

Traceability as a Tool of Management Risk

*Inmetro's experience
on regulation and traceability*

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Inmetro/Brazil: National Institute for Metrology, Quality, and Technology

Schedule

1. About Inmetro

2. Regulation and Traceability

3. Inmetro in ICPSC Pilot Tracking and Traceability Project

4. Final words

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What's Inmetro?

Inmetro's laboratorial infrastructure



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Brazilian Regulatory Structure *The agencies*

Electric Energy National Agency (Aneel)	Water National Agency (ANA)
Telecommunication National Agency (Anatel)	Aquaviary Transport National Agency (Antaq)
Oil National Agency (ANP)	Land Transport National Agency (ANTT)
Sanitary Vigilance National Agency (Anvisa)	Cinema National Agency (Ancine)
Supplementary Health National Agency (ANS)	Civil Aviation National Agency (Anac)

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Inmetro is the heart of the National System for Metrology, Normalization, and Industrial Quality (created in 1973).

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Inmetro's action main areas are:

Scientific metrology

Legal metrology

Assessment Conformity

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- Inmetro's action main areas are:
- Scientific metrology
 - Legal metrology
 - Conformity Assessment**

Conformity Assessment is a

“Demonstration that specific requirements for a product, process, system, people or organism are attempted”.
[ABNT NBR ISO/IEC 17000:2005]

“Sistematic process, with pre-established rules, which is monitored and evaluated, in order to provide enough reliable level that a product, process, service, or a professional attempt standard and regulation requirements, with the lowest cost for society”.
[Inmetro's Conformity Assessment Guide]

Conformity Assessment (CA)

It can be:

- *Mandatory*
- *Voluntary*

Its mechanisms are:

- *Certification (3rd part) - The most common*
- *Supplier's Conformity Declaration (1st part)*
- *Inspection (2nd part)*
- *Test (2nd part)*

Some data:

- ▶ Inmetro has already developed about 180 programs, more than 80% of them are mandatory.
- ▶ Other 88 programs are under development.
- ▶ About 230.000 product types certificated.
- ▶ Examples of products under Inmetro's regulation:
 - Toys
 - Cribs
 - Bicycles
 - Ovens
 - Water heaters by gas, solar energy, and electricity
 - Microwave
 - Refrigerators
 - Lamps
 - Forest management, and chain of custody
 - Water filters
 - Party articles
 - Computing goods
 - Wheel chair
 - Fire extinguisher
 - Mattress
 - Electricity Cabs
 - Needle, syringe, and equipment for medical use
 - Others

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Regulation and traceability in AC

- For Inmetro, a traceability mechanism is an important issue for a Conformity Assessment Procedure (CAP).
- In CAP regulation, usually when certification, Inmetro requires that the supplier must guarantee that its product is traceable.
- For that, in order to get the product certification, the supplier has its quality management system audited by Certification Bodies, under ISO 9000 serie criteria.
- An implemented traceability mechanism demonstrates that the supplier has a production control, and that it has means to recall a eventual batch in nonconformity.

Regulation and traceability in AC

Although Inmetro regulation usually requires an implemented traceability mechanism, it is not imposed an specific way to define a traceability code for a product.

In that way, for Inmetro, the suppliers must be free to determine its own traceability code. After all, each industry, and each company have its singularities for being considered.

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A brief history

- Inmetro began to participate of ICPSC meetings and to be part of the Tracking-and-Traceability Project in december 2010, during the International Safety Week, in Brussels.
- ICPSC is the International Consumer Product Safety Caucus.
- The current ICPSC President is Stefano Soro, member of EU Directorate General for Health and Consumers.
- Membership in the ICPSC is open to consumer product safety regulators and market surveillance authorities anywhere in the world.
- On April 13, 2011, in Paris, during ICPSC Uniform Tracking and Traceability Pilot Project meeting, it was agreed that the jurisdictions participating in the project, and other jurisdictions that might be interested, should indicate their preferred distribution of tracking and traceability information.

Consensus “label”: a proposition

- The jurisdictions participating in the project had to feel a matrix as an initial and informal survey to gather their preferences on distribution of tracking and traceability information.

Name of Jurisdiction: XXX			
Content Classification	Visual Form		
	Human Language	Decodable Characters	Machine Language
Core Data			
Category Data			
Jurisdiction Data			
Trading Partner Data			

* indicates that human language is required by law or regulation
 (R) indicates information that only a regulator or relevant commercial actor should be able to access

The project focused on strollers to be the pilot product.



Consensus “label”: a proposition

Trading partner: Data that is required to meet individual trading partner requirements. For the exercise, this is not applicable. N/A.

Jurisdiction data: Data that is required to meet regulatory requirements within a jurisdiction.

Category data: Data that is specific to the nature of the product (i.e. product category).

Core data: Data that is common. Context is Global.

Human language: TT information that, to meet your jurisdiction’s legal, social, or other needs, must or should be presented on the stroller in written human language.

Decodable characters: TT information that, to meet your jurisdiction’s legal, social or other needs, must or should be presented on the stroller, if not in human language, at least in characters that a person can decode with the use of publicly available information via sources such as a media announcement, a company’s web site, or a toll free telephone number.

Machine language: TT information in images that humans cannot read or easily decode without the use of a technology that can scan / receive and interpret the information, such as bar codes.

Name of Jurisdiction: XXX		Visual Form		
Content Classification	Human Language	Decodable Characters	Machine Language	
Core Data				
Category Data				
Jurisdiction Data				
Trading Partner Data				

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The Brazilian matrix

Name of Jurisdiction: Brazil			
	Visual Form		
Content Classification	Human Language	Decodable Characters	Machine Language
Core Data	Country and city of production Name, CNPJ, telephone and address of producer, importer, or selling organization *		Country and city of production Name, CNPJ, telephone and address of producer, importer, or selling organization *
Category Data	Date of production Batch or run number * Model name, and number, if any		Date of production Batch or run number * Model name, and number, if any
Jurisdiction Data	Regulator mark * Labeler mark *		Regulator mark * Labeler mark *
Trading Partner Data	N/A	N/A	N/A
* indicates that human language is required by law or regulation (R) indicates information that only a regulator or relevant commercial actor should be able to access			

To compose the Brazilian matrix, Inmetro has consulted the Brazilian standard ABNT NBR 14389 requirements for Baby Strollers.

ABNT NBR 14389 requirements will turn mandatory after CAP being published.

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- ICPSC-Tracking-and-Traceability Project isn't finished yet. So there isn't further conclusions about the pilot.
- Still, it is being a great experience to Brazil, since it is an opportunity to discuss within Inmetro about ways to think traceability in our regulation.
- Besides that, it is important to notice that Inmetro is currently developing the Brazilian Conformity Assessment Program (CAP) for Baby Strollers, which is the object of the pilot project.
- In that way, some definitions made in ICPSC-Tracking-and-Traceability Project can be introduced in the CAP for Baby Strollers, as our first experience in detail tracking-and-traceability requirements.

Thank you!

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