



Ministry of Trade and Industry



Product Inspection (Imported and Domestic) and Regulation: Applying the EU System in Egypt



High Level Briefing

Current Situation

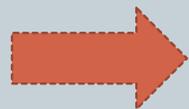


- **Inspection and conformity assessment of industrial goods undertaken by:**
 - Industrial Control Authority (domestic inspection of industrial manufacturing facilities)
 - Domestic trade sector (domestic inspection of fraud cases)
 - Egyptian Organization for Standardization (issuing of standards and conformity assessment of domestic goods)
 - General Organization for Export and Import Control (conformity assessment of imported industrial goods)

Challenges of Current Situation



- Different inspection and conformity assessment procedures and systems result in:
 - Inspection target is quality and not safety, health, and environment as required by WTO (e.g. Annex 8 of import and export regulations)
 - Similar domestic and imported goods are of varying safety levels
 - Lack of coordination between agencies in product alerts, traceback and recalls
 - High likelihood of non-compliance with WTO national treatment provisions



Lack of confidence of Egyptian factories and consumers in safety of goods sold in Egypt

Overall Goal and Activity Objective



- **Overall Goal:**
 - Improve the safety of industrial and consumer goods sold in Egypt
- **Activity Objective:**
 - Unify domestic and import inspection and conformity assessment system
 - Target inspection resources towards high risk goods (for health, safety, and environment)

Main Features of Proposed Plan



- Adopt features similar to EU System, including:
 - One market surveillance authority that targets unsafe or hazardous (high risk) domestic and imported goods (quality is not the issue: safety, health, and environment are)
 - Focus of inspection is internal but explicit instructions to and close coordination with Customs
 - Strong standards based on 22 EU industrial product directives
 - Conformity assessment procedures include strict measures to ensure conformity to directives and result in issuing of conformity mark
 - Require manufacturers/authorized representative to keep technical documentation and to file declaration of conformity
 - General product safety directive (targets consumer products not otherwise covered by other legislation)
 - Product liability directive (severe conditions and penalties for parties responsible for unsafe products that cause injuries or damage)

Advantages of Applying EU Approach in Egypt



- Raise level of sophistication of Egyptian industry so that it can compete more effectively not only in EU but other markets
- Boost industrial and consumer good exports to the EU and EU investment in Egypt
- Target high risk products through market surveillance, thereby reducing unnecessary or duplicative official visits to industry
- Ensure compliance with WTO national treatment provisions since domestic and imported goods will be subject to similar inspection and conformity assessment procedures
- Promote manufacture, sale, and distribution of safer products in Egypt to benefit the consumer



Snapshot of the EU Approach

EU Approach: Outline



- Key features of EU product regulation (“New Approach”) and conformity assessment (“Global Approach”)
- Critical complementary laws
- Other important features of EU product regulation
- EU market surveillance system (main features)
- Responsibilities of the parties (manufacturer, distributor, importer, etc.)
- How the EU system might work in Egypt



**EU product regulation (“New Approach”)
and conformity assessment (“Global
Approach”)**

Main Features of EU Product Regulation ("New Approach")



- Includes “directives” for 22 product categories
- Each directive includes essential requirements (mandatory), conformity assessment procedures, etc.
 - How manufacturers meet the essential requirements is voluntary but they are encouraged to use laid out harmonized standards
 - Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements

“New Approach” Directives for CE Marking

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1. Appliances burning gaseous fuels
 2. Cableway installations designed to carry persons
 3. Construction products
 4. Electromagnetic compatibility
 5. Equipment and protective systems in potentially explosive atmospheres
 6. Explosives for civil uses
 7. Lifts
 8. Low voltage equipment
 9. Machinery safety
 10. Measuring instruments
 11. Medical devices: Active implantable
 12. Medical devices: General
 13. Medical devices: In vitro diagnostic
 14. New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)
 15. Non-automatic weighing instruments
 16. Packaging and packaging waste
 17. Personal protective equipment
 18. Pressure equipment
 19. Radio and telecommunications terminal equipment
 20. Recreational craft
 21. Simple pressure vessels
 22. Toys safety

“New Approach” Directives



- New Approach Directives apply to new products manufactured in Member States, and to new, as well as used and second-hand, products imported from third countries
- New Approach Directives apply mostly to industrial products and are complemented with two powerful and complementary directives:
 - Directive on General Product Safety
 - Directive on Product Liability

Conformity Assessment (“Global Approach”)



- **Conformity assessment is based on:**
 - Manufacturers’ internal design and production control activities;
 - Third party type examination combined with manufacturers’ internal production control activities;
 - Third party type or design examination combined with third party approval of product or production quality assurance systems, or third party product verification;
 - Third party unit verification of design and production; or
 - Third party approval of full quality assurance systems.



