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Labelling Requirements and post market surveillance data

Cosmetics Information Day , September 15th 2010

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Overview

- Labelling Requirements
Directive 76/768/EEC Article 6
- Additional data for Product Information File
 - Claims substantiation
 - Data on undesirable effects
- Reporting of products posing a risk to the Competent Authority

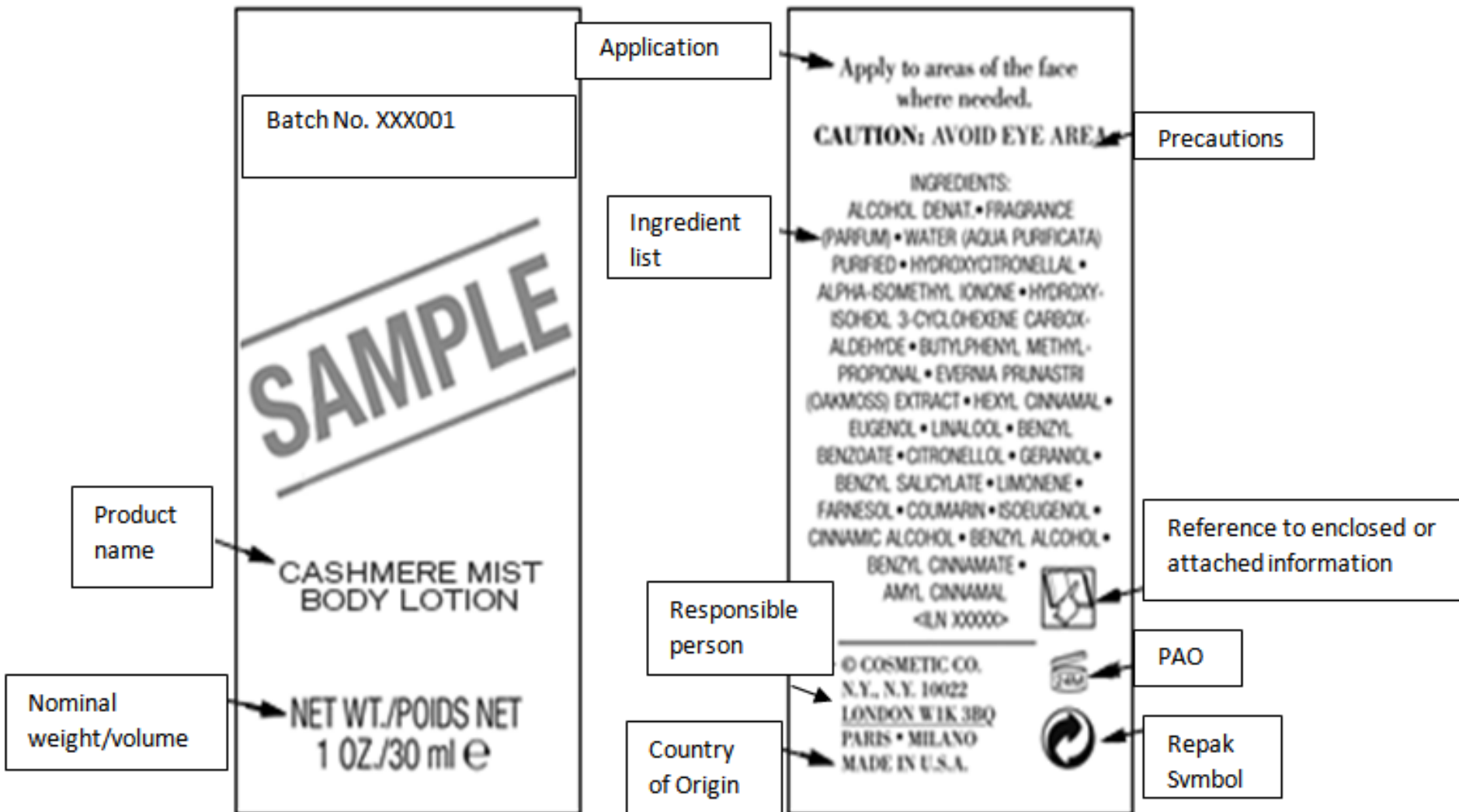


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Labelling Requirements – Article 6

