

The EU model for controlling chemicals in products and articles

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The EU model for controlling chemicals in products and articles

- The EU legislation on hazardous chemicals in products
- Institutional arrangements for market surveillance & enforcement
- Incentives for reducing hazardous chemicals in products
- Member State examples
- Conclusions

EU Legislation on Hazardous Chemicals in Products

1. REACH & CLP as the foundation General Product Safety framework
2. The New Legislative Approach Method (e.g. Toys Safety)
3. Specific rules for consumer products (e.g. Cosmetics)
4. Rules covering end-of-product life
5. Other rules (biocide-treated articles, nanomaterials)

Directive 2001/95/EC on General Product Safety

- Catch-all legislation; applies where no other specific requirements in place
- Holds producers responsible for
 - Placing only safe products on the market
 - Informing consumers of any risks associated with the products they supply
 - Taking appropriate measures to prevent such risks
 - Being able to trace any dangerous products they place on the market

Directive 2001/95/EC on General Product Safety

‘safe product’ shall mean any product which, under normal or reasonably foreseeable conditions of use ... does not present any risk or only the **minimum risks compatible with the product’s use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons**, taking into account ... :

- (i) the **characteristics** of the product ... ;
- (ii) the **effect on other products**, where it is reasonably foreseeable that it will be used with other products;
- (iii) the presentation of the product, the **labelling**, any warnings and instructions for its use and disposal ... ;
- (iv) the **categories of consumers at risk** when using the product, in particular children and the elderly.

Directive 2001/95/EC on General Product Safety (3)

- Safety of a product to be assessed in accordance with:
 - Specific national rules if they exist
 - European standards
 - EU technical standards
 - Codes of good practice
 - State of the art
 - Expectations of consumers
- Member States responsible for market surveillance & enforcement
- Community Rapid Information System (RAPEX) established

The New Legislative Approach to Technical Harmonisation & Standards

- Established in 1985; updated in 2008
- Internal Market legislation aimed at free circulation of goods
- EU Directives set 'essential requirements' for categories of products
- European standard-setting body given mandate to set harmonised technical standards to meet the 'essential requirements'
- Draft technical standards adopted by European Commission thru comitology process & published in *Official Journal*

The New Legislative Approach Method (2)

- The European standard setting bodies
 - *Comité européen de normalisation (CEN)*
 - *Comité européen de normalisation en électronique et en électrotechnique (CENELEC)*
 - *European Telecommunications Standards Institute (ETSI)*
- If a product complies with the technical standards:
 - presumed to meet the essential requirements
 - can be labelled with CE marking
 - allowed to be sold anywhere within EU



The New Legislative Approach Method (3)

- The producer is responsible for:
 - ensuring that the products are designed and manufactured according to the specific requirements,
 - carrying out the assessment to show conformity with the requirements, and
 - having a EU declaration of conformity drawn up

The New Legislative Approach Method (4)

- Mutual recognition scheme (Regulation (EC) No 764/2008)
 - Products lawfully marketed in one Member State must be accepted in another Member State
- Requirements for Member State market surveillance and accreditation of conformity assessment bodies (Regulation (EC) No 765/2008)
- Common framework for the marketing of products (Decision No 768/2008/EC)

NLAM rules for specific products

- Toys Safety Directive
- Construction Products Directive
- Packaging and Packaging Waste Directive

Directive 2009/48/EC on Safety of Toys

- Sets essential safety requirements for toys (Annex II)
- Toys to be submitted to EC-type examination, carried out by accredited conformity assessment bodies
- Only toys complying with the essential safety requirements can be placed on the market
- Member States responsible for market surveillance, i.e., for ensuring that toys not in compliance are not marketed

Directive 2009/48/EC on Safety of Toys (2)

- Toys can be articles or mixtures, e.g. paints
- Use of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) prohibited in toys, but certain derogations allowed
- Substance-related requirements include:
 - Ban on nitrosamines and nitrosable substances in toys intended for use by children under 36 months
 - Ban on certain allergenic fragrances
 - Migration limits for heavy metals in various types of materials used in toys

Directive 2009/48/EC on Safety of Toys (3)

- Before marketing a toy, manufacturers must:
 - carry out a safety assessment of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present
 - assess the potential exposure to such hazards
 - keep technical documentation of the toy's design and manufacture, including:
 - the safety assessment
 - the safety data sheets (SDS) of chemicals used
 - description of the conformity assessment procedure followed, and
 - a copy of the EC declaration of conformity

Regulation (EU) No 305/2011 on construction products

- Sets essential requirements for any product marketed for permanent incorporation in construction works
- Overall objective: to ensure that reliable information is provided concerning the product's performance
- Life cycle view: the construction works must
 - **Not be a threat to the hygiene or health and safety** of the workers, occupants or neighbours, or
 - **Not have an exceedingly high impact on the environmental quality** or on the climate

