



European Weighing Industry



Blue Guide 2016

News & Changes

Daniel J. Meier, Vienna, 2nd June 2016

- INTRODUCTION
- NEWS & CHANGES
 - E-Commerce
 - Product Risk Assessment



- INTRODUCTION
- NEWS & CHANGES
 - E-Commerce
 - Product Risk Assessment



Introduction – European Regulatory System?



Structure:

1. Regulation/Decision: New Legislative Framework (NLF)
2. Directives: NAWI-, MI-, and other Directives
3. Guidance: The **Blue Guide**

Introduction – The Target of the Blue Guide?



The Blue Guide is:

1. The official interpretation of the European Commission for the New Legislative Framework and its derived directives;
2. Guidance for harmonized and uniform application by member states, and all other stakeholders.

Introduction – Version 2016?



1992	2014	2016	...
First Guide for global approach	1st Version for NLF	Update with new developments	

The Blue Guide is a living document, new versions are to be expected.

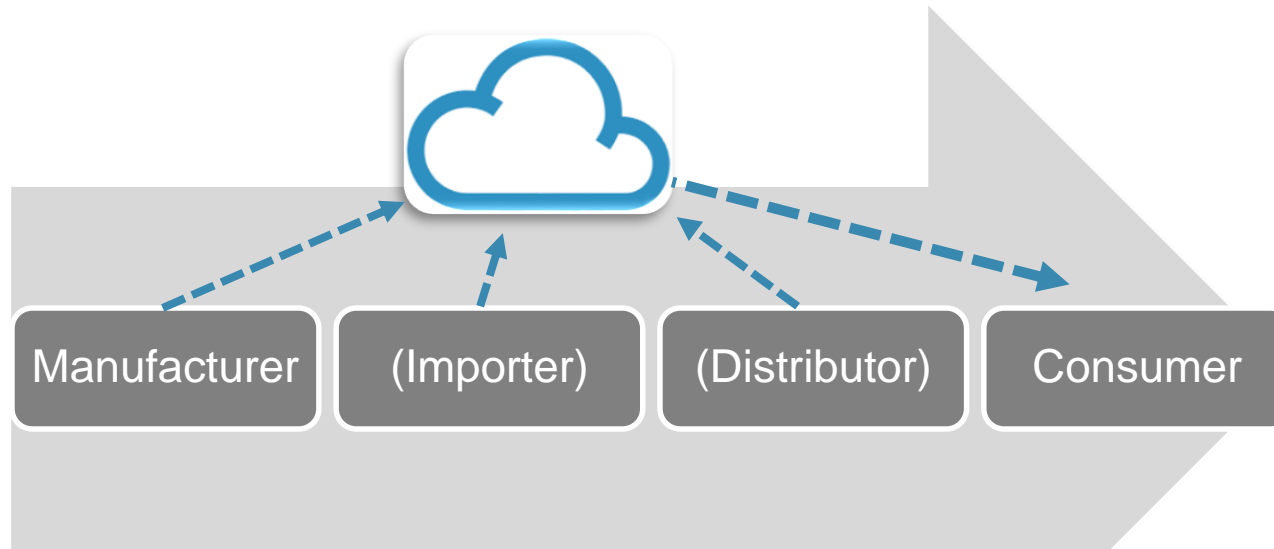
- INTRODUCTION
- NEWS & CHANGES
 - E-Commerce
 - Product Risk Assessment





e-Commerce

1. Traditional Distribution Chain
2. E-Commerce: **Information host**





e-Commerce - Information host



- a) Products offered for sale by online operators based in the EU are considered to be placed on the Union market, regardless of who placed them on the market (the online operator, the importer, etc.)
- b) Products offered for sale online by sellers based outside the EU are considered to be placed on the Union market if sales are specifically targeted at EU consumers or businesses. These products are considered as supplied for distribution, consumption or use in the Union market when products are offered for sale by an online operator and are likely to be (or have already been) ordered by consumers or businesses in the EU. If this offer specifically addresses the consumer in the EU, the supply is considered to be made on the Union market.



e-Commerce - Information host



- The legal consequence is that products offered for sale by online operators need to comply with all applicable EU rules when placed on the market, i.e. when offered for sale online.

