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Training seminar for distributors of cosmetic products

Introduction to market surveillance

Camden Court Hotel, 29th March 2012

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Healthcare Products Distribution

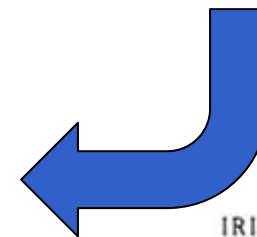
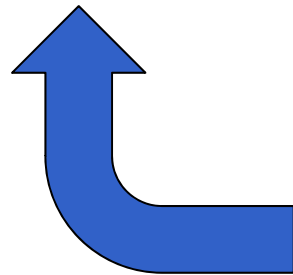
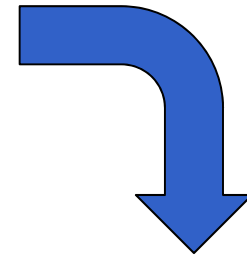
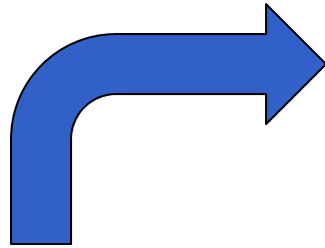
Overview

- What does it involve?
- Who carries it out?
- What happens at EU level?
- What does this mean for the Irish market?



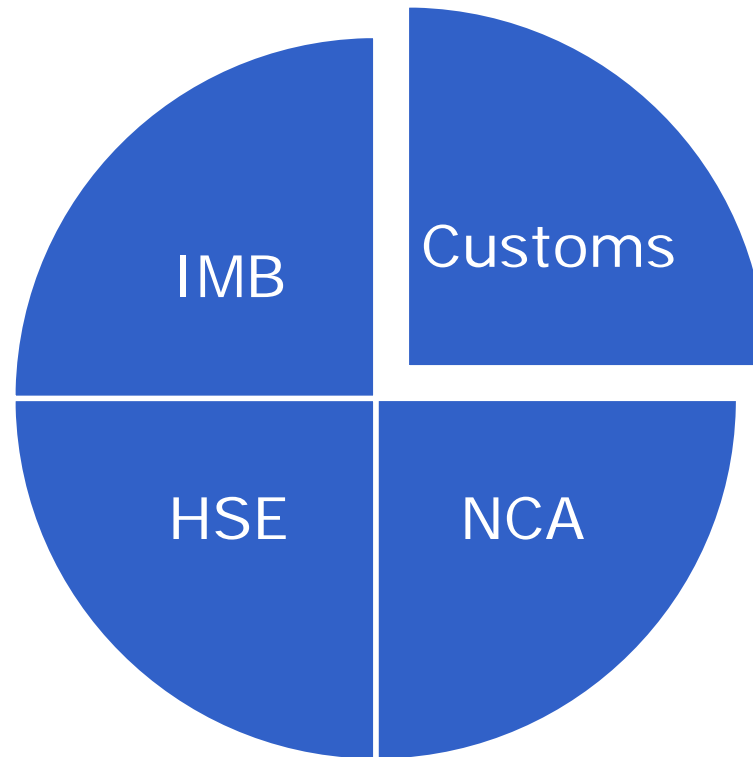
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What is Market Surveillance?



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Stakeholders Involved



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How does it work?

- National Cosmetics Surveillance Forum (NCSF) – IMB & HSE (EHO & PALS)
- Meet biannually
- Develop a market surveillance programme
- Proactive and reactive surveillance
- Proactive – risk based market surveillance plan
- Reactive – survey market for product that has been highlighted as posing a risk to consumers



