Performance Chemicals for Coatings, Plastics and Specialties

Colourants for Polymers –

Global Compliance with Governmental and Industry Standards and Responsible Care of Colorants for the Polymer Industry –

a Topic growing in Complexity and Relevance

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7. – 9. February 2007 - Convention on Colourants

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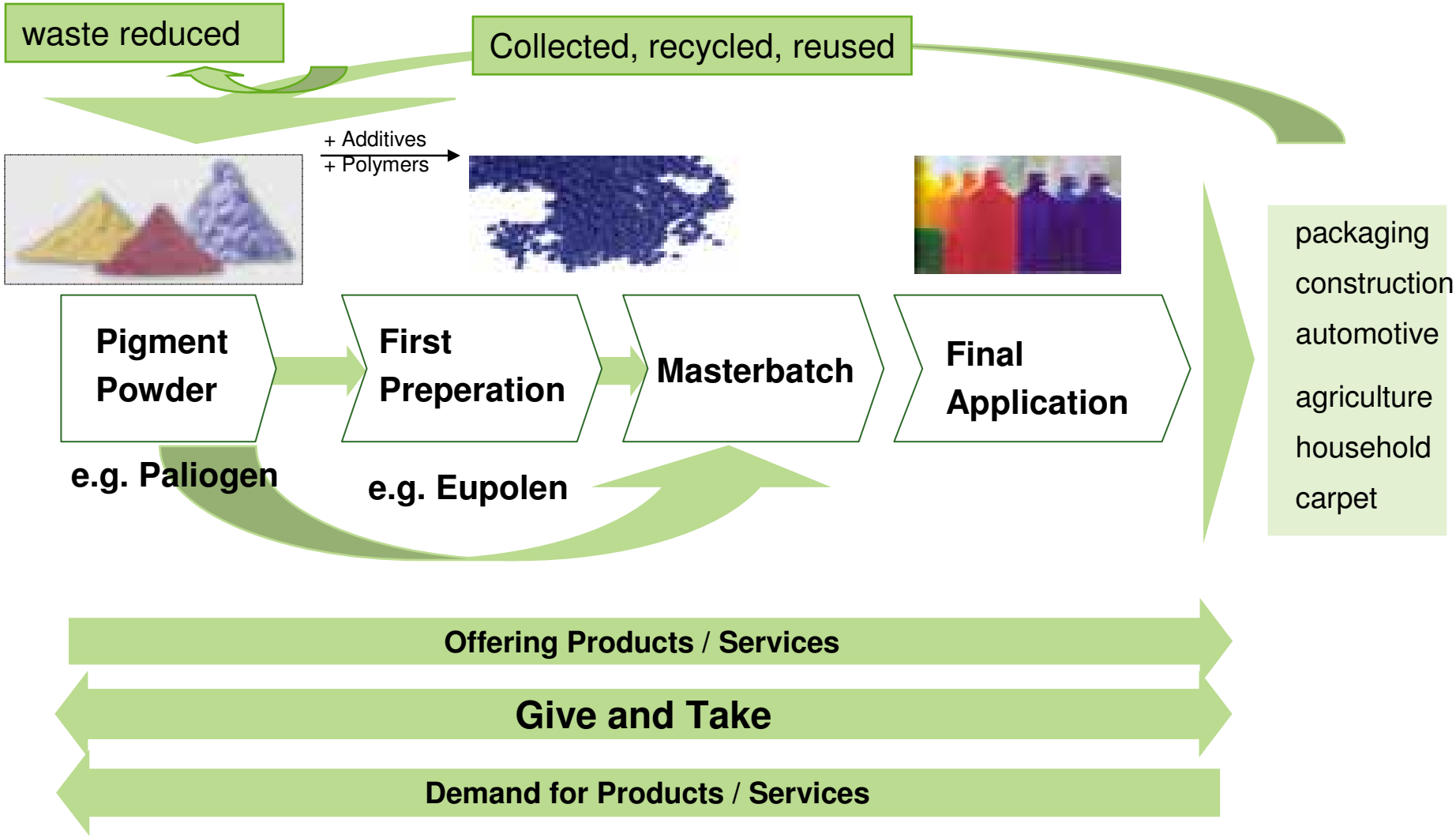
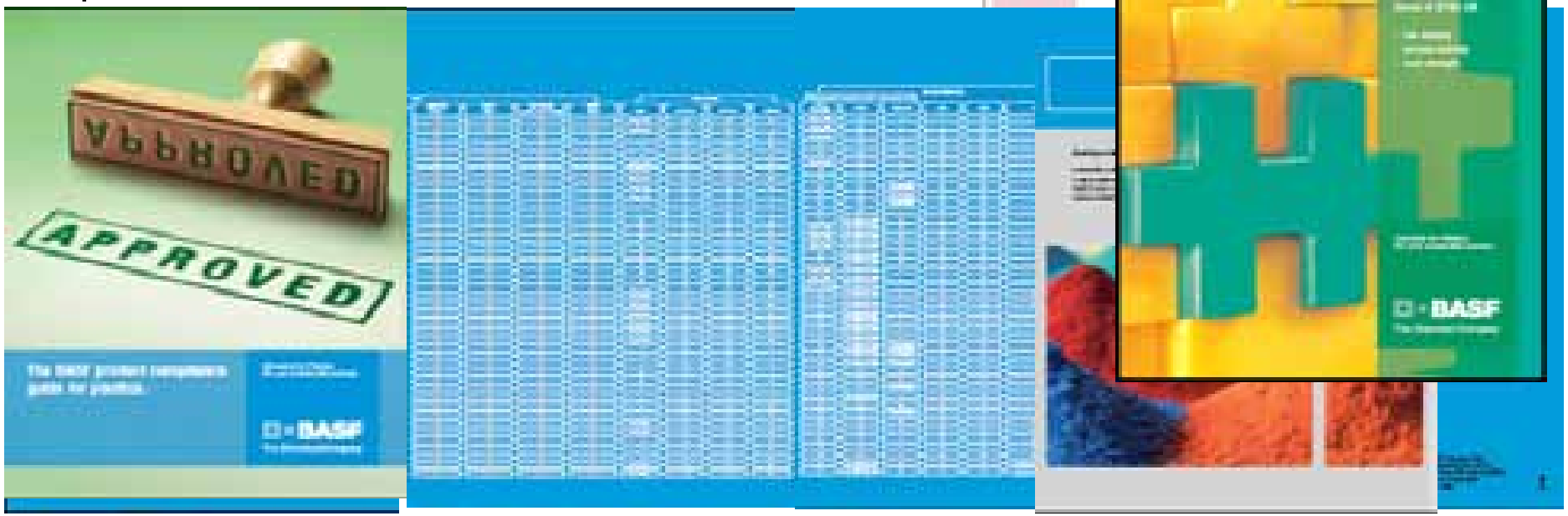
Performance Chemicals for Coatings, Plastics and Specialties