	<i>LABELLING REQUIREMENTS</i>
1	Name and address of Responsible Person
2	Nominal content (weight or volume)
3	Date of minimum durability <u>or</u> Indication of PAO
4	Precautions for use (including those listed in Annex III to VI)
5	Indications for Professional Use Only products
6	Batch Number or equivalent
7	Function of product as applicable
8	Ingredient list – INCI nomenclature
9	Acceptable language of the MS where the product is being made available

Product Labelling – Article 6




CosIng Database

The screenshot shows the CosIng Database website in a Windows Internet Explorer browser window. The address bar shows the URL: <http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>. The browser's menu bar includes File, Edit, View, Favorites, Tools, and Help. The Favorites bar shows the current page. The website header features the European Commission logo and the text "European Commission Health and Consumers Cosmetics - Cosing". A navigation menu includes "Health and Consumers" and "CosIng". The main content area is titled "Simple Search" and contains a "Welcome to CosIng" section. This section explains that CosIng is the European Commission database for cosmetic ingredients and lists the following information it contains:

- "Cosmetics Directive" 76/768/EEC (Cosmetics Directive), as amended;
- [Inventory of Cosmetic Ingredients](#), as amended; and
- Opinions on cosmetic ingredients of the [Scientific Committee on Consumer Products](#).

Cosing also allows for search for the relevant CAS, ELINCS or EINECS numbers. Cosing includes all data since the adoption of the Cosmetics Directive in 1976. Therefore the current data are mentioned as "active" and the historical data as "not active". However, references to scientific opinions of the Scientific Committee on Consumer Safety are restricted to those published on the internet.

You can search for the name of a substance (small letters) as it is referred to in the Cosmetics Directive or for the name of an INGREDIENT (CAPITAL LETTERS), listed in the Inventory for labelling purposes, or for the name of a FRAGRANCE also in the Inventory by:

Name  or
CAS/EINECS/ELINCS #
Scope
Status

or go to the:

Claim Substantiation

Cosmetics Directive 76/768/EEC

Article 6, para 3:

- ... in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have...

Article 7a, para 1 (g):

- Proof of the effect claimed ... where justified by the nature of the effect or product



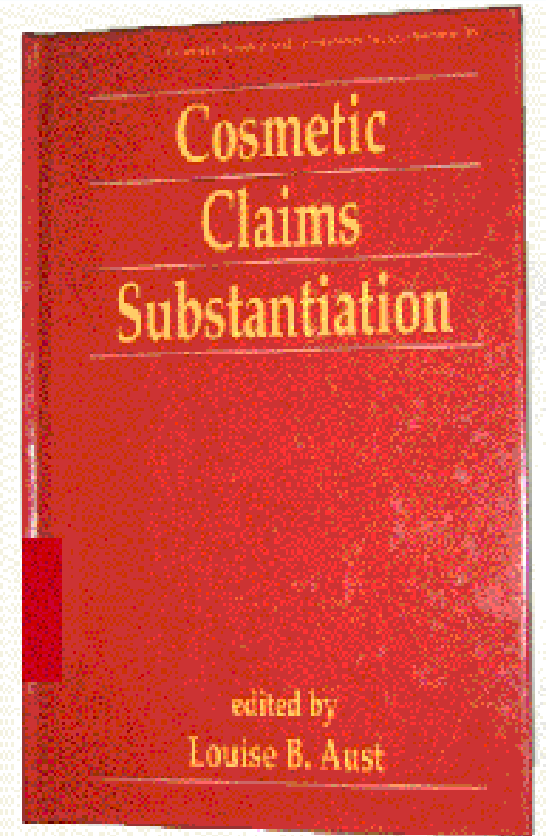
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Claim Substantiation

New regulation 1223/2009

Article 20, para 1 & 2:

- By July 2016 the Commission shall submit a report regarding the use of claims on the basis of the common criteria adopted