Cooperation in market surveillance

Products identified within the NCSF

EHO samples product and sends to PALS

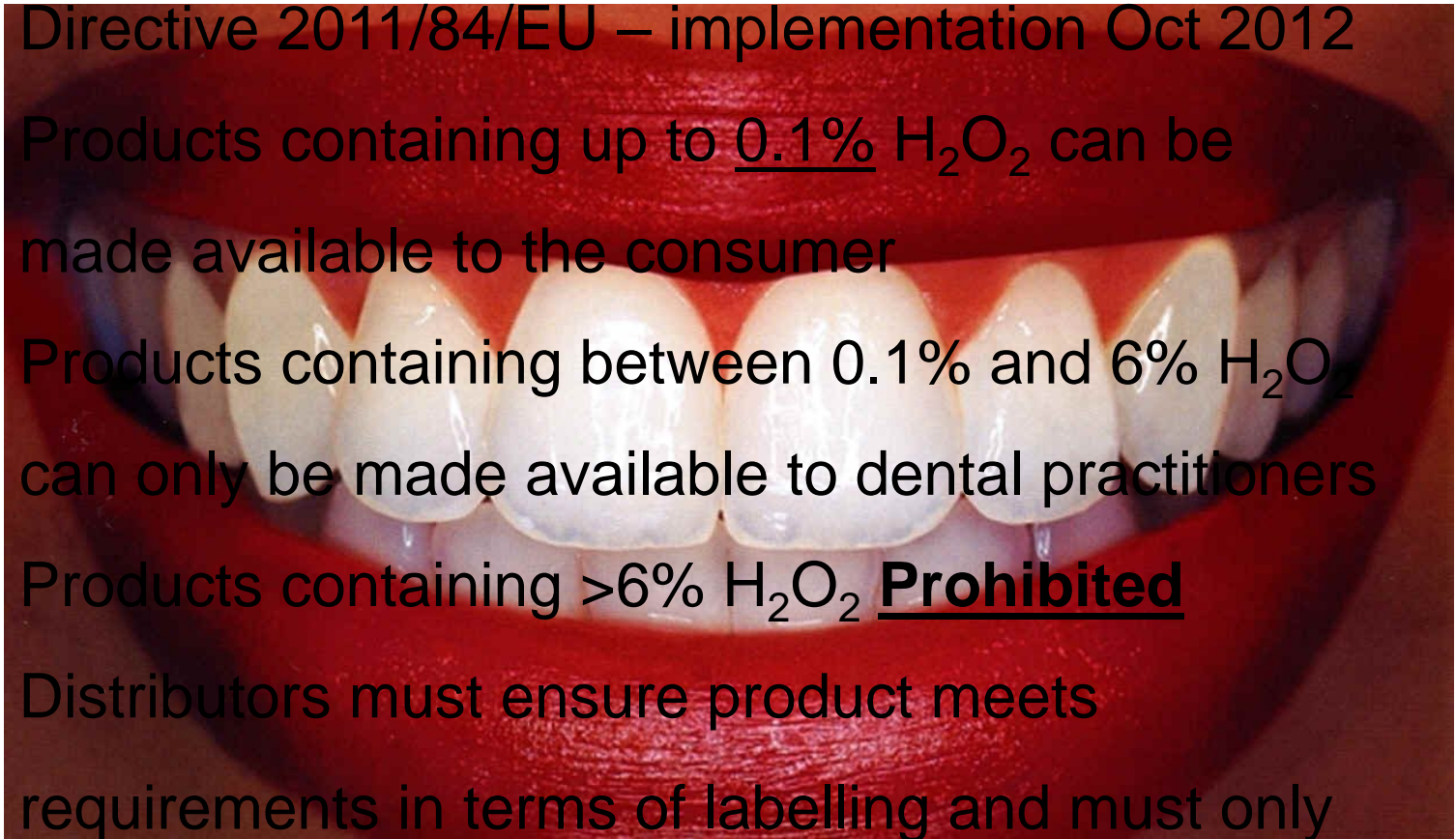
Lab report circulated to EHO and IMB

IMB risk assessment in cooperation with HSE and decide on future action

IMB to contact RP or Manufacturer
IMB/ EHO to contact Distributor

Key area for 2012 – tooth whitening

- Directive 2011/84/EU – implementation Oct 2012
- Products containing up to 0.1% H₂O₂ can be made available to the consumer
- Products containing between 0.1% and 6% H₂O₂ can only be made available to dental practitioners
- Products containing >6% H₂O₂ **Prohibited**
- Distributors must ensure product meets requirements in terms of labelling and must only supply to dental practitioners



Labelling requirements for $\text{H}_2\text{O}_2 > 0.1\%$

- Contains hydrogen peroxide
- Concentration of H_2O_2 present or released indicated as %
- *'Avoid contact with eyes, rinse immediately if product comes into contact with them'*
- Not to be used on a person under 18 years of age
- **To be only sold to dental practitioners.**
- For each cycle of use, the first use to be carried out only by dental practitioners