Plastics Industry – Life cycle, value chain



Volantary information of companies

- Information on the web (e.g. www.basf.com/pigments)
- Technical information
- Brochures
- Data Sheet on product safety
- e-commerce platform
- Quality management (e.g. ISO certificates)
- Expert service



Requirements in detail

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Product - Legally required:

- Safety Data Sheets
- Classification and Labelling
- Transport
- Registration in different national chemical inventories

Application - Requirements

- Packaging
- Food
- Toys
- Automotive etc.

Environment and Health requirements

- Toxicology and Eco-toxicology
- Discussion on heavy metals
- Specifications of customers
- Responsible Care
- Sustainable Development

Topics

1. **Registration**
2. **Heavy metals**
3. **Specific requirements**
4. **Company specifications**
5. **Food**
6. **Toys**
7. **Sustainable development and responsible care**

Substance inventories

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Many countries and regions have a chemical legislation including substance inventories for chemicals:

USA	TSCA
Canada	DSL
EU	EINECS
Japan	ENCS
China	IECSC
Australia	NICNAS
and others	

Chemical products containing substances which are not listed in the relevant inventory must not produced or market in the country.

New legislation REACH in Europe

EINECS is a list of "old" substances - marketed before 1980. It does not contain data on hazard of substances.

REACH

shall replace EINECS.

shows for each substance

- **Toxicological and eco-toxicological properties of the substances**
- **Each manufacturer/importer with the correspondent amounts**
- **Measurements for safe handling and exposure data of the substances**

Authorisation possible

Each manufacturer in the EU or Importer into the EU must register all components (substances) of his products.