Regulation (EU) No 305/2011 on construction products

- Annex IV lists 35 product areas to be covered by technical standards:
- Includes both 'articles' and substances/mixtures under REACH
 - E.g., adhesives, coatings, sealants
- REACH information required, i.e., Safety Data Sheets, any SVHC in concentration above 0,1% by weight
- Manufacturer must provide certificate of performance

Directive 94/62/EC on packaging & packaging waste

- Requires Member States to take measures to
 - prevent formation of packaging waste
 - Develop packaging reuse systems
 - Introduce systems for return and/or collection of used packaging to attain specific targets
- Sets essential requirements for design & manufacturing of packaging
 - Weight & volume to be kept to minimum needed for safety
 - Hazardous substances and materials to be minimised
 - Concentration limits for heavy metals in packaging
- First draft technical standards from CEN not accepted

Rules for specific products

- Cosmetic products
 - Focus on protection of human health
- Detergents
 - Focus on environmental protection (limits nutrients in water → prevent eutrophication)
- Paints and varnishes
 - Focus on prevention of ozone in the troposphere

Regulation (EC) No 1223/2009 on cosmetic products

- Defined as any substance or mixture intended to be put into contact with the human body for the purpose of cleaning, changing appearance, etc.
- Before placing a cosmetic product on the market, the persons 'responsible' must:
 - Carry out a safety assessment
 - Prepare a 'Cosmetic Product Safety Report' justifying why it is safe to use
 - Label it according to the rules

Regulation (EC) No 1223/2009 on cosmetic products (2)

- Provides 'positive lists' – substances authorised for use in specific types of cosmetics
- Also sets restrictions
 - 'Negative lists' of substances restricted or banned for use in cosmetics
 - Substances classified as CMR (unless special risk assessment)
 - Nanomaterials (labelling requirement)
- Member States must have market surveillance in place
- Note: REACH exempts substances used in cosmetics from health assessment because of Cosmetic Products Regulation's own assessment process

Regulation (EC) No 648/2004 on detergents

- Sets biodegradability requirements for surfactants in detergents & other cleaning products
- Focus on protection of aquatic environment
 - By limiting nutrients in water, helps prevent eutrophication
- Requires labelling if allergens present
- Exempts surfactants that are also biocidal active substances & used as disinfectants because authorised for that biocidal use thru the Biocidal Products Regulation
- Member States must have market surveillance in place

Directive 2004/42/EC on the limitation of VOC emissions in certain paints and varnishes

- Volatile organic compounds (VOCs)
 - formation of tropospheric ozone
 - negative effects on health & environment
- Sets maximum limits for VOC content for various categories of paints
- These paints can be marketed in the EU only if they:
 - comply with the limit values &
 - are labelled to show VOC content
- Member States must have market surveillance systems in place

Rules for end-of-life products

- Restriction of hazardous substances in electrical & electronic goods
 - Directive 2012/19/EC on waste electrical and electronic equipment (WEEE Directive) ; and
 - Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)
- Directive 2000/53/EC on end-of-life vehicles
- Directive 2006/66/EC on batteries & accumulators

Restrictions of HS in electrical & electronic goods

- Waste electrical and electronic equipment (WEEE Directive)
 - Producers responsible for separate collection & treatment of WEEE
 - Collection targets of 65% of EEE placed on market
- Restriction of certain hazardous substances in electrical and electronic equipment (RoHS Directive)
 - Limits use of certain hazardous chemicals in EEE so as to minimise environmental impact at end of product life (lead, mercury, cadmium, hexavalent chromium, PBBs, PBDEs)
 - Manufacturers must carry out conformity assessment & affix CE marking
 - Member States must have market surveillance systems in place

Directive 2000/53/EC on end-of-life vehicles

- Member States must
 - establish collection systems for waste arising from vehicles
 - ensure that end-of-life vehicles transferred to authorised treatment facilities, which shall issue the owner or holder of an end-of-life vehicle with a certificate of destruction
- Manufacturers & importers of vehicles must:
 - limit the use of hazardous substances in new vehicles (specifically lead, mercury, cadmium and hexavalent chromium)
 - design and produce vehicles in a way which facilitates and recycling, and
 - increase the use of recycled materials

Directive 2006/66/EC on batteries & accumulators

- aims to protect the environment and human health through reducing the amount of heavy metals in batteries, in particular mercury, cadmium, and lead, disposed of in mixed municipal waste
- prohibits sale of most batteries or accumulators that contain more than trace amounts of cadmium or mercury (>0.0005% mercury or 0.002% cadmium by weight)
 - Certain exemptions permitted, e.g., button cells containing less than 2% mercury
- sets labelling requirements & minimum collection targets
 - producers responsible for separate collection & treatment of waste batteries
- prohibits disposal of untreated batteries in landfills or incineration