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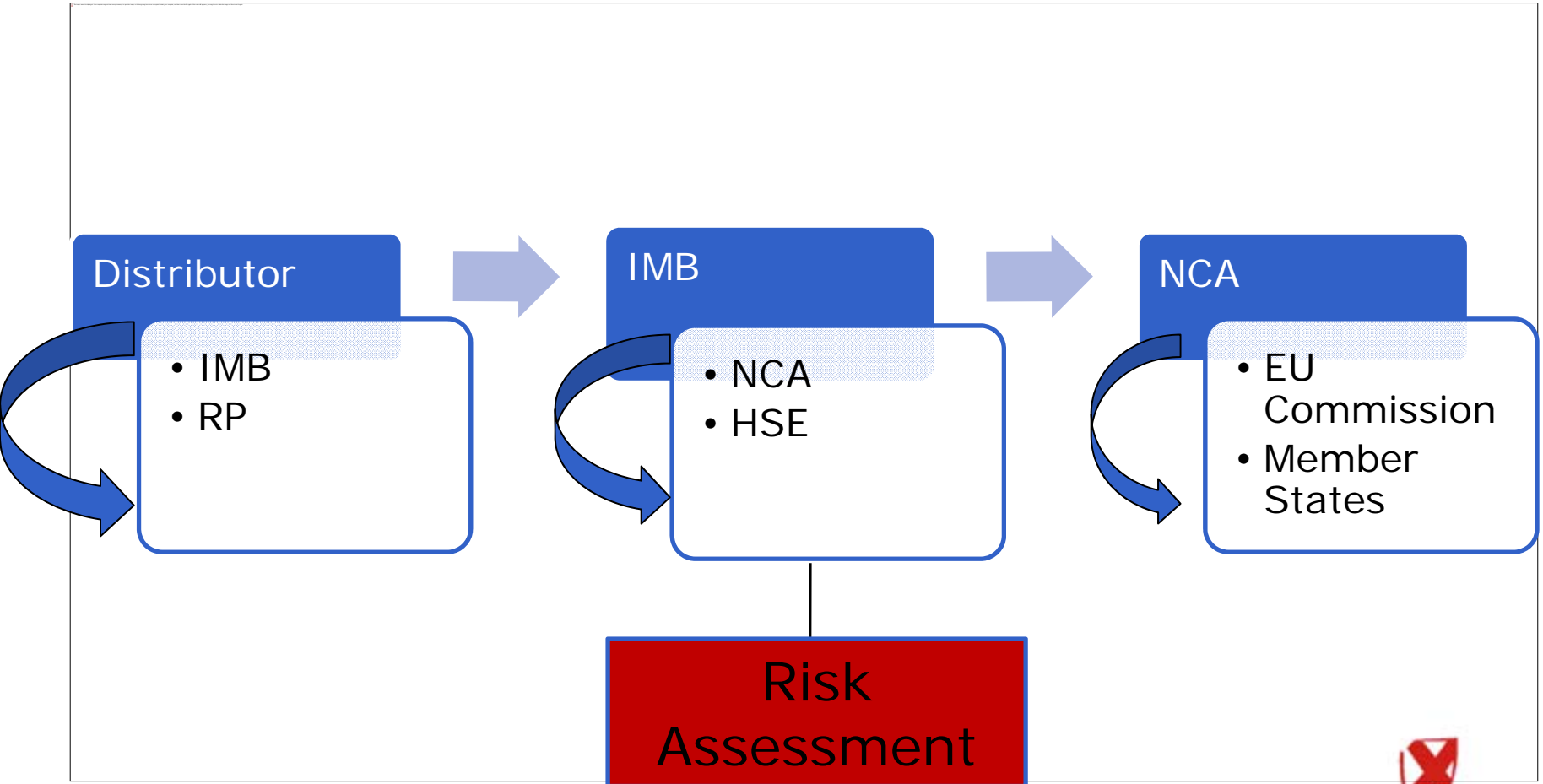
Stakeholders roles?

- Knowledge of legislation and your respective obligations
- Only place compliant product on the market
- Cooperate with the authorities for documentation and sampling requests as well as any corrective actions required



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Products posing a risk



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Products on the Irish Market

- If risk is deemed to be serious – RAPEX notification is completed
- Cooperative process involving
 - PAL report (CoA)
 - EHO completes RAPEX notification form and photographs product
 - IMB completes risk assessment form
- IMB sends all appropriate information to the NCA
- NCA notifies the EU Commission



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RAPEX ALERTS

- EU rapid alert system for products posing a serious risk
- Measures ordered by CAs and taken voluntarily by distributors and producers are reported by RAPEX
- National Contact Point in each Member State



national consumer agency
gníomhaireacht náisiúnta tomhaltóirí



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National Consumer Agency

- Manages Ireland's input to the EU RAPEX system
- Recalls notified through RAPEX are listed on the NCA website