If not – loosing right to market their chemicals in Europe:

"No data – No market"

Required data in Europe

	§ 7 > 1 t/a	§ 7a(2) No. 1 100-999 kg	§ 7a(2) No. 2 10-99 kg
0.2.10/20 Identity of Notifier/Manufacturer	x	x	x
0.3.00 ELINCS	x	x	x
1. Identity of the substance			
1.1.00 General description	x	x	x
1.1.05 Composition of the substance	x	x	x
1.3.10 Identity of the substance	x	x	x
1.3.20 Impurities/by-products	x	x	x
1.3.40 Auxiliaries	x	x	x
1.3.50 Spectral data	x	x	x
UV/VIS and IR	x	x	x
NMR or MS	x	x	x
1.3.60 GC/HPLC	x	x	x
1.4.00 Methods of detection and determination	x	x	x
1.5.10 Composition of the test substance	x	x	x
2. Information on the substance			
2.0 Production (Process/exposure)	x	x	x
2.1 Proposed uses	x	x	x
2.2 Estimated production (Manufacture/Importation)	x	x	x
2.3.00 Safety recommendations	x	x	x
2.4.00/2.5.00 Emergency measures	x	x	x
2.6.00 Packaging	x	x	x
3. Physico-chemical properties			
3.0.00 State of the substance	x	x	x
3.0.10 Melting-point	x	x	
3.0.20 Boiling-point	x	x	
3.0.30 Relative density	x		
3.0.40 Vapour pressure	x	x	
3.0.50 Surface tension	x		
3.0.60 Water solubility	x	x	
3.0.80 Partition coefficient	x	x	
3.0.90 Flash-point	x	x	x
3.1.00 Flammability	x	x	x
3.1.10 Explosive properties	x		
3.1.20 Self-ignition temperature	x		
3.1.30 Oxidizing properties	x		
3.1.50 Granulometry	x 1)2)		

	§ 7 > 1 t/a	§ 7a(2) No. 1 100-999 kg	§ 7a(2) No. 2 10-99 kg
4. Toxicological studies			
4.1 Acute toxicity			
4.1.11 Administered orally	x	x6)	x6)
4.1.20 Admistered by inhalation	x		
4.1.30 Administered cutaneously	x		
4.1.50 Skin irritation	x	x	
4.1.60 Eye irritation	x	x	
4.1.70 Skin sensitization	x	x	
4.2.10 Sub-acute/sub-chronic toxicity	x		
4.3 Mutagenicity			
4.3.10 Bacterial test	x	x 7)	
4.3.20/4.3.30 Non-bacterial test	x12)		
4.4 Test for reproduction toxicity	x2)		
4.5.10 Assessment of the toxicokinetic behaviour	x		
5. Ecotoxological studies			
5.1.01 Acute toxicity for fish	x		
5.1.02 Acute toxicity for daphnia	x	x	
5.1.03 Growth-inhibitor test on algae	x		
5.1.06 Bacterial inhibition	x		
5.2.11 Ready biodegradability	x	x	
5.2.21 Hydrolysis as a function of pH	x3)		
5.3 Adsorption/Desorption	x2)		

Topics

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Heavy metals - Essential Trace Elements

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Element	Body content mg/70 kg	Needed dayly mg	Function	Results of lack of element
Zink	2.300	20	Contained in over 100 enzymes	spectacular deficiency symptoms, up to death
Iron	4.200	18	Hemoglobin for oxygen transport	Iron anemia, up to death
Manganese	20	4	different Enzymes	Sterility
Copper	100	3	different Enzymes	Hair loss, Hypercholesterinamie
Chromium	20	ca. 0,01	Enzymw, Glucosetoleranzfaktor	Diabetes
Molybdenum	5	ca. 0,1	decontamination function	kidney damage, up to death
Cobalt	3	0,01	Vitamin B 12	Anemia
Nickel	10	ca. 0,1	Enzymes	Growth disturbances, anemia
Vanadium	20	ca. 0,1	Metabolism, Karies decreasing	Growth inhibition
Arsenic	14	-	Growth-promoting	Growth disturbances
Tin	30	-	Hormone Gastrin	Growth inhibition

