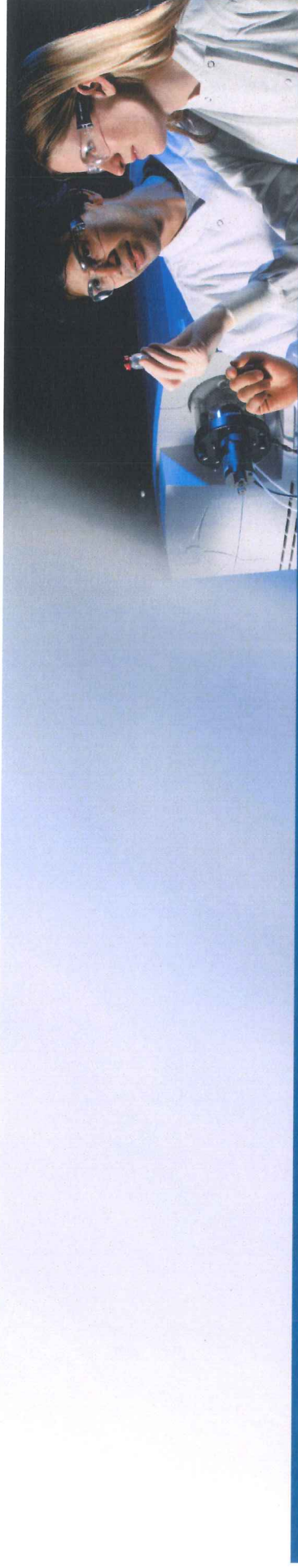




*Setting standards
in analytical science*



Ian Axford

Consumer Safety Team

Hazardous Chemicals and Consumer Safety

Presentation to Bureau of Standards Metrology & Inspection

Control of Chemical Hazards & Consumer Products



Setting standards
in analytical science

1. Horizontal legislation specifically for chemicals across a number of different industrial sectors or product types:
 - REACH Regulation (EC No. 1907/2006)
 - Biocidal Directive (98/8/EC)
2. Horizontal legislation generally for products that may contain chemical hazards:
 - General Product Safety Directive (2001/95/EC)
 - Packaging and Packaging Waste Directive (94/62/EC)
3. Sectoral legislation for sectors/products containing specific chemical hazards.
 - Cosmetics Directive (76/768/EEC)
 - Toy Safety Directive (2009/48/EC)
 - Restriction of Hazardous Substances Directive (2002/95/EC)

REACH Regulation



Setting standards
in analytical science

- Prohibition on manufacture or placing on the market of substances on their own, in preparations or in articles without registration (Article 5)
 - Health and Safety Executive (HSE)
- Registration and notification of substances in articles (Article 7)
 - HSE
- Duty to communicate information on substances in articles including SVHC (Article 33)
 - HSE & Local (consumer safety) authorities
- Prohibition on the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article for which Annex XVII applies [restrictions on the manufacture, placing on the market and use of certain dangerous substances and preparations and articles] (Article 67).
 - HSE, Environment Agency & Local (consumer safety) authorities

Substances in Articles



- The REACH Regulation requires that companies producing, importing or placing on the market have the relevant information on substances used in articles and identify substances intended to be released.
- Information held by the company as part of its QA programme.
- Chemical analysis of substances in articles where information is not available.
 - no formal requirements on which method and laboratories to use. However where-ever possible use existing standard methods of sampling and analysis. Consult experts in particular areas for appropriate tests.

REACH Regulation Annex XVII

27. Nickel CAS No 7440-02-0, EC No 231-111-4 and its compounds
1. Shall not be used:
 - (a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body.....
 - (b) in articles intended to come into direct and prolonged contact with the skin such as:
 - earrings,.....
- if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week.
- The standards adopted by the European Committee or Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.
 - EN1811
Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin

REACH Regulation Annex XVII



Setting standards
in analytical science

51. The following phthalates (or other CAS- and EINECS numbers covering the substance): bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7

Shall not be used as substances or as constituents of preparations, at concentrations higher than 0,1 % by mass of the plasticised material, in toys and childcare articles.

No methods or standards cited in legislation.

General Product Safety Directive



Setting standards
in analytical science

Where specific product legislation covers exactly the same ground as the General Product Safety Directive the specific legislation such as National Regulations will apply . Where there is no relevant specific product legislation, safety will be assessed using:

- Voluntary European Standards e.g. EN1400 Safety of Soothers
- Standards of the International Standards Organisations

Conformity with the criteria designed to ensure product safety (e.g. national legislation, standards referenced in the Official Journal of the European Union etc) will not bar the enforcement authorities from taking appropriate measures where there is evidence that despite such conformity the product is dangerous.

- **RAPEX**

Exchange of information on dangerous products sold in the EU.

http://ec.europa.eu/consumers/safety/rapex/index_en.htm

Cosmetics Directive & Toy Safety Directive



Setting standards
in analytical science

Cosmetics Directive

- Official methods & CEN Standards
- Good Manufacturing Practise (GMP) ISO 22716:2007

Toy Safety Directive

- CEN Harmonised Standards EN71 series
- Notified Bodies

science • expertise • quality • service • research • measurement • innovation • industry • science

Compliance & Enforcement



- Regulations are framed by Government Departments such as DEFRA & BIS.
- Enforcement of regulations is devolved to competent authorities such as HSE, EA or Local Authorities
- Burden on the manufacturer/supplier to demonstrate conformance to the Regulations.
- Use of accredited (UKAS) laboratories to certificate products to ISO 17025 & GMP.
- Surveillance testing by local (consumer safety) authorities using UKAS accredited laboratories and in particular public analysts.

Discussion



Setting standards
in analytical science

science • expertise • quality • safety • Service • research • measurement • innovation • science

science • expertise • quality • safety • Service • research • measurement • innovation • science