

# Regulatory Compliance of Imported Goods

*Chemicals, Food, Pesticides, Toys, Electronics, Cosmetics*

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# Overview

- Product and Chemical Safety - Introduction
- Essential requirements and harmonized standards
- Conformity assessment and EU declaration of conformity
- CE marking
- Traceability
  
- REACH and CLP Regulation
- Foodstuffs
- Pesticides
- Toys
- Electronics
- Cosmetics
- Ecolabel

# Product and Chemical Safety – Development

- **Old Approach**

- Detailed technical regulations on national and EU level

- **Aim of harmonization: support single market** (elimination of barriers)

- **New Approach**

- EU legislation sets out essential health, safety and environmental requirements
- Non-essential technical details provided in voluntary harmonized standards
- Conformity assessment, accreditation and market surveillance including the control of products from outside the Union
- For not harmonized products: reliance on the Mutual Recognition Principle

# Product and Chemical Safety - Introduction

- **General principle**

- Requirements apply to products made available on EU market → manufactured and imported goods are treated alike

- **Made available / Placed on the EU market**

- Product is supplied for distribution, consumption or use
- Products are presented to customs under the release for free circulation procedure
- **Online sales** by economic operators located outside the EU: placing on the market can take place before the release for free circulation
- → **Obligation and power of customs authorities and market surveillance authorities**
- RAPEX notifications

# Essential Requirements + Harmonized Standards

- **Essential Requirements - Public interest**

- Hazard based: physical and mechanical resistance, flammability, chemical, electrical or biological properties, hygiene
- Product or its performance: materials, design, construction, manufacturing process, instructions of use
- Do not contain technical solutions

- **EU harmonized standards**

- Regulation (EU) No 1025/2012
- Established by standardisation bodies → **voluntary** application
- Publication in the OJ of the EU → **presumption of conformity with the essential requirements**
- Specification in harmonised standards are not alternatives to a relevant essential or other legal requirement but only a possible technical means to comply with it!

# Conformity Assessment + EC Declaration of Compliance

## Decision No 768/2008/EC on common framework for the marketing of products

### • **Conformity Assessment**

- Undertaken by the manufacturer to demonstrate compliance with specified requirements relating to the product
- Design and production phases
- Third party involvement might be required: notified body / in-house
- Eight modules

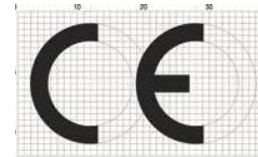
### • **EC Declaration of Compliance**

- Drawn up and signed by manufacturer
- Must identify the Union harmonisation legislation, the manufacturer, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other technical specifications

# CE Marking + Traceability

- **Symbol indicates compliance but NOT proof thereof**

- Regulation (EC) No 765/2008 lays down the definition, the format and the general principles governing the CE marking
- Mandatory for a wide variety of products
- Prohibited for products that does not fall into one of the “mandatory” categories
- Affixed after conformity assessment visibly, legibly and indelibly by the manufacturer (number of notified body)
- Sanctions included in national legislation
- Does not indicate origin of manufacturing (EU)



- **Traceability**

- Following three elements: their (1) name, (2) registered trade name or registered trade mark and (3) the address of the manufacture
- Name and address of EU importer
- Type, batch, serial or model number or other element allowing their identification

# Some Regulated Products

- **European Commission Blue Guide – Non-exhaustive**
  - RoHSII - Directive 2011/65/EU
  - EEE - Directive 2006/95/EC and Directive 2014/35/EU
  - Toys' safety - Directive 2009/48/EC
  - Machinery - Directive 2006/42/EC
  - Active implantable medical devices - Directive 90/385/EEC
  - Medical devices - Directive 93/42/EEC
  - Pressure equipment - Directive 97/23/EC and Directive 2014/68/EU
  - Labelling of Tyres - Regulation (EC) No 1222/2009
  - Personal protective equipment - Directive 89/686/EEC
  - Ecodesign requirements for energy-related products - Directive 2009/125/EC
  - Energy labelling - Directive 2010/30/EU
  - Etc. (more than 30).



# Substances, Mixtures and Articles

## REACH Regulation

- **Registration requirements – registration number**
- **Restriction of substances – Annex XVII**
- **Substances included in Annex XIV**
- **Authorisation of substances**
- **Obligations for importers of articles – Article 33 REACH**
- **Supply chain communication SDS**

# Has REACH Achieved its Goals So Far? – In Numbers from ECHA

- 21500 registered substances (vs. > 100 000 existing chemicals and cca. 40 000 estimated substances (for 2018: 6 824 vs. estimated 25000)
  - Minus non-phase-in and intermediates
    - Are there many substances on the EU market > 1 MT without registration?
- 88 319 registration dossiers for all tonnage bands
  - In average 4 registrants per substance
    - Are there manufacturers/importers on the EU market > 1 MT without registration?
- 13 620 companies registered (vs. 28 329 existing companies in EU28 (data: CEFIC Landscape 2018) → Are they all only DUS?
- SMEs: only 17% → expected to be the largest number in 2018 (Ueapme)