Environmentally relevant heavy metals – Lead, Cadmium and Mercury compounds

- Endanger Health
- Bioaccumulating
- relatively easily volatile
- Enrichment in the soil
- Uptake with food

Also other heavy metals can become toxic for humans and environment, but only with clearly higher concentrations

Colorants containing heavy metals

BASF	Inorganic	Constitutionally contained heavy metal(s)
Sicotrans	Ironoxide Pigments	Iron (Fe)
Sicotan	Nickeltitanium-Pigments	Nickel (Ni), Antimony (Sb)
Sicotan	Chromtitanium-Pigments	Chromium(III) (CrIII), Antimony (Sb)
Sicopal	Bismutvanadats-Pigments	Bismut (Bi), Vanadium (V)
Sicopal	Spinels on basis of Metaloxides	Iron (Fe), Cobalt (Co), Nickel (Ni), Chromium(III) (CrIII), Zink (Zn)
Sicomin	Leadchromat-Pigments	Lead (Pb), Chromium(VI) (CrVI), Molybdenum (Mo)
	Organic	
Heliogen	Phthalocyanin-Pigments and Dyes	Copper (Cu)
Neozapon	Metalcomplex-Dyes	Chrom(III) (CrIII)

EU-Regulations concerning heavy metals

- EU „Cd prohibition directive“ 91/338/EWG

  Prohibition of application of Cd pigments in plastic material

- EU-“package directive“ 94/62/EG

  Sum of Cd, Pb, Hg und Cr(VI) max. 100 ppm

  Use of Cadmium- und Leadchromate Pigments forbidden

- EU-“Old vehicle directive“ 2000/53/EG

  Prohibition of Cd, Pb, Hg und Cr(VI) in vehicles

- RoHS (2002/95/EC) and WEEE (2002/96/EC) directives

  Regulation on heavy metals in electrical and electronic equipment

European "RoHS" and "WEEE" Directives - Legislations: Facing the Environmental Problem of Electrical and Electronic Equipment

Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE).

- Designed to tackle the fast increasing waste stream of EEE and to prevent the generation of hazardous waste going into landfill and incineration.
  In 1998, Waste of Electronic and Electrical Equipment (WEEE) in European Member States (MS) was more than 6 million tons.
- RoHS requires the substitution of various heavy metals (lead, mercury, cadmium and hexavalent chromium) and brominated flame retardants (polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE) in new EEE put on the market from 1 July 2006

Non governmental regulations – Heavy metals and Ecolabels

- European Ecolabel
  - No colorants with Cd, Pb, Hg, Cr(VI), As
- German Ecolabel
  - No colorants with Cd, Pb, Hg, Cr(VI)
- Nordic Swan - Skandinavia
  - No colorants with Cd, Pb, Cr
- Öko Tex Standard 1000 (Textil Industry)
  - No colorants with Cd, Pb
- Conclusion: the other heavy metals in colorants are of no concern for substitution

Chromium Compounds

- Essential Trace Element
- Uptake rather insufficiently as too high
- In colorants valences of III and VI
- Chromium of valence VI is strongly oxidizing,

  Factor 1000 more toxic than Chromium of valence III
- Zink- und Strontiumchromates are carcinogenic
- Leadchromates are suspicious to cause cancer
- Chromoxidgreen, Chromtitaniumyellow, Kobaltblue based on Chrom III,

  are practically not toxic

Lead chromate pigments – e.g. Sicomin

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- **Restrictions on use in the EU**
  - Always for food packaging
  - Now also for packaging in general, automotive aplications, and electrical and electronic equipment
  - For products with an eco-label
  - For chidren‘s toys
  - Employment restrictions for young people and women

Chromium- and Nickeltitanium pigments – e.g. Sicotan

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- Complex inorganic coloured pigments based on titanium dioxide
- 3 % Ni or Cr and 10 % Sb are firmly incorporated in the rutile lattice
- The chemical, physical and ecological properties of the heavy metal oxides get lost
- No toxic effects when exposed orally or by inhalation
- No toxid effects in animal feeding studies with 1 % pigment in the feed
- Nickeltitanium Yellow shows no allergic reactions
- Contain no Cr(VI)
- Practically insoluble in acids and alkaline
- No problems in landfills – no migration possible
- Heat resistance > 1200 °C, shows practically inert behaviour in incineration plants
- Worldwide approved as colorants in food-contact applications and children‘s toys

