

*Market Surveillance in Practice – a practical overview of market surveillance of cosmetics on the Irish market*

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# EC (Cosmetic Product) Regulations 2004, as amended

- The sale of cosmetic products in Ireland is Regulated by the EC (Cosmetic Product) Regulations 2004, as amended
- Environmental Health Officers (EHO) are authorised to implement these Regulations
- EHOs are employed by the HSE

# Legislation – Main Points

- EC (Cosmetic Product) Regulations 2004, as amended
- Directive 76/768/EEC of 27 July 1976, as amended
- Labelling Requirements
- Enforcement / Penalties
- Illustrative List of Cosmetics
- Schedules – Long Lists of Prohibited/Restricted Substances

# Legislation – Main Points

- Misleading Claims & Signs
- Restrictions on Animal Testing
- Information to be retained by manufacturers
- Handling of Samples by Authorised Officers
- Prescribed Methods for Official Testing

# Legislation

- *'A cosmetic product shall not be sold by retail or otherwise supplied to a consumer unless it complies with the provisions of these Regulations relating to the placing of a cosmetic product on the market.'* **(Section 16)**



# Legislation

- *'a person shall not place on the market any cosmetic product which is liable to cause damage to human health when it is applied under -(a) normal conditions of use, or (b) conditions of use which are reasonably foreseeable', (Section 7(1))*

# Powers of Authorised Officers

- Section 19(3)
- At all reasonable times enter/inspect/search premises
- Seize and detain cosmetic products
- Take (without payment) samples of cosmetics



# Powers of Authorised Officers

- Inspect and take copies of any books/records/documents etc.
- Remove books/records/documentation
- Require a person to open any container or packaging / open a vending machine

# Importing (Section 13)

- Importers of cosmetics into Ireland from outside EU must notify the competent authority
- Importer will act as responsible person in EU
- Product Information file kept at EU address



# Routine Inspections by EHOs

- Anywhere where cosmetic products are sold:-
  - Pound Shops & Discount Stores
  - Pharmacies
  - Supermarkets
  - Hair dressers / Salons
  - Ethnic Shops
  - Toy Shops
  - Distributors / Wholesalers
  - Large multiples
  - Importers

# Some Issues of Concern

- Hydroquinone in Skin Lighteners
- Mercuric Iodide in Skin Lighteners
- Heavy Metals (Lead) in Kids Face Paints and Make-Up Sets
- Counterfeit products
- Significant Labelling breaches
- Referrals to IMB
- Other Issues

# Hydroquinone in Skin Lighteners

- Used as a skin lightening agent
- Has been linked with skin damage / cancer
- Not permitted in skin creams / lotions under Regulations

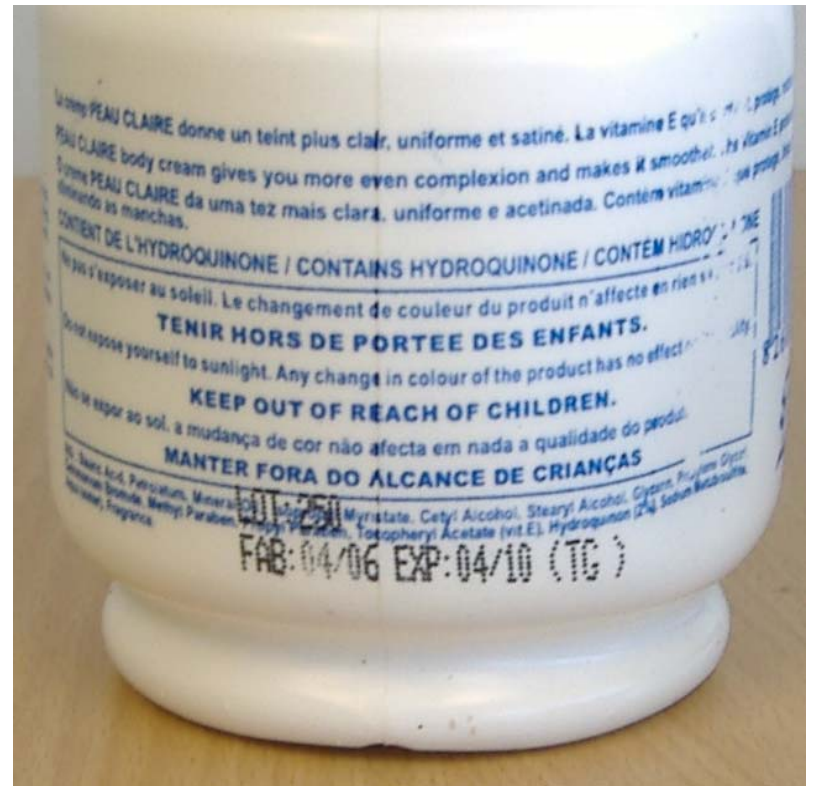


# Hydroquinone in Skin Lighteners

- Can cause ochronosis
  - Bluish black darkening
- Uneven Skin Tone
- Sometimes found on analysis even though not listed in ingredients
- Might be listed on website



