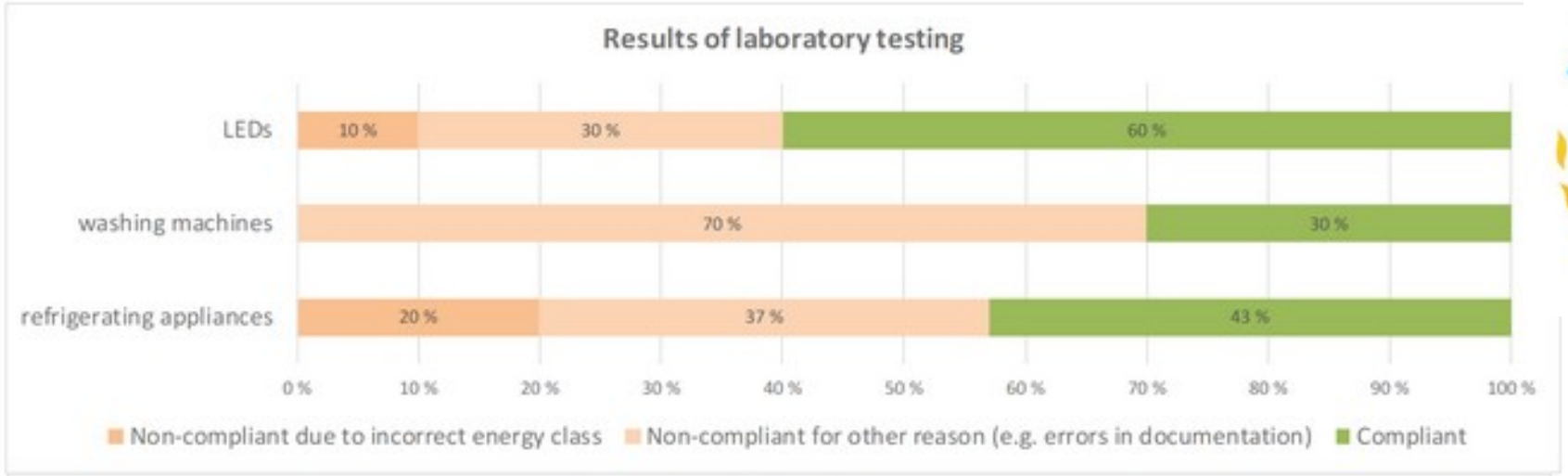
- 40% of household refrigerators
- 79% of professional refrigerators
- 80% of network stand-by related products tested