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Evaluation of Claims

- Sensorial approach
 - User testing – perception of product efficacy based on factors they can observe or feel
 - Trained panel of experts – profile of product drawn up based on predefined criteria
- Instrumental approach
 - Laboratory tests – for example skin hydration
 - Instrumental measurements – e.g. measurement of colour



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Communication of Undesirable effects

Cosmetics Directive 76/768/EEC

Article 7a, para 1 (f):

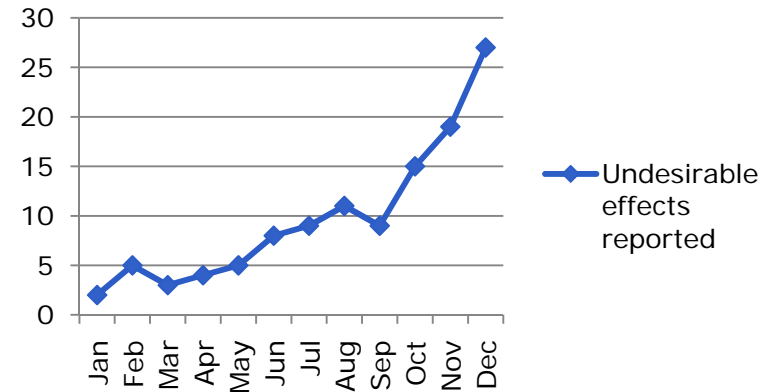
- keep existing data on undesirable effects

Article 7a, para 1 (h):

- Make information on undesirable effects easily accessible to the public

<http://www.european-cosmetics.info/site/index.cfm?SID=14075>

Undesirable effects reported



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Colipa Public Access Directory

The screenshot shows a Windows Internet Explorer browser window displaying the website www.european-cosmetics.info. The address bar shows the URL `http://www.european-cosmetics.info/site/index.cfm?SID=14075`. The browser's Favorites bar includes 'CosIng - Cosmetics - Health ...' and 'www.european-cosmetic...'. The website content features a header with the logo 'EUROPEAN DIRECTORY OF PUBLIC ACCESS' and the text 'Platform provided by Colipa'. A language dropdown menu is set to 'English'. The main heading is 'WELCOME'. A left-hand navigation menu lists: 'Welcome', 'Explanation', 'Instructions to the public', 'Company contact details', 'National Cosmetic Industry Associations', 'Member state competent authority contact details', 'Terms & Conditions', and 'Instructions to companies'. Below this menu is a 'Login' button with a lock icon. The main content area contains the text: 'Welcome to the European Directory for Public Access enabling you to make contact with cosmetic companies in the EU member states, Norway and Switzerland.' and 'Please note that the use of this directory is subject to the [Terms & Conditions](#)'. At the bottom, it states 'Copyright 2004 Colipa. All rights reserved' with three small square icons. The browser's status bar at the bottom shows 'Done' and 'Internet'.

Communication of Undesirable effects

New regulation 1223/2009

Article 23, para 1:

- responsible person and distributors shall notify the competent authority of all serious undesirable effects known to them



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Communication of Undesirable Effects

GPSD Article 5 (3)

Products posing a RISK to consumers must be reported to the competent authority

A product that has been placed on the market and has been found to be dangerous is notified (under Article 5(3) of GPSD) if:

- the product is intended for or likely to be used by consumers
- the product presents a risk to consumers