<http://www.nca.ie/nca/product-recalls>

- Sign up to Product Recall RSS feed



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The screenshot shows a Windows Internet Explorer browser window displaying the National Consumer Agency (NCA) website. The address bar shows the URL <http://www.nca.ie/product-safety>. The page features a navigation menu with links for News, About us, and Contact us. A search bar is present with a 'Go' button. Below the navigation, there are several menu items: Your rights, Your money, Compare financial products, Tools & calculators, How to complain, and Product safety (which is circled in red). The main content area is titled 'Product safety' and includes a sub-header 'All products placed on the European market must be safe. Safety should always come first when you are thinking about buying a product. A safe product is one that does not cause harm when used in the normal way.' Below this, there are links for 'What we do', 'Product recalls', 'The CE mark', 'Business responsibilities', and 'What to do if you find an unsafe or dangerous product'. On the right side, there are two promotional boxes: 'Download our Toy safety booklet (PDF, 1.84MB)' and 'Check the make and model of your gas cooker'. The Windows taskbar at the bottom shows the start button, several open applications, and the system clock displaying 17:07 on 29th March 2012.

Product safety - National Consumer Agency - Windows Internet Explorer

http://www.nca.ie/product-safety

File Edit View Favorites Tools Help

Google consumer connect Search Share Sidewiki Sign In SnagIt

Favorites CPNP - Cosmetic Products N... Login ECAS password initialisation CosIng - Cosmetics - Health... http--www.pcs.agriculture...

Product safety - National Consumer Agency

News About us Contact us

Search Go

Your rights Your money Compare financial products Tools & calculators How to complain **Product safety**

Home > Product safety

Product recalls

Protect your child's safety

Banned products

Gas and electrical appliance safety

Product safety

All products placed on the European market must be safe. Safety should always come first when you are thinking about buying a product. A safe product is one that does not cause harm when used in the normal way.

[What we do](#)

[Product recalls](#)

[The CE mark](#)

[Business responsibilities](#)

[What to do if you find an unsafe or dangerous product](#)

Download our Toy safety booklet (PDF, 1.84MB)

Check the make and model of your gas cooker

Helpline lo-call 1890 432 432

Internet 100%

start Inbox - Mic... 2 Windows... 3 Internet... SI 0870 of 2... 5.MarketSur... EN Google 17:07

http://www.nca.ie/rss_pr.jsp

nca.ie News - Windows Internet Explorer

http://www.nca.ie/rss_pr.jsp

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nca.ie News

You are viewing a feed that contains frequently updated content. When you subscribe to a feed, it is added to the Common Feed List. Updated information from the feed is automatically downloaded to your computer and can be viewed in Internet Explorer and other programs. Learn more about feeds.

[Subscribe to this feed](#)

Dunnes Stores recalls soft toy farm animals

27 February 2012, 00:00:00 →

Dunnes Stores is carrying out a voluntary recall of a series of soft toys due to a potential safety issue which may cause the eyes to detach from the toys leading to a choking hazard.

The following toys are affected:

Mixed Soft Toy Farmyard Animals

- Style No. 62-78165, Black and White (cow), Yellow (chick), Pink (pig)
- Style No.62-78137 Black and White (cow), Lemon (chick), Pink (pig), White (lamb)

Furry Soft Toy Farm Animals

- Style No. 62-78135, Black and White (cow), Grey (donkey), Pink (pig)
- Style Number 62-78164, Grey (donkey), Pink (pig), Brown (horse)

Displaying 20 / 20

Sort by:

- ▼ Date
- Title

Online business notification process

- Producers and distributors have the option of notifying dangerous product via an online system
- Easier for businesses required to notify national authorities in a number of EU States at the same time.
- GPSD – Business Application Database
- Further information on NCA website:

http://corporate.nca.ie/eng/Media_Zone/news-archive/news-2009/New%20online%20notification%20process%20pages%20live.html



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https://webgate.ec.europa.eu/gpsd-ba/index.do

GPSPD - Business Application - Windows Internet Explorer

https://webgate.ec.europa.eu/gpsd-ba/index.do

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Google Search Share Sidewiki Sign In SnagIt

Favorites CPNP - Cosmetic Products N... Login ECAS password initialisation CosIng - Cosmetics - Health... http--www.pcs.agriculture....

Product safety - Natio... Home - IMB-Intranet GPSPD - Business Applic... GPSPD - Business A...

Help Languages About

Business Application

Welcome to GPSD-Business Application

Overview of the Application

For Producers and Distributors

Please note that in order to use the notification form, you need Acrobat Reader version **8.1.2** or higher installed in your computer.