Such compliance can be physically verified by responsible authorities when the products are in their jurisdiction, at the soonest, at the customs.



e-Commerce - Information host



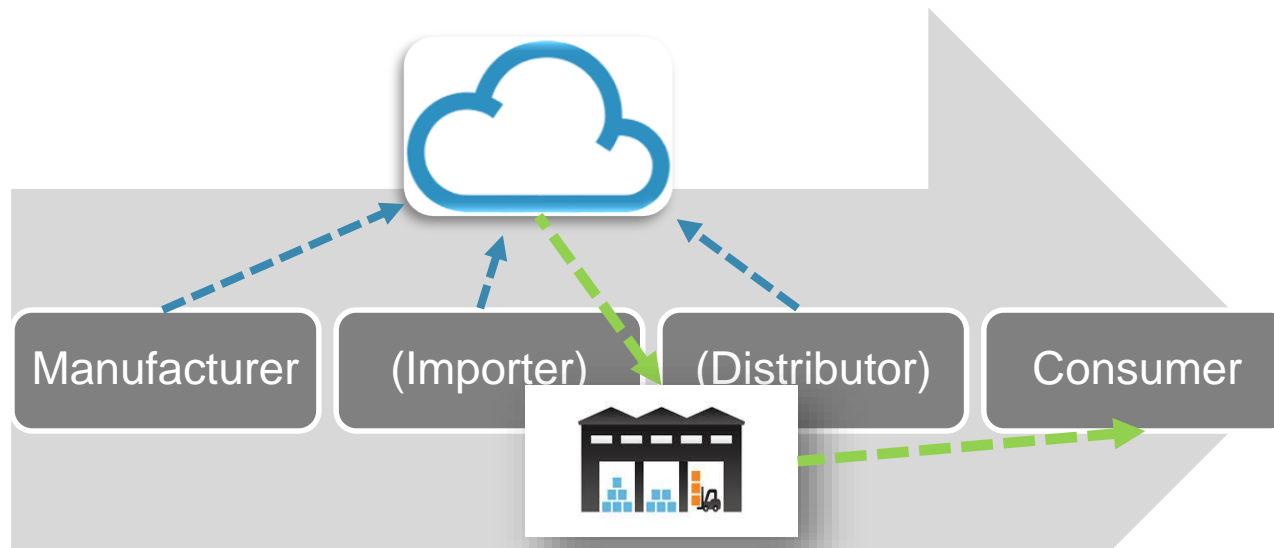
- Reflecting additionally the E-Commerce Directive¹⁾ following consequences for hosting service providers are derived: When national authorities cannot contact the responsible economic operator making unsafe/ non-compliant products available online, they can contact the hosting providers.
- When notified of unlawful activity, intermediaries or hosting service providers have to remove or disable the content, meaning that the unsafe/ non-compliant products would no longer be accessible to EU customers through their services.

¹⁾ Directive 2000/31/EC



e-Commerce

1. Traditional Distribution Chain
2. E-Commerce: **Fulfilment Houses**



e-Commerce - **Fulfilment Houses**



- Products offered by online operators are generally stored in fulfilment houses located in the EU to guarantee their swift delivery to EU consumers. Accordingly, products stored in such fulfilment houses are considered to have been supplied for distribution, consumption or use in the EU market and thus placed on the EU market.
- When an online operator uses a fulfilment house, by shipping the products to the fulfilment house in the EU the products are in the distribution phase of the supply chain.

- INTRODUCTION
- NEWS & CHANGES
 - E-Commerce
 - Product Risk Assessment





Product Risk Assessment

➤ Process Requirements



The interpretation of "essential requirements" clarify now the tasks of the manufacturers related to their responsibility for their products.



Product Risk Assessment

➤ Process Requirements

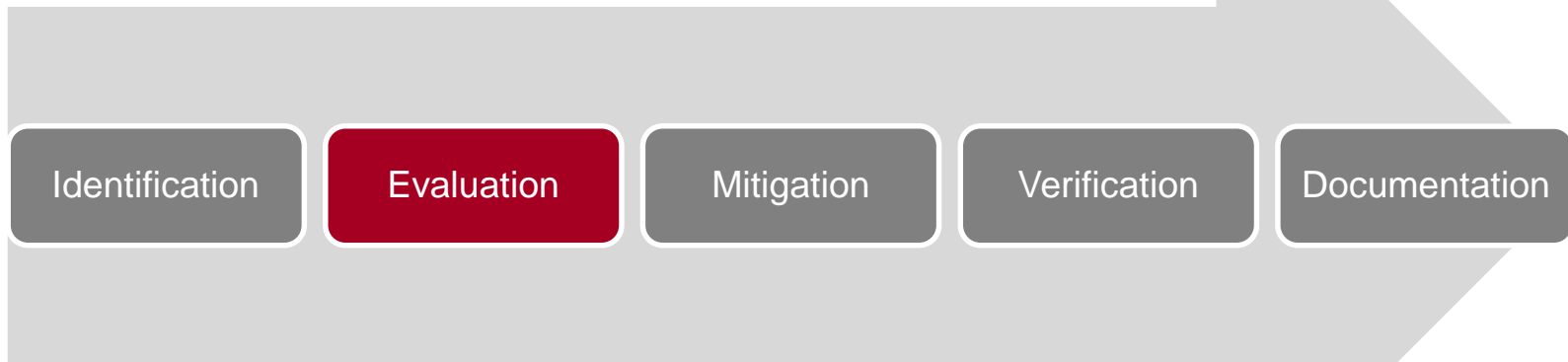


- Manufacturers have to carry out a risk analysis to first identify all possible risks that the product may pose.