# Labelling of Substances and Mixtures – CLP Regulation

- **Criteria for classification of a substances or mixtures (Part 2-5 of Annex I to CLP)**
- **Harmonized classification vs. self-classification**
- **Labelling**
  - Supplier must label substances or mixtures in accordance with CLP rules before placing them on the market
  - Provide a SDS to customers in the supply chain when hazardous substances and mixtures are involved
  - Labelling if Classified as hazardous;
    - or A mixture which contains one or more substances classified as hazardous above a certain threshold
  - Hazard symbols (pictograms) & signal words (“warning”, “danger”)



*Pictograms for labelling*

# Foodstuff – Labelling: FIC Regulation 1169/2011

- **Mandatory labelling**
  - the list of ingredients (allergens!)
  - the name or business name and address of the food business operator
  - a nutrition declaration
- **Nutrition and health claims made on food**
- **Additional requirements (composition and labelling and sometimes pre-market authorisation)**
  - Fishery + beef
  - Spirit drinks and Wine products
  - vitamins + minerals; additives;
  - Food supplements; baby food; sports food; meal replacements; enriched food
  - Novel food; GMO food / Organic food

# Foodstuffs– Impact by Other Legislation

- **Maximum residue limits (MRL)** is the highest level of a pesticide residue that is legally tolerated in or on food or feed – **Regulation 396/2005** + Amendments
  - Apply to 315 fresh products and to the same products after processing
  - Legislation covers pesticides currently or formerly used in agriculture in or outside the EU (around 1100)
  - Commission fixes MRLs for all food and animal feed
  - The default lowest limit in EU law is **0,01 mg/kg**.
  - Enforcement: local authorities – Regulation 2017/660 sets out the focus of enforcement, Annex I lists the pesticide/product combination in focus, e.g. for 2018: grapes, bananas, grape fruits, aubergines, broccoli, melons, Cultivated fungi, sweet peppers, wheat grain and virgin olive oil

# Foodstuffs – Sanitary and Phytosanitary Requirements

- **Veterinary checks on products of animal origin entering the EU from third countries**
  - From countries approved by the EU
  - From approved processing establishments
  - Health controls (veterinary checks carried out at the border inspection post (BIP) in the EU country of arrival) and health certificates
  - Common Veterinary Entry Document
  - Fishes: catch certificate
- **Plants**
  - Plant-health certificate
  - Customs and phytosanitary inspections at the point of entry into the EU;
  - Announced to the customs office before arrival at the point of entry.

# Pesticides: Plant Protection Products and Biocides

- **Plant protection products - Regulation 1107/2009**
  - Centralized EU system for approval of active substances
  - National authorisation of products
  - Requirements apply for placing on the market or use → holding for the purpose of sale, including offering for sale or any other form of transfer; release for free circulation into the territory of the Community shall constitute placing on the market for the purposes of this Regulation;
  - Enforcement: national
- **Biocides – Regulation 528/2012**
  - Centralized EU system for approval of active substances
  - National/EU authorisation of products
  - Requirements for treated articles
  - Requirements apply for making available on the market and use: any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge;
  - Enforcement: national

# Toys – Directive 2009/48/EC

- **Obligations for manufacturers**

- Conformity assessment (compliance with essential requirements/harmonized standards (physical and chemical properties))  
→ draw up an EC declaration of conformity → affix CE marking
- Include traceability



- Instructions and safety information in a language
  - **Functional toys** “To be used under the direct supervision of an adult”
  - **Rollers** “Protective equipment should be worn. Not to be used in traffic”
- **Obligations of importers**



# Electronics – RoHS 2 and WEEE

## Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment



- **Obligation for manufacturers**

- Conformity assessment (compliance with essential requirements/harmonized standards (compliance with ban and restrictions on substances – Annex II)) → draw up an EC declaration of conformity → affix CE marking
- Include traceability

- **Obligations for importers**

## Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)

crossed-out wheelee bin

- **Obligations for Responsible Person**

- Technical documentation: product information file, PIF
- Before placing a cosmetic product on the EU market, the Responsible Person must notify the cosmetic product to the European Commission via the Cosmetic Products Notification Portal (CPNP)
- Labelling: contact details; the nominal content at the time of packaging; date of minimum durability; precautionary information; traceability; a list of ingredients (prohibited and restricted substances in Annexes!)
- Product claims

# Ecolabel – Regulation 66/2010

- **Voluntary environmental labelling**
  - Criteria related to energy consumption and pollution
  - Criteria exist for more than 20 product types: detergents, rinse-off, cosmetic products, footwear, textiles, paints, paper, computers, household appliances and wooden furniture, etc. (individual EU decisions)
- **National ecolabel voluntary standards:**
  - *Blaue Engel* in Germany
  - *Nordic Swan* in Nordic countries



# Questions?



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