1. [Read the manual](#)
2. [Download the form](#)
3. [Complete the form](#)

- + English
- + French
- + German
- + Italian
- + Spanish

For National Authorities

You can access the application by clicking [here](#)*

**Please note that only national authorities of Member States responsible for receiving notification submitted by business have access to this application*

Internet 100% NES BOARD

start GPSPD - Business A... Windows Explorer Inbox - Microsoft ... Microsoft PowerPoi... EN Google 11:50

Serious risk – RAPEX communication flow

EU Commission – circulates RAPEX alert to Member States NCP

NCA receives RAPEX alert

Sends to IMB for review

IMB risk assessment & circulates to EHOs & PALS as appropriate

EHOs carry out surveillance & report back to IMB

European Commission website

- http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm
- Weekly overview published every Friday



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EUROPA - Consumer Affairs - Safe Products - Microsoft Internet Explorer provided by Irish Medicines Board Explorer

http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

File Edit View Favorites Tools Help

Consumer Affairs

EUROPA > European Commission > DG Health and Consumers > Consumer Affairs > Consumer Safety: Products and Services > Unsafe products

Strategy and programmes Consumer Research Safety Rights Enforcement Redress Consumer empowerment Cosmetics Medical devices

RAPEX - Latest notifications

RAPEX is the EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers with the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms. Since 1 January 2010, as regards goods subject to EU harmonisation regulation, the system also facilitates the rapid exchange of information on products posing a serious risk to the health and safety of professional users and on those posing a serious risk to other public interests protected via the relevant EU legislation (e.g. environment and security). Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are reported by RAPEX.

Every Friday, the Commission publishes a weekly overview of the products posing a serious risk as reported by the national authorities (the RAPEX notifications). This weekly overview gives you all information on the product, the possible danger and the measures that were taken by the reporting country. (**Disclaimer - Important notice concerning re-use of RAPEX notifications**)

NEW

Enforcement is a top priority of the EU Consumer Policy Strategy 2007-2013. Both measures leading to RAPEX notifications and measures which come to the attention of the Commission and other Member States as reactions are indications of enforcement activity in the Member State concerned.

In order to give a better view on the overall level of enforcement, including the follow-up activities of the national market surveillance authorities, the Commission RAPEX team has decided to publish on the RAPEX website also the names of the countries that have found the notified product on their market and have taken appropriate measures (and have submitted a reaction to a RAPEX notification as a consequence).

Information about the reacting countries is available in the RAPEX weekly overviews in the column 'Products were found and measures were taken also in'. The Commission RAPEX team will publish reactions sent (from May 2009 onwards) to 2009 RAPEX notifications.

Have a look at **last notifications** (published on 23-03-2012)

Besides, you can use the search tool by typing one or more key words (e.g. toy,chemical) and then the system will display all notifications containing these words.

Limit search : From 2005 Search

2012

- Report 12 (published on 23-03-2012)
- Report 11 (published on 16-03-2012)
- Report 10 (published on 09-03-2012)
- Report 9 (published on 02-03-2012)
- Report 8 (published on 24-02-2012)
- Report 7 (published on 17-02-2012)
- Report 6 (published on 10-02-2012)
- Report 5 (published on 03-02-2012)
- Report 4 (published on 27-01-2012)
- Report 3 (published on 20-01-2012)

printable version

Media

- Speeches
- Press releases
- Events
- Campaigns
- Publications

Key Documents

- Consultations
- Reports
- Eurobarometers

Quick Links

- ADR
- ECC-Net
- Latest product warnings (RAPEX)
- National consumer organisations
- Tenders and grants

Related information

- Links
- News archive
- Video : Keeping European Consumers Safe : RAPEX

EU Activity in market surveillance

- Platform of European Market Surveillance Authorities in Cosmetics (PEMSAC)
- Representatives from Member States responsible for market surveillance
- Facilitate a cooperation framework
 - Coordination of activities
 - Exchange of information
 - Development of joint projects
 - Exchange of expertise and best practise



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PEMSAC subgroups

- **Analytical Methods Group**
 - Development of analytical methods
 - Shared database of analytical methods
 - Screening method for detection of preservatives
- **Market surveillance group**
 - Vigilance for cosmetic products
 - Guidance on communication of SUE
 - Focus on use of nanomaterials in cosmetics
 - Campaign on skin bleaching products



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Impact on our market

- Focus of PEMSAC influences Irish market surveillance programme
- Cooperation in method development
- Participation in EU campaigns and studies
- Network of support and expertise



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In Summary

- Stakeholders – important to ensure product is in compliance with the legislation
- Must ensure informed of regulatory updates
- Market surveillance – carried out by a number of authorities in Ireland
- Must cooperate with the authorities
- Through compliance that we can ensure safe product is available to the consumer



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