

# Documentation of Productdata for Risk Prevention

Basics for the Toxicological Documentation and Information Network in Germany



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## Structure

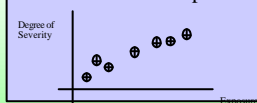
- Documentation of Health Impairment
- Documentation of Products
- German Regulatory Measures
- Existing Product Documentation Process
- Product Monitoring  
- General / Special Aspects
- Conclusions



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## Documentation of Health Impairment

- TDI-precursor project 1991-1993 EVA 
- Proper documentation of poisonings means !
- Documentation of health impairment vs. exposure



- Most important pre-condition
- Exact product/ substance involved



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## Needs for Product Data Access

- Having rapid access to product data involved
- Access to the product itself
  - Package
  - Label / Trade-name
- Access to centralised updated product data files on a high data maintenance level
- Assistance by computer network on high technology level



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## Corporate Documentation of Product Data

### National Concept in Germany:

The realisation of a powerful and sufficient product data base in the term of a toxicological information and data-network between industry, Federal Institute and PCCs

Based on:

- Co-operation between BgVV, PCC and industry in division of work
- Harmonised computer and data exchange concepts
- Harmonised updating and data maintenance concepts

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## Network Foundations in Germany

**1982:** Legislation in the Federal Republic of Germany laid the foundation of the Chemicals Act in a systematical assessment of

- New and existing chemicals due to EU regulation (evaluation by three federal agencies)
- Selected environmental relevant existing chemicals by a group of experts

**1990:** New Notifications were introduced

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### Risk Documentation by §16e Chemicals Law

- Para 1** Manufacturers /Distributors /Importers shall be required to inform the BgVV of trade name, details on composition, details on use, labeling first aid and emergency measures..... → **Product Data Base**
- Para 2** Any physician appointed for the treatment or assessment of the consequences of an illness suspected of being ascribable to the effects of hazardous substances must inform the BgVV with the appropriate data (age/ sex of the patient, cause of exposure, amount, symptoms established.....) → **Case Data Base**
- Para 3** The Information and Treatment Centres (Poison Control Centres -PCC-) shall report to the BgVV of any findings resulting from their activities in relation to substance-related illnesses ..... → **Information from PCC**

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### Product Documentation in Germany

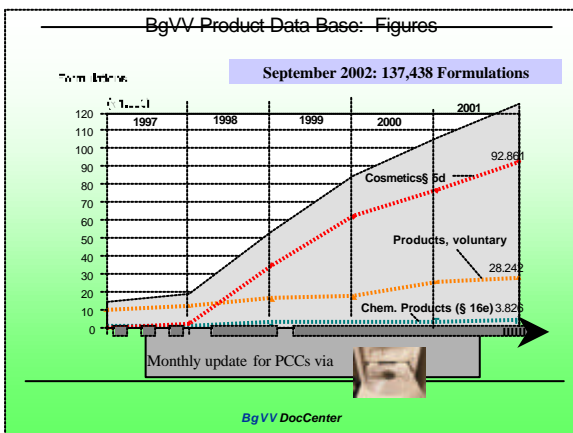
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### From Formulation to Data for Risk Prevention

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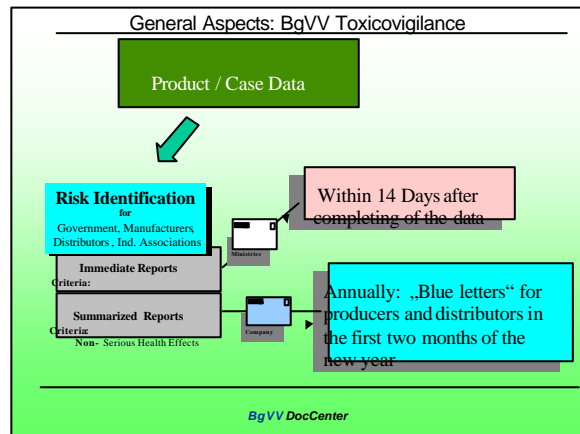
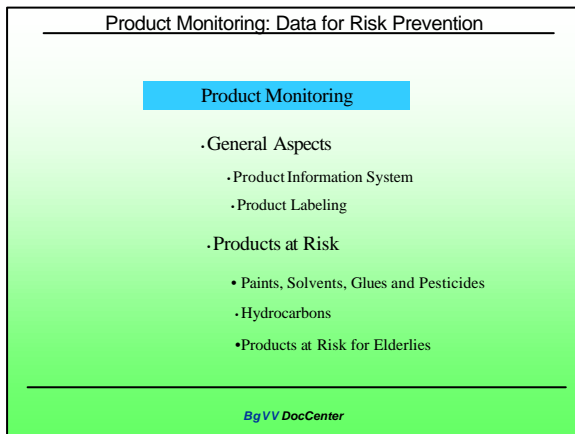
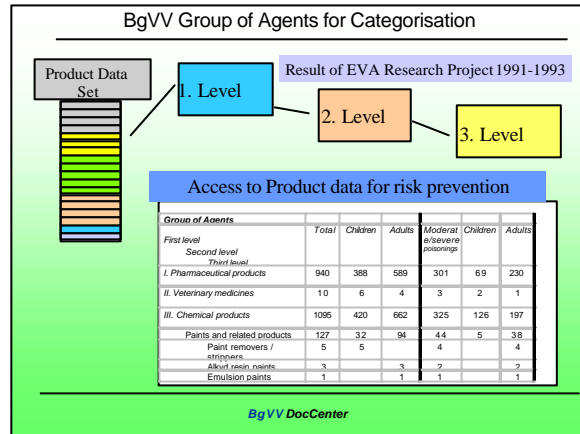
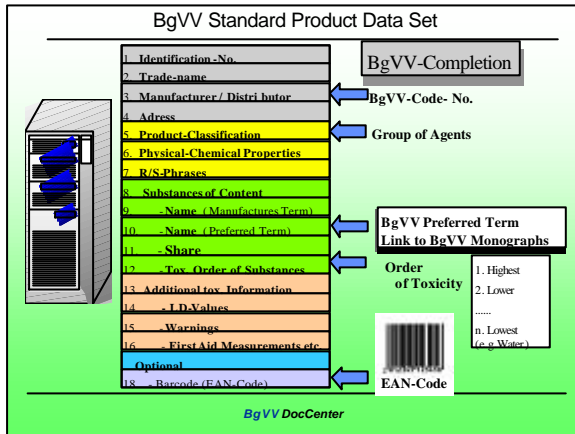
### Work-Flow of BgVV Product Data Collection