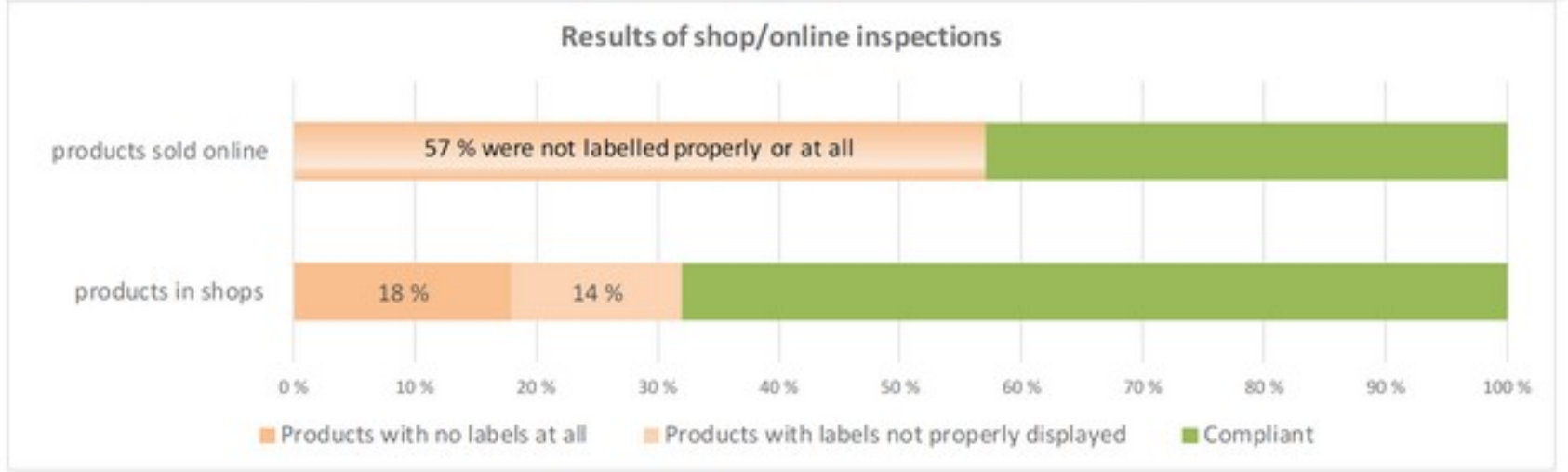


https://www.prosafe.org/images/EEPLIANT2/EEPLIANT2_2nd%20Press%20release_Master_Final_20200312.pdf

What Does the Data Say?

Figure 10 – Findings of EU-funded projects





Source: ECA, based on the relevant EU-funded projects' final reports.

https://www.eca.europa.eu/Lists/ECADocuments/SR20_01/SR_Ecodesign_and_energy_labels_EN.pdf

U.S. Approach to Conformity Assessment

OMB Circular A-119:

"When properly conducted, conformity assessments conducted by private sector conformity assessment bodies can increase productivity and efficiency in government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment"

https://www.nist.gov/system/files/revised_circular_a-

Considerations for Post-Market Approach

- Risk and impact of non-compliance is low and risk of product is low
- There is **no** need for higher levels of confidence
- There is appropriate government funding for market surveillance and recalls
- There is stringent civil/criminal penalties, product liability laws and effective legal system
- There are voluntary industry / retailer-led schemes that address regulators' objectives
- Str
- Indu andi ng / repu

Legal framework, stringent penalties, recall capabilities and fully-funded market surveillance are key to drive compliance

Considerations for Pre-Market Approach

- High risk of non-compliance
- High risk products
- Need for independence and impartiality
- Need for higher levels of confidence of compliance
- There are limited government resources to fully fund post-market surveillance systems

The level of confidence needed based on risks is key to determine the most appropriate conformity assessment model

Risk Assessment Considerations

1. What is the level of confidence required? What is the perceived risk?
2. What are the societal risks and impacts of non-compliance?
3. Are products coming from countries with history of risk factors and complex supply chains?
4. Is there a documented history of industry compliance? And of Industry non-compliance?
5. Is there evidence that product liability is an effective deterrent?
6. Do regulatory statutory provisions provide severe an effective deterrent?

Government Conformity Assessment Programs -- Examples

- **Environmental Protection Agency's Energy Star program** for energy efficiency relies on certification and post-market surveillance by third-parties
- The program used to rely on supplier's declaration, until an investigation found massive fraud and third-party certification was instated to ensure trust and integrity

In 2018 alone, ENERGY STAR helped Americans save nearly 430 billion kilowatt-hours of electricity and **avoid $35 billion in energy costs**

https
%20

Conformity Assessment Programs – Government - Examples

- **Federal Communication Commission (FCC)** requires third-party certification for certain types of Radio Frequency (RF) Devices

- **Food and Drug Administration (FDA) ASCA Pilot** will allow accredit testing laboratories to perform premarket testing for medical device companies

Conformity Assessment Programs – Government - Examples

- **OSHA's Nationally Recognized Testing Laboratory (NRTL) Program**

  requires third-party certification to ensure products can be safely used on the workplace

- Third-party approval include initial assessment, testing, and mechanism to ensure ongoing compliance such as market surveillance, factory audit and inspections etc