Critical Complementary Laws

Complementary Directives: Directive on General Product Safety



- Imposes a general safety requirement on any product put on the market for consumers or likely to be used by them
- Manufacturers must put on the market products which comply with the general safety requirement; must provide consumers with necessary information in order to assess a product's inherent threat and take the necessary measures to avoid such threats (e.g. withdraw products from the market, inform consumers, recall products which have already been supplied to consumers, etc.).
- Distributors are also obliged to supply products that comply with the general safety requirement, to monitor the safety of products on the market and to provide the necessary documents ensuring that the products can be traced
- Rapid alert system for products that pose serious risk

Complementary Directives: Directive on Product Liability



- Purpose is to ensure consumer protection against damage caused to health or property by a defective product and to reduce the disparities between national laws
- Applies to all products covered by New Approach directives
- Covers any defective product manufactured or imported into the European Union that causes damages to individuals or private property

Complementary Directives: Directive on Product Liability (continued)



- Introduces the concept of strict liability on the part of the producer in favor of the victim
- Places burden of proof on the injured party insofar as the damage, the defect, and the causal relationship between the two is concerned
- Establishes joint and several liability of all operators in the production chain in favor of the injured party, so as to provide a financial guarantee for compensation of the damage



Other Important Features of EU Product Regulation

Technical Documentation



- Manufacturer must draw up a technical file (technical documentation)
- Technical documentation is intended to provide information on the design, manufacture and operation of the product
- Technical documentation must be kept for at least 10 years from the last date of manufacture of the product

EC Declaration of Conformity



- Manufacturer or the authorized representative established within the Community must draw up an EC declaration of conformity as part of the conformity assessment procedure
- EC declaration of conformity must ensure that the product satisfies essential requirements of applicable directives
- Declaration may take the form of a document, a label or equivalent, and should contain sufficient information to enable all products covered by it to be traced back to it

Notified Bodies



- Notified bodies carry out the tasks pertaining to the conformity assessment procedures when a third party is required
- The assessment of the body seeking notification determines if it is technically competent and capable of carrying out the conformity assessment procedures in question, and if it can demonstrate the necessary level of independence, impartiality and integrity
- Notified bodies are free to offer their conformity assessment services, within their scope of notification, to any economic operator established either inside or outside the EC. They may carry out these activities also on the territory of other Member States or of third countries

CE Marking



- CE marking symbolizes the conformity of the product with the applicable Community requirements imposed on the manufacturer
- The CE marking affixed to products is a declaration by the person responsible that:
 - the product conforms to all applicable Community provisions, and
 - the appropriate conformity assessment procedures have been completed

Affixing the CE Marking



- The CE marking must be affixed by the manufacturer, or by the authorized representative established within the EC
- Where a notified body is involved in the production control phase according to the applicable directives, its identification number must follow the CE marking. The manufacturer or the authorized representative established in the EC affixes the identification number, under the responsibility of the notified body
- CE Marking and notified body identification do not necessarily have to be affixed within the EC. They may be affixed in a third country, for example if the product is manufactured there and the notified body carried out conformity assessment in accordance with the directive in that country



Responsibilities of Parties in EU Product Regulation

Responsibilities of Parties in EU Product Regulation System



- **Manufacturer**
 - The manufacturer has an obligation to ensure that a product intended to be placed on the EC market is designed and manufactured, and its conformity assessed, to the essential requirements in accordance with the provisions of the applicable New Approach directives.
 - The manufacturer may use finished products, ready-made parts or components, or may subcontract these tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility for the product
- **Authorized Representative** must be established inside the Community
- **Distributor** shall act with due care in order not to place clearly non-compliant products on the Community market. He shall also be capable of demonstrating this to the national surveillance authority.

