

Concept for Product Information about Cosmetics

Notification of (Frame) Formulations

Berlin, 10 September 2002
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What are cosmetics?

Examples:

- Soap
- Shower and bath products
- Hair shampoo, hair spray
- Tooth paste, mouth rinses
- Deodorants, perfumes
- Lipstick, make up, mascara
- Shaving products
- Hair colours



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Tuesday, September 10, 2002

**Baby died after drinking
IKW - shampoo**

**Mother called Poison Centre -
No information from company
was available!**

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The situation

- Cosmetics are present in every household
- Accidents with cosmetics are rare
- Statistics of 2000:
 - ✓ Germany 4,5 % (GIZ Nord, Göttingen)
 - ✓ Switzerland 4,7 %

Is notification to Poison Centres for all cosmetics really necessary?

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Tuesday, September 10, 2002

**BABY DIED AFTER
DRINKING
IKW-SHAMPOO**

**MOTHER CALLED POISON CENTRE!
NO INFORMATION FROM COMPANY
WAS AVAILABLE!!**

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The regulation in the EU

- Product liability
- Art. 7 (3) of Cosmetics Directive (76/768/EEC) requires industry to give information to competent authorities = Poison Centres

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The Frame Formulation System

- 105 frame formulations for cosmetics
- Notification of products to Poison Centres according to sheets developed by industry and EAPCCT
- Three different forms
 - ✓ product falls under frame formulation
 - ✓ product falls under frame formulation additional information required
 - ✓ full formula

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Example of a frame formulation

Frame Formulation No. 2.7 – 2000: Hair Shine Wax or Brilliantine

<i>Ingredients</i>	<i>max. levels (% w/w)</i>
Waxes and oils (e.g. mineral oils, silicones)	99
Emulsifying agents (e.g. ethoxylated fatty acids)	3
Parfum	3
Additional ingredients	2
Preservatives, antimicrobials, antioxidants	1
Cosmetic colorants	1

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Notification Type 1: Data to be declared

- Product data:
 - Trade name of the cosmetic product
 - Frame formulation number
 - Date of first marketing
- Company data:
 - Name and address of the company
 - Phone/fax numbers of contact person(s)

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Notification Type 2

- Additional information required
- exact concentration of certain ingredients, e.g.
 - ethanol or 2-propanol
 - antidandruff agents
 - Vitamin A and its derivatives
 - cationic surfactants
 - Solvents in hair sprays, hair colorants/bleaches, nail lacquers
 - Fluorine compounds in tooth pastes / mouth rinses

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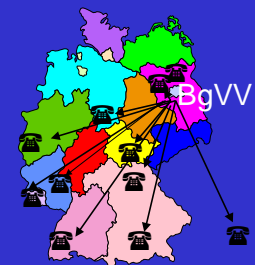
Notification Type 3

- Information required instead of a frame formulation number:
 - Product type (e.g. cosmetic chewing gum)
 - Qualitative and quantitative formula (concentration ranges accepted in some countries, e.g. 75 - 100 % or 0,1 - 1 %)

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German Situation

- Government accepted EAPCCT/COLIPA-system in 1997
 - ✓ system and frame formulae published in the Official Gazette (Bundesanzeiger)
 - ✓ competent authority: BgVV
 - ✓ notification to BgVV only
 - ✓ BgVV gives information monthly to 10 German and the Austrian PCC on CD-ROM



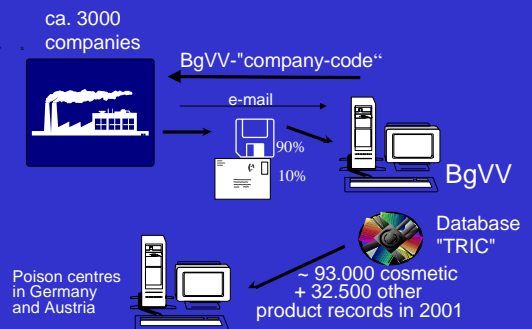
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Solution

- Submitting data on diskette by companies
 - ✓ refer data from their data base into the structure of the software
 - ✓ export information from the software into their data base
 - ✓ easy to handle

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Notification and distribution



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Situation in Europe

- Presentation of IKW-software („SYSDECOS“) to EAPCCT
- acceptance of software by PCC in Austria, Belgium, and other countries
- language problems
 - ✓ translation of frame formulations into national languages
 - ✓ adaptation of software to national languages

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Frame Formulations

- Frame formulations have been accepted by EAPCCT in 2000
- Publication of frame formulations by COLIPA
- Translation into national languages might be necessary
 - ✓ available in German, English, French

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Further Steps - EAPCCT

- Close cooperation with new EAPCCT Task Force
 - ✓ Modification of existing frame formulations
 - ✓ Amending of new frame formulations

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Further steps - Member States

- Software available in English, French, and German, but manageable by other countries
 - ✓ Translation into other languages possible
- **Advantage for companies**
 - ✓ data can be developed once and sent to authorities in all countries
- More acceptance necessary to bring system to all Member States

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