# Hydroquinone in Skin Lighteners



# Mercuric Iodide in Skin Lighteners

- Not permitted in cosmetics
- A prescription only medicine
- Mercury absorbed through skin



# Mercuric Iodide in Skin Lighteners

- Can damage kidneys and central nervous system
- Can damage skin and cause rashes / blotchy spots
- Used for skin lightening / disinfecting properties

# Heavy Metals in Kids' Face Paints / Make up Sets

- Recently a number of products imported from outside the EU have been found to contain elevated levels of Lead
- Lead is not permitted in cosmetics under the Regulations
- Children are especially vulnerable
- A number of Rapex Alerts have been initiated for kids products containing Lead

# Heavy Metals in Kids Products



# Lead in Kids' Face Paints / Make up Sets

- Can effect children's mental development & intelligence
- Brain & Neurological damage
- Nerve disorders in adults

## Lead exposure

About 310,000 U.S. children ages 1 to 5 have elevated blood lead levels, which can accumulate over months and years and cause serious health problems.

### Effects on children

- Kids absorb up to 70 percent of lead, adults about 20 percent
- Often undetected; no obvious symptoms
- Can lead to learning disabilities, behavioral problems, malformed bones, slow growth
- Very high levels can cause seizures, coma, death

### Sources

- Lead-based paint, contaminated dust in homes built before 1978
- Drinking water from lead pipes
- Contaminated food
- Soil (lead does not biodegrade, decay)
- Toys\*

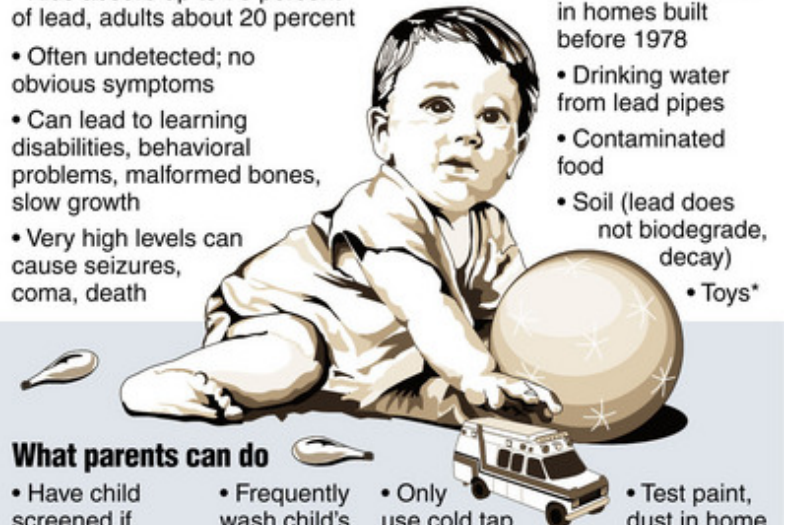
### What parents can do

- Have child screened if there is concern of lead exposure
- Frequently wash child's hands, toys, pacifiers
- Only use cold tap water for drinking, cooking
- Test paint, dust in home if it was built before 1978

\*Old toys with lead paint a known risk, but new toys from China now have come under scrutiny

Source: U.S. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

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# Counterfeit Products

- Some fake products on the market
- Recently large amounts of fake products were discovered by EHOs in Dublin Port
- Contaminated with Lead on analysis



# Significant Labelling Breaches

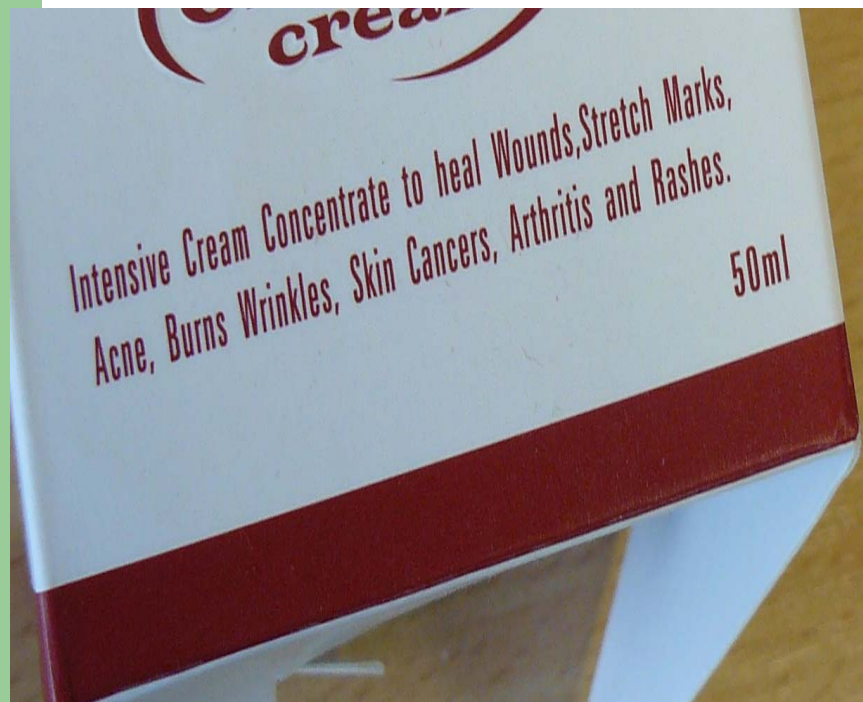
- The lack of an EU address on a product labels
- No list of ingredients
- No list of minimum durability
- A banned ingredient is openly listed on the product label
- Some products have more than one list of ingredients with conflicting information