Responsibilities: Importer



- An importer is any natural or legal person established in the Community who places a product from a third country on the Community market
- The importer must ensure that he is able to provide the market surveillance authority with the necessary information regarding the product, where the manufacturer is not established in the Community, and has no authorized representative in the Community
- The natural or legal person who imports a product into the Community may, in some situations, be considered as the person who must assume the responsibilities placed on the manufacturer according to the applicable New Approach directives
- Importers placing products on the Community market from third countries are all considered to be producers according to the Directive on product liability



EU Market Surveillance

Market Surveillance



- Definition:
- Activities carried out and measures taken by public authorities to ensure that products are in compliance with legal requirements...or do not endanger health, safety or other issues of public interest protection
- Market surveillance authority cannot be a “notified body” (i.e. cannot conduct third-party conformity assessment)

Scope of EU Market Surveillance



- Products = Substances, preparations & goods produced through a manufacturing process, except food, feed, human blood and tissues, living plants and animals
- Sectors dealt with under specific laws: Pharmaceuticals, aviation, drug precursors, medical devices and motor vehicles
- Border controls: All products covered
- Authorities can also take more specific measures under the General Product Safety Directive

Market Surveillance



- Market surveillance authorities to conduct documentary checks and, where appropriate, physical and laboratory checks (on basis of samples)
- Authorities may enter premises of economic operators and take samples
- Authorities may destroy or otherwise render inoperable products presenting serious risk
- Authorities to take due account of test reports or certificates attesting conformity
- Decisions to recall products based on risk assessment taking into account hazard and risk of occurrence
- Measures taken must be proportionate and justified

Market Surveillance



- Border authorities to suspend release when they find any of the following:
 - Product displays characteristics which may present serious risk to health, safety, the environment, or other public interest
 - Product is not accompanied by required written or electronic documentation
 - CE Marking affixed in a false or misleading manner
- Border control authorities to notify market surveillance authorities of any such suspension
- Product to be released if border control authorities not notified by market surveillance authority within 3 days of any action taken



How the EU system might work in Egypt

Main Features of an Egyptian System



- Review Egyptian industrial standards to roughly match the 22 EU New Approach directives, including:
 - Essential requirements
 - Conformity assessment procedures
 - Harmonized standards to meet technical specifications
- Set conformity assessment process similar to the EU that ensures that more hazardous goods have to meet more stringent and comprehensive procedures
- Labs that conduct third-party conformity assessment have to be accredited by EGAC in the test they conduct
- A special mark like the CE Mark would be affixed by manufacturer/authorized representative if product conforms to specifications
- Mutual recognition agreement with EU to recognize each other's conformity assessment procedures

Main Features of an Egyptian System



- Establish an **Egyptian Market Surveillance Authority (EMSA)** that unifies industrial inspection in Egypt
- Scope of the EMSA would **exclude food, feed, live animals and plants**, etc. (same as EU) and would cover domestic and imported goods
- EMSA would draw a market surveillance strategy to track and test higher risk products (imported or domestic)
- Manufacturers will need to keep **technical documentation** that includes information on the design, manufacture and operation of the product
- Manufacturer or the authorized representative in Egypt must draw up a **declaration of conformity** as part of the conformity assessment procedure
- All in the supply chain need to keep sufficient information for **traceability and recalls**
- **Labs that are part of** the market surveillance authority cannot conduct third-party conformity assessment

Main Features of An Egyptian System



- Need complementary regulations on:
 - General product safety (if not already covered in Consumer Protection legislation)
 - Product liability (a strong incentive for producers to comply)
- Similar responsibilities as EU legislation for manufacturer, authorized representative, distributor, and importer
- Consumer Protection Agency and consumer associations would play a key role in reporting complaints about product safety issues
- Rapid alert system for dangerous products
- PLUS: Unique shipment/product identifier to prevent fraud and allow trace back and recalls

Next Steps



- Develop a detailed plan for unifying industrial inspection in Egypt, including consultations with and public awareness of stakeholders
- Issue MTI decree unifying inspection for domestic and imported industrial products into one market surveillance entity with broader functions
- Review Egyptian standards and issue MTI decree consolidating industrial standards into groupings similar to the EU New Approach (this would be done sequentially) and setting an Egyptian safety mark for covered goods
- Set up a “notified body” system to approve labs that can conduct third-party conformity assessment
- Issue decrees and industry guidance on required technical documentation and declaration of conformity, trace back and recalls, and product liability