Product Risk Assessment

➤ Process Requirements

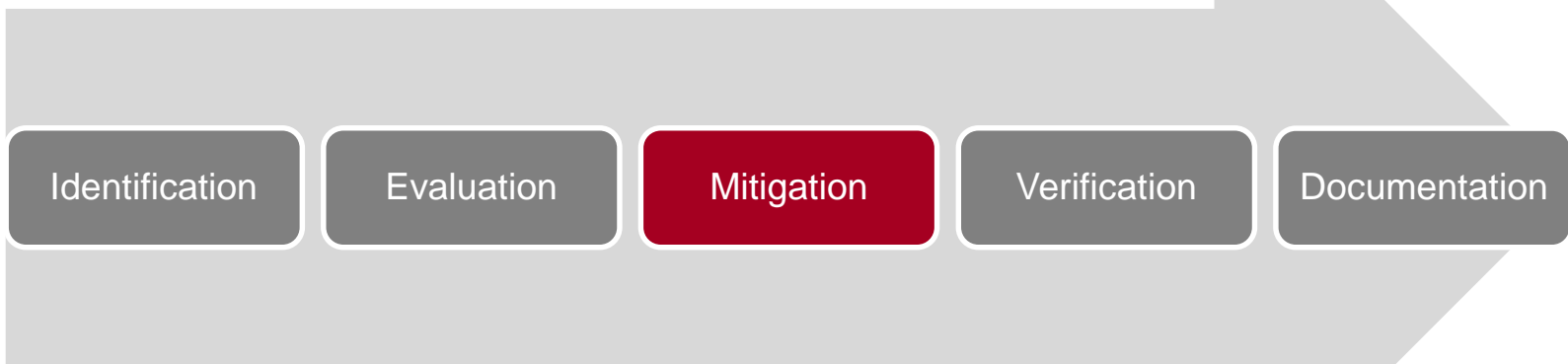


- Manufacturers have to determine the essential requirements applicable to the products.



Product Risk Assessment

➤ Process Requirements



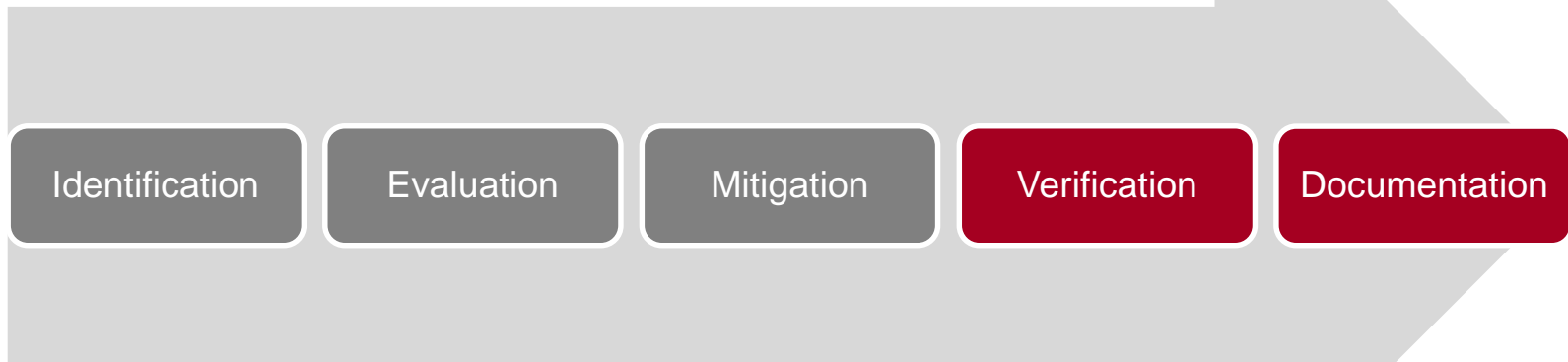
- Manufacturer needs to address the risks identified to ensure that the product complies with the applicable essential requirements (for example, by applying harmonized standards).

If only part of the harmonized standard is applied or it does not cover all applicable essential requirements, then the way applicable essential requirements not covered by it are dealt with, should be documented.



Product Risk Assessment

➤ Process Requirements



- The results of the risk assessment have to be documented and included in the technical documentation.

Recap:

- INTRODUCTION
- NEWS & CHANGES
 - E-Commerce
 - Product Risk Assessment





Where to find the Blue Guide 2016?

Document: Committee Notification C(2016) 1958 final

<http://ec.europa.eu/DocsRoom/documents/12661/attachments/1/translations/en/renditions/native>

Daniel J. Meier

Mettler-Toledo International Inc.

Im Langacher 44, 8606 Greifensee, Switzerland

daniel.j.meier@mt.com

+41 44 944 2564, +41 79 909 3741



European Weighing Industry



Thank you