# Referrals to IMB

- Products with Medicinal Claims are sometimes found in ethnic premises
- Topical corticosteroid Creams often sold under the counter



# Referrals to IMB



# Other Issues

- Dibutyl Phthalates in Nail Varnishes
- Diethylene Glycol (DEG) in Toothpastes
- Formaldehyde in Hair Straightening products above permitted levels
- p-phenylenediamine in hair dyes
- Methylidibromo Glutaronitrile in Skin Creams



# Most Common Reasons For Seizures by Environmental Health Officers

- Where a banned substance is listed on the list of ingredients:
  - Hydroquinone in skin lighteners
  - Mercuric Iodide
  - Methylidibromo Glutaronitrile in skin creams
- Where there are significant labelling breaches (e.g. no EU address, no list of ingredients etc.)
- Where a health risk is identified through a Rapex Alert

# Seizures by Environmental Health Officers

- Some products find their way onto to the market through suitcases/personal luggage from third countries
- Some products have been placed on the market without notification to the competent authority
- Many Products sourced from other EU states

# Cosmetics Surveillance in Ireland

- Samples are taken in line with a Cosmetic Surveillance Programme
- Samples are analysed in the Public Analyst's Laboratories
- Different parameters are tested each month
- Retailers/Distributors are notified of results
- Products Found to be unsafe may result in the initiation of a Rapex Alert

# Cosmetics Surveillance in Ireland

- 2010 Programme
  - Diethylene Glycol (DEG) in Toothpastes
  - Heavy Metals in Cheap Cosmetics
  - Heavy Metals in Children's Cosmetics
  - P-Phenylenediamine in Hair Dyes
  - Samples divided up between the Regions

# Sampling

- Sampling may be formal or informal
- Formal Sampling involves dividing samples into three identical parts
- Where formal sampling takes place one part is left with the retailer



# Rapex Alerts

- RAPEX is the EU rapid alert system for dangerous consumer products
- The Rapex System enables Member States to share information about dangerous products on the market
- Cosmetic Products are included in the Rapex System

# Generating Rapex Alerts

- Hazard/Contamination reports often precede Rapex Alerts
- Advantageous – these can be circulated to PEHOs around the country for prompt action
- In case of Lead currently  $>20\text{mg/kg}$  is unsatisfactory
- Rapex Alerts also emailed to various interest groups
- Rapex alerts are also listed on the NCA website
- [www.consumerconnect.ie/eng/](http://www.consumerconnect.ie/eng/)

# NCA Website

55 H+ Paris cosmetic products withdrawn - Windows Internet Explorer

http://www.consumerconnect.ie/eng/News\_+\_Research/Product\_Recalls/55H-paris.html

File Edit View Favorites Tools Help

55 H+ Paris cosmetic products withdrawn

Home > Consumer Property site > Corporate site > Contact Us

National Consumer Agency Putting consumers first

national consumer agency

Taking Action Guides + Multimedia News + About Us

You are here: Home > News > Research > Product Safety

**News + Research**

- News
- Volcanic Ash - Updates
- Product Safety
- Market Research
- Price Comparisons
- Other Research
- Latest Campaigns
- Newsletter

**55 H+ Paris cosmetic products withdrawn**

**12 August 2010**

The Department of Health and Children has issued an alert on safety grounds on:

- Harmonie
- Reparateur Strong Bleaching Treatment
- Harmonie Reparateur Crème Eclaircissant Extrême



These products were sold in Earth Angel, 81 Ilac Centre, Moore Street, Dublin 1.

Tests showed that both products contained levels of hydroquinone. Hydroquinone is a bleaching agent and has been found to be toxic and carcinogenic to the skin.

Frequent and long-term use of this product can pose a health risk.

**What to do**

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**Research**

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http://www.consumerconnect.ie/eng/

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# Rapex Alerts

- Ireland has initiated Rapex Alerts on a number of cosmetic products further to sampling in recent years:
- Kids Face Paints / Make up Sets (Lead)
- Skin Lightening Products (Hydroquinone)
- Hair Straightening Products (Formaldehyde)

# Rapex Alerts

- EHOs follow up on Rapex Alerts to see if products are on the market
- Random checks carried out around Ireland
- If affected products are found, products are removed from sale

# Legal Action

- Significant non compliances have resulted in the initiation of legal proceedings
- Regulations allow for €3000 fine per breach
- Or to imprisonment for a term not exceeding six months or both

# Legal Action

- Most recent prosecution taken in April 10
- Business Owner was convicted and fined for selling illegal skin lighteners
- Received a suspended prison sentence and fine





Thank You for Listening!