Biocide-treated articles

- Two reasons to treat articles or materials with biocides:
 - To protect from degradation, e.g., deterioration due to fungus or other microorganism;
 - To deliver a biocidal product, e.g., a flea collar for a pet.
- Regulation (EU) No 528/2012 on biocidal products
 - Sets regulatory framework for authorisation of biocidal products and for mutual recognition of these authorisations within the EU
 - establishes at EU level a positive list of active substances that may be used in biocidal products
 - decisions not to include a product on the positive list serve as a negative list
 - Producers & formulators must apply to Member States for authorisation of the specific product

Nanomaterials

- Current EU policy – nanomaterials covered by REACH definition of ‘substance’
 - all nanoforms of a substance to be included in registration dossier
 - should be classified if they fulfill the criteria for classification on basis of having a hazardous property
- 2011 – Commission Recommendation on definition of ‘nanomaterial’

‘A natural, incidental or manufactured material containing particles ... where, for 50 % or more of the particles ... one or more external dimensions is in the size range 1 nm - 100 nm....’
- 2009 Cosmetic Products Regulation requires labelling of any nanomaterial content

Market surveillance & enforcement

- Member States responsible for implementation & enforcement in their territories
- Market surveillance required in:
 - General Product Safety Directive
 - New Legislation Approach, e.g., Toys Safety Directive
 - Cosmetics Regulation
 - Detergents Regulation
 - etc.

Community Rapid Information System (RAPEX)

- RAPEX ensures that relevant authorities throughout the Member States are rapidly informed whenever a dangerous product has been identified
- Weekly overviews of RAPEX notifications published on Commission website
- If necessary, Commission may adopt a formal Decision to ban or withdraw an unsafe product from the market or to recall it from consumers

Member State examples

- Spain

- The General Secretariat of Health and Consumers of the Ministry of Health, Social Services and Equality holds competence for hazardous substances in products
- Regional level -- the Autonomous Communities are competent for surveillance, inspection, control and sanctioning

- United Kingdom

- The Health and Safety Executive (HSE) holds competence for hazardous substances in products
- Local Authority Trading Standards Departments are responsible for market surveillance and enforcement

Policies for reducing hazardous chemicals in products

- Ecolabelling
- Green Public Procurement
- Integrated Product Policy
- Product Registers

Regulation (EC) No 66/2010 on the EU Ecolabel

- Aim: to promote products with a high level of environmental performance
- Criteria set out the environmental requirements that a product must fulfil in order to participate, considering the product's whole life cycle
- May not be awarded to goods containing substances or mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR)
- A product must comply with the criteria in order to bear the EU Ecolabel

Product groups with Ecolabel criteria

Cosmetics and Hygiene

- Rinse-off Cosmetic Products
- Absorbent Hygiene Products

Cleaning Up

- All-Purpose Cleaners and Sanitary Cleaners
- Detergents for Dishwashers
- Industrial and Institutional Automatic Dishwasher Detergents
- Hand Dishwashing Detergents
- Laundry Detergents
- Industrial and Institutional Laundry Detergents

Clothing and Textiles

- Textiles
- Footwear

Do-It-Yourself

- Paints and Varnishes

Electronic Equipment

- Imaging Equipment
- Personal Computers
- Notebook Computers
- Televisions

Coverings

- Wooden Floor Coverings
- Hard Coverings
- Textile Floor Coverings

Furniture

- Wooden Furniture

Gardening

- Growing Media* and Soil Improvers (*materials in which plants can grow, excluding soil)

Household Appliances

- Light Sources
- Heat Pumps
- Water-Based Heaters

Lubricants

- Lubricants

Other Household Items

- Bed Mattresses
- Sanitary Tapware
- Flushing Toilets and Urinals

Paper Products

- Converted Paper
- Newsprint Paper
- Printed Paper
- Copying and Graphic Paper
- Tissue Paper

Holiday Accommodation

- Campsite Services
- Tourist Accommodation Services

Green Public Procurement

- 2008 Commission Communication “Public Procurement for a Better Environment”
 - indicative target: by 2010, 50% of all public tendering procedures in the EU should be green
- 2012 study: only 26% of contracts signed in the 2009-2010 period by public authorities in the EU included all surveyed EU core GPP criteria
- 2015: calls for a stronger and more coherent implementation of GPP, including establishment of a European GPP network

Evaluation of the EU system for controlling chemicals in products

- Advantages:
 - REACH & other acts clearly put burden on industry to collect data on hazardous properties of substances they produce
 - New Legislative Approach relies on industry knowledge to develop technical standards
 - Responsibility of producers to show compliance with standards and to ensure product is safe for use
- Disadvantages:
 - Costly to producers to carry out required testing, especially for SMEs
 - Implementation is taking time

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Thank you!

Questions?