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### From Formula to the BgVV Product Data Set

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### 1998-2001: Immediate Reports for Risk Prevention

Year	Product	Substance of tox. relevance	Agegroup	Outcome	BgVV Proposal (P) and Results (R)
1998	Impregnation agent	Fluorinated HC	Adult	Death	P: Warnings R: Accepted
1998	Disinfectant	Quaternary Ammonia-compound (Detergent)	Elderly	Death	P: Information R: Labelling R: Accepted
1999	Draincleaner	Sodiumhydroxide	Adult	Burns	Nothing
1999	Solvent	Naphtha	Adult	Edema of the lung	Nothing
1999	Depilation-Creme	Thiodykolic acid	Adult	Scars	Nothing
1999	Disinfectant	Quaternary Ammonia-compound (Detergent)	Elderly	Death	V: Information, Labelling
1999	Industrial Cleaner	Sodiumhydroxide	Infant	Burns	Nothing
1999	Drug	Dimenhydrinate	Toddler	Death	P: Warnings R: Accepted
2000	Creme Bath	Detergent	Elderly	Death	Nothing
2000	Lampoil	Paraffine	Infant	Severe pneumonia	P: Prohibition R: Accepted, Substitutes
2001	Disinfectant (Detergent)	Alkyamine	Elderly	Death	P: Information
2001	Essence for hair	Atropa belladonna	Adolescent	Death	Substitution
2001	Drug (Tea)			depression	

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### 1998-2001: Annual Summarized Reports for "Responsible Care"


Year	Cases	Manufactures	Products
1998	112	57	88
1999	63	37	54
2000	204	70	159
2001	408	139	287

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### General Aspects: Product Labeling

**Needs of Consumers**

„Easy to Identify Area“ for tradenames on labels of packages or containers, where product - information for exact identifying of the products formula is placed.



**Solution:**

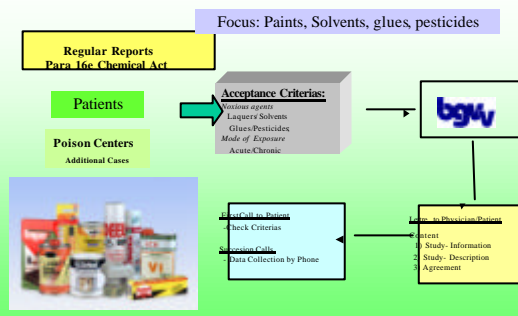
CEN- standardization project with an definite product identification area on product labels close to the bar-code with a symbol  for orientation.

The German draft will be submitted for CEN in 2002

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### Products at Risk: Example BgVV Human Exposure Study

Focus: Paints, Solvents, glues, pesticides



Regular Reports Para 16c Chemical Act

Patients

Poison Centers Additional Cases

Acceptance Criteria:  
 - Organic solvents  
 - Lacquers Solvents  
 - Glues Pesticides  
 - Mode of Exposure  
 - Acute/Chronic

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Acceptance Criteria:  
 - Study- Information  
 - Study- Description  
 - Agreement


Check Criteria:  
 - Acceptance Criteria  
 - Check Criteria  
 - Selection Calls  
 - Data Collection by Phone

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### Products at Risk: Example Dangerous Lampoils

Paraffines / Kerosine : Physico- chemical Data

- Very **low** viscosity ( $\leq 2 \text{ mPa} \times \text{s}$ )
- Low surface tension ( $\leq 25 \text{ mN/m}$ )
- Low volatility ( $\leq 5 \text{ kPa}$ ), contrast to literature!
- Minor water solubility
- Short-chain composition ( $\leq \text{C}16$ )




- Product data shows a high risk of aspiration
- EC- Prohibition brings substitutes to the market (Rape-oil)

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### BgVV Postmarketing Study on Lampoils

- For 3 years almost all German Children's Hospitals (450) document their Lampoil Ingestions
- The 2 years results (01.03.2002 to 28.02.2003) of 164 cases show
- that the change of the formulation will lead to a decrease of the risk of aspiration after lampoil ingestions!



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### Products at Risk: Elderly People

**Problem:**

Some cases of mistaken, but fatal, ingestion of chemical preparations, namely detergents and disinfectants, have shown that elderly persons may represent a population at risk, particularly for confused persons.


**Activities**

With a round table of experts the BgVV discussed products at risk and appropriate measures to be initiated for risk reduction. For personnel in hospitals/nursing homes/ elderly residential tailor made information was spread in five different languages.

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### Conclusions

- The Process of Documentation/Assessment of Health Impairment
  - needs a co-operated Product Documentation System,
  - supported by German Regulatory Measures .
  - This is the TDI Project with the partners German PCCs, BgVV and Industry,
- based on data exchange in division of work!



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Thank You for Your Interest

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Questions welcome!



Guten Appetit!

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