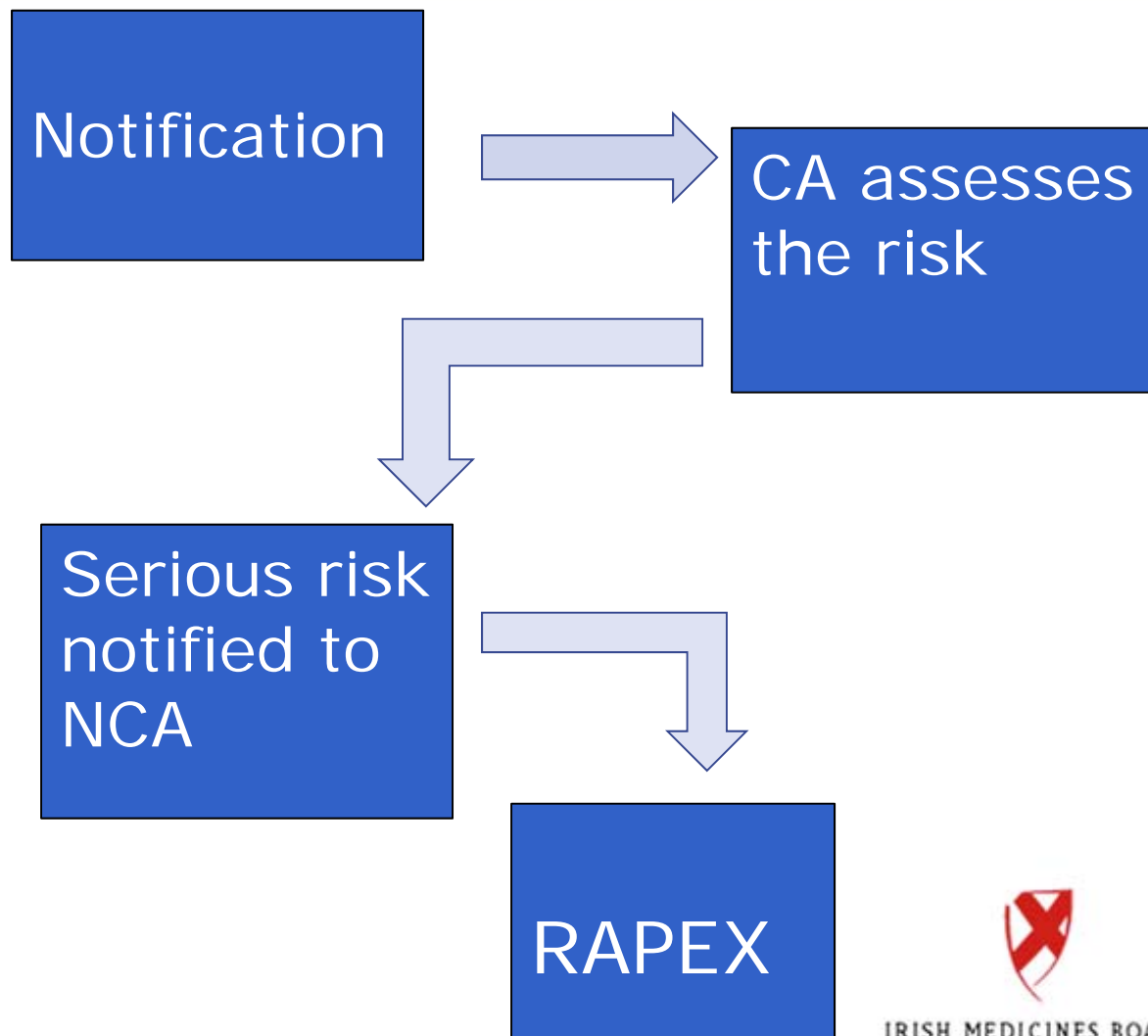


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Communication of Undesirable Effects

GPSD Article 5 (3)

GPSD Annex I –
conditions and
details for this
notification



national consumer agency



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RAPEX System

- Community Rapid Information System
- Established under Art 12 GPSD
- Member States legal obligation to notify the Commission when notification concerns:
 1. Consumer Product
 2. Subject to preventive and restrictive measures
 3. Serious risk associated with product
 4. Cross border effect



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Information Required for RAPEX

Information to be submitted for a serious risk:

- Product Identification
- Description of the risk
- Product traceability information
- Action taken



RAPEX
KEEPING EUROPEAN CONSUMERS SAFE



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Summary

- Labelling must comply with provisions of the Directive and related Statutory Instruments
- Product claims must be substantiated
- Undesirable effects must be investigated by the RP and included in the PIF
- Products posing a Risk must be reported to the Competent Authority so that they can assess the need for RAPEX notification



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