

**PRESENTATION
ON
THE SUPPLIER'S DECLARATION OF CONFORMITY (SDoC)
IN THE EUROPEAN MARKET**

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What is SDOC?

- ◆ One of the Conformity Assessment Procedures
- ◆ Definition of Conformity Assessment

Conformity Assessment

◆ Definition as per WTO TBT Agreement

“Any procedure used, directly and indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled”

◆ Includes, *inter alia* :

- Procedures for sampling, testing and inspection
- Evaluation, verification and assurance of conformity
- Registration, accreditation and approval as well as their combinations

Types of Conformity Assessment

◆ Three ways, broadly :

- First Party Assessment – by supplier (SDOC)
- Second Party Assessment – by Customer or its appointee
- Third Party Assessment – by independent (like ISO)

Types of Conformity Assessment

Item	First Party Assessment	Second Party Assessment	Third Party Assessment
Conformity Assessment Party	Supplier, Manufacturer	Customer or Appointee	Independent Testing Body/Regulatory Body
Description	Manufacturer/Supplier provides written assurance of the conformity of its product to specified requirements	Purchaser's own inspectors perform the assessment of supplier's products and certify	Assessment by an Independent Technically Competent Body (not under the control of buyer or seller)
Examples	EC SDOC for Electrical items Motor Vehicles Certification in US	Aircraft manufacturers certifying their suppliers of components	BIS / Spice Board / FDA etc.

EC SDOC

◆ Definition as per submission (G/TBT/W/218) by EC to WTO

“The supplier himself declares conformity of his product with the requirements of the applicable legislation without any mandatory third party intervention – neither in design phase nor the production phase of the manufacturing process – that would involve product tests according to the relevant legislation. SDOC is based on an assessment or test performed by the manufacturer himself or any other party”

EC SDOC

- ◆ EC Council Decision of 22 July 1993
 - Modules for Conformity Assessment Procedures
- ◆ Module A (Basic Model) relates to SDOC

EC SDOC

◆ Module A (SDOC) Internal Production Control

- Describes procedure whereby the manufacturer or his authorised representative within the community Declares that the products concerned satisfy the requirements of the directives that apply to them

◆ Technical Documentation

- To be kept for 10 years, at least
- Covers the design, manufacture and operation of the product

EC SDOC – Product Coverage

- ◆ Mostly used for products and sectors involving a low or medium risk to health, safety & environment
- ◆ Not only guided by risk analysis approach but also depends on :
 - Regulatory and legal infrastructure existing in the sector
 - Level of commercial confidence
- ◆ Higher risk products – third-party intervention required through certification body

EC SDOC – Product Coverage

- ◆ Certain Categories of products in :
 - Electrical Equipment
 - Machinery
 - Medical Devices
 - Radio & Telecommunication equipments
 - Toys
 - Personal Protective Equipment
 - Recreational crafts
 - Equipments for use in potentially explosive atmospheres

EC SDOC – Scope

- ◆ Mostly linked to application of harmonised European standards
- ◆ Deviation from Harmonised standards entails mandatory third-party intervention

SDOC – Effectiveness

◆ In order to be effective

- Effective product liability laws
- Well developed market surveillance
- Penalties for false declarations
- Incentives to encourage suppliers' compliance
- Customer redress system

Benefits of EC SDOC

◆ OECD Study 2008

- Enabled trade among new countries with EU (more so in the case of radio & telecommunication devices, medical devices)
- Results are ambiguous in case of machinery
- Imports from non-OECD countries benefitted most - surprising ??
- ◆ Reduces complexity & cost - ???
- ◆ Faster time to market & access to new products

Concerns of Indian Exporters with EU

- ◆ Lack of Harmonisation of Standards
- ◆ Stringent norms – excessive MRL limits, much beyond international standards
- ◆ Private Standards (BRC, HACCP, Kosher etc)

EC SDOC – Issues & Concerns for Indian Exporters

Private Standards

- Fundamental concern is rising private standards in EU that are out of the scope of SDOC
- OECD Study 2008 : “Abandonment by regulators of a mandatory requirement for 3rd party certification may simply be replaced by a demand by the market for 3rd party certification”
- Encourage private certification schemes (e.g. German GS mark continues to be used for electrical consumer products)

EC SDOC – Issues & Concerns for Indian Exporters

SMEs

- More administrative resources required to obtain information by exporter (especially merchant exporter)
- Internal technical expertise, facilities and test required
- Non-transparent regulations could further complicate process for SMEs

EC SDOC – Issues & Concerns for Indian Exporters

◆ Lag in detection

- If any deviation found after a long period, the entire production may go waste
- For instance, in case of steel exports to EC well after 5 months of supply violations of norms was found

EC SDOC – Issues & Concerns for Indian Exporters

Technical Documentation

- Need to be kept with the manufacturer or his authorised representative established within EC for at least 10 years
- If not established within EC, then importer has to bear the responsibility – why should the importer take this responsibility for 10 years?
- Ten years – Is it too long?

EC SDOC – Issues & Concerns for Indian Exporters

◆ Product Testing

- Evidence suggests that introduction of SDOC does not necessarily lead to reduction in testing and thereby in cost & time
- Test Reports in any case have to be part of technical file for a variety of needs – request from surveillance inspectors

◆ Module A(a)

- Notified Body carries out product checks at random intervals – Third Party intervention
- Notified Bodies have to be located within EU (Not so the case in US)

EC SDOC –

Issues & Concerns for Indian Exporters

- ◆ Different risk perceptions within EU → Different interventions for same violation
- ◆ Norms/procedures related to market surveillance not harmonized – Essential because more reliance on market surveillance under SDOC

EC SDOC –

Issues & Concerns for Indian Exporters

- ◆ India's Exports to EU - \$34.5 billion
- ◆ Top Items of Export Interest to India
 - Textiles & Apparels : 21%
 - Minerals : 13%
 - Metals & Articles : 12%
 - Chemicals & Allied Products : 10%
 - Machinery & Appliances : 9.4%
 - Vehicles : 4.3%
- ◆ Machinery, Electrical & Electronic items and Vehicles are the top two exporting items of EU
 - EU Exports of Electrical & Electronic Items : \$193 billion

Thank You