Copperphthalocyanine pigments – e.g. Heliogen

- Blue contains constitutionally 10 %, Green 5 % organic bound copper, also copper free phthalocyanines available on the market
- Copper is fixed via complexation and therefore not bioavailable
- Copper is essential to humans and animals
- Soluble copper is toxic to bacteria and algae
- Limit on copper in waste water

- Phthalocyanines can be mechanically removed from waste water

Heavy metal discussion around the globe

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Task of product safety experts is to point out:

the major toxicological and ecotoxicological differences between

- **Pigments containing Lead and/or Cadmium**

  and

- **other colourants, which contain other heavy metals (e.g. Chromium- and Nickeltitaniumpigments)**

Topics

1. Registration
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Special Requirements (1)

- **CMRs should not be used**
  - Azo colorants and aromatic amines

    Azo colorants that can release carcinogenic aromatic amines contained in the list of aromatic amines (22) in directive 2002/61/EC may not be used.

- **Polycondensated hydrocarbons (PAH)**

- **Polychlorinated biphenyls (PCB)**
- **Polychlorinated Dibenzodioxins and –Dibenzofuranes**
- **Chlorinated Paraffins**

- **Flame retartands Polybrominated Biphenyls (PBB) and Polybrominated Diphenylethers (PBDE)**

Special Requirements (2)

- **Endocrine disrupters**
  are substances which are able to disturb the hormonsystem of humans or animals
  - Nonylphenol
  - Alkylphenylethoxylates (APEOs)

- **VOC content**
  volatile organic compounds according to EU directive 1999/13/EG and Decopaint-Directive 2004/42/EG

- **„BSE“ risk substances**
  Substances of animal origin

- **Biocides**
  only notified biocides according to the biocide directive 98/8/EG

Company Specifications

of different industries

- VDA (Verband der Automobilindustrie, German Automotive Industry Association), Autoliv, GM, Toyota, Renault, Volvo, Ford, DaimlerChrysler, BMW, VW
- Tetra Pak
- Otto, Ikea, Nike, Lego
- Bosch, Matsushita, Sony
- Coca-Cola and many others

Topics

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Conformity of colorants with „indirect“ food contact and with toy regulations

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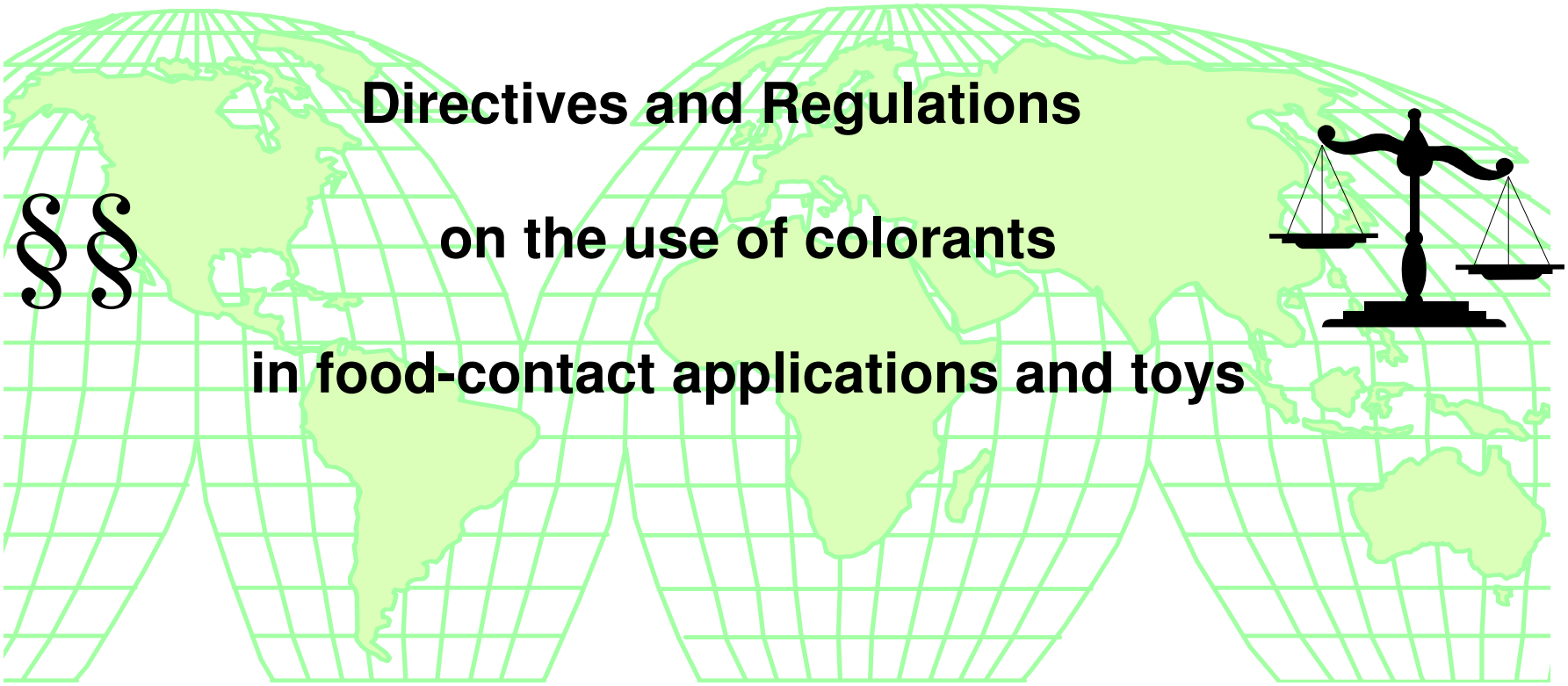

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Directives and Regulations

on the use of colorants

in food-contact applications and toys

European Regulations for Colorants

Applicable for all materials coming In contact with food

EC 1935/2004
Framework Regulation
on materials and articles
intended to come into contact with food

Materials and articles must not transfer constituents to food in amounts which
- endanger human health
- bring about an unacceptable change in the compositon of the food or
- Detiorate the organoleptic properties of the food

Plastics 2002/72/EU

Ceramics

. . . . others

- **Positive list for monomers and additives**
- **Colorants are not regulated there**

Resolutions of the Council of Europe (CoE) (www.coe.int)

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The committee of Ministers has adopted the following resolutions

- **European Resolution AP (96) I**

  on surface coatings

  - Positivlist Monomers and Additives
  - Colorants are not regulated there

- **European Resolution AP (89) I**

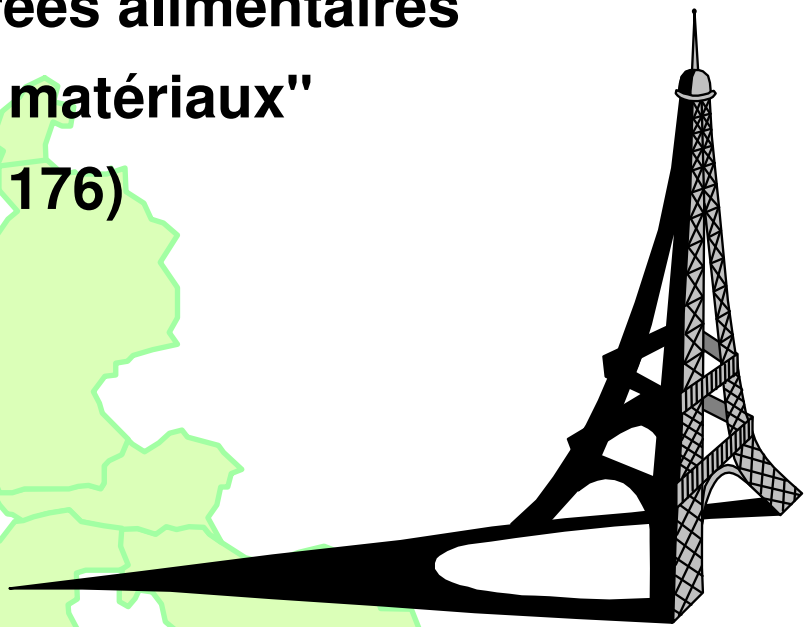
  on the use of colorants in plastic materials coming in contact with food

  - Purity requirements for colorants

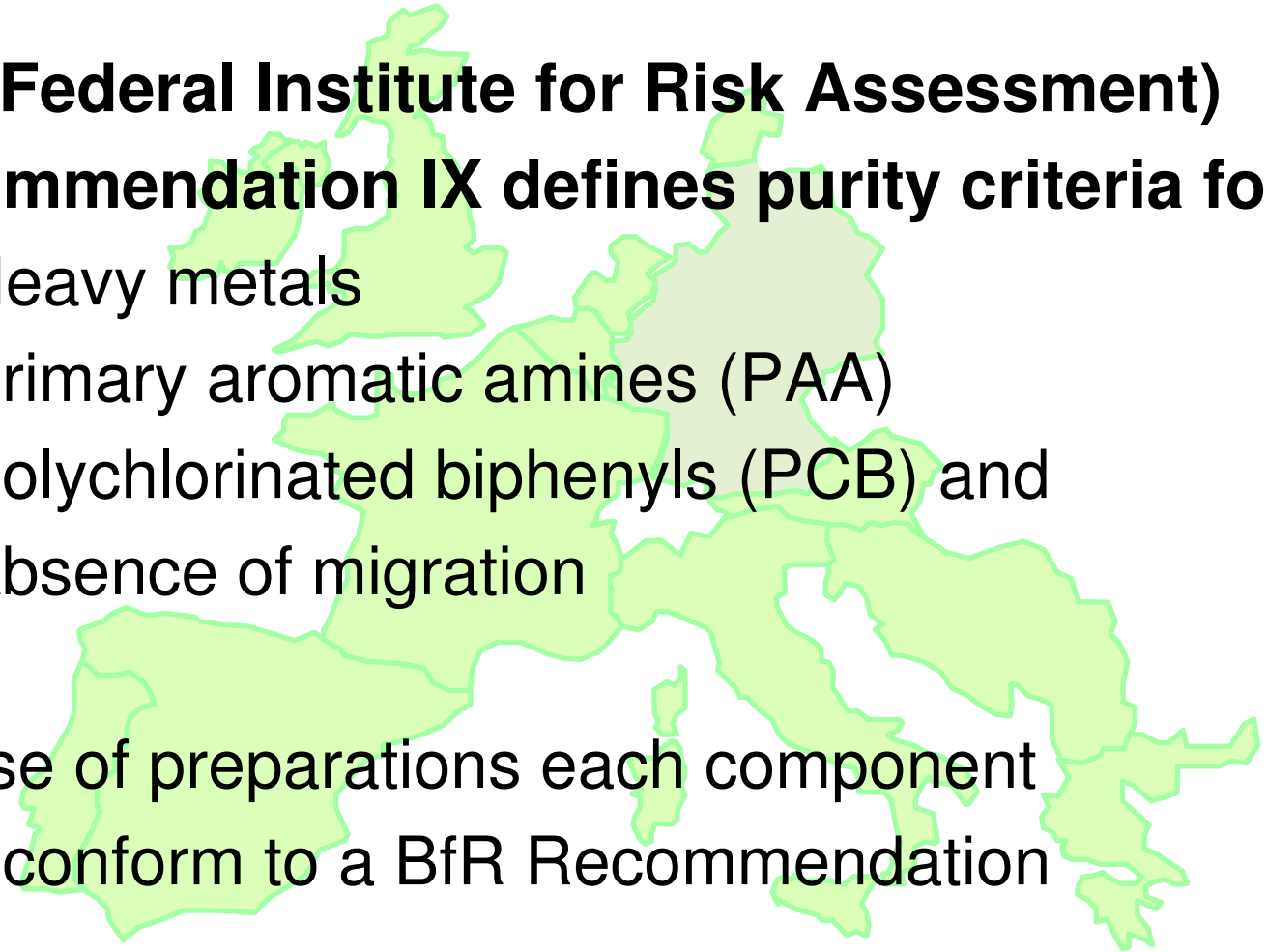
Country specific Regulation in Europe - France: „French Positive List“

"Matériaux au contact de denrées alimentaires produits de nettoyage de ces matériaux" (Brochure N° 1227, Circulaire 176)

- Requires migration testing and
- Toxicological Data for new listing
- DefinesPurity criteria for:
  - heavy metals,
  - Primary aromatic amines (PAA) and
  - Polychlorinated biphenyls (PCB)
- Regulation may be updated



Country specific Regulations in Europe
Germany: Recommendation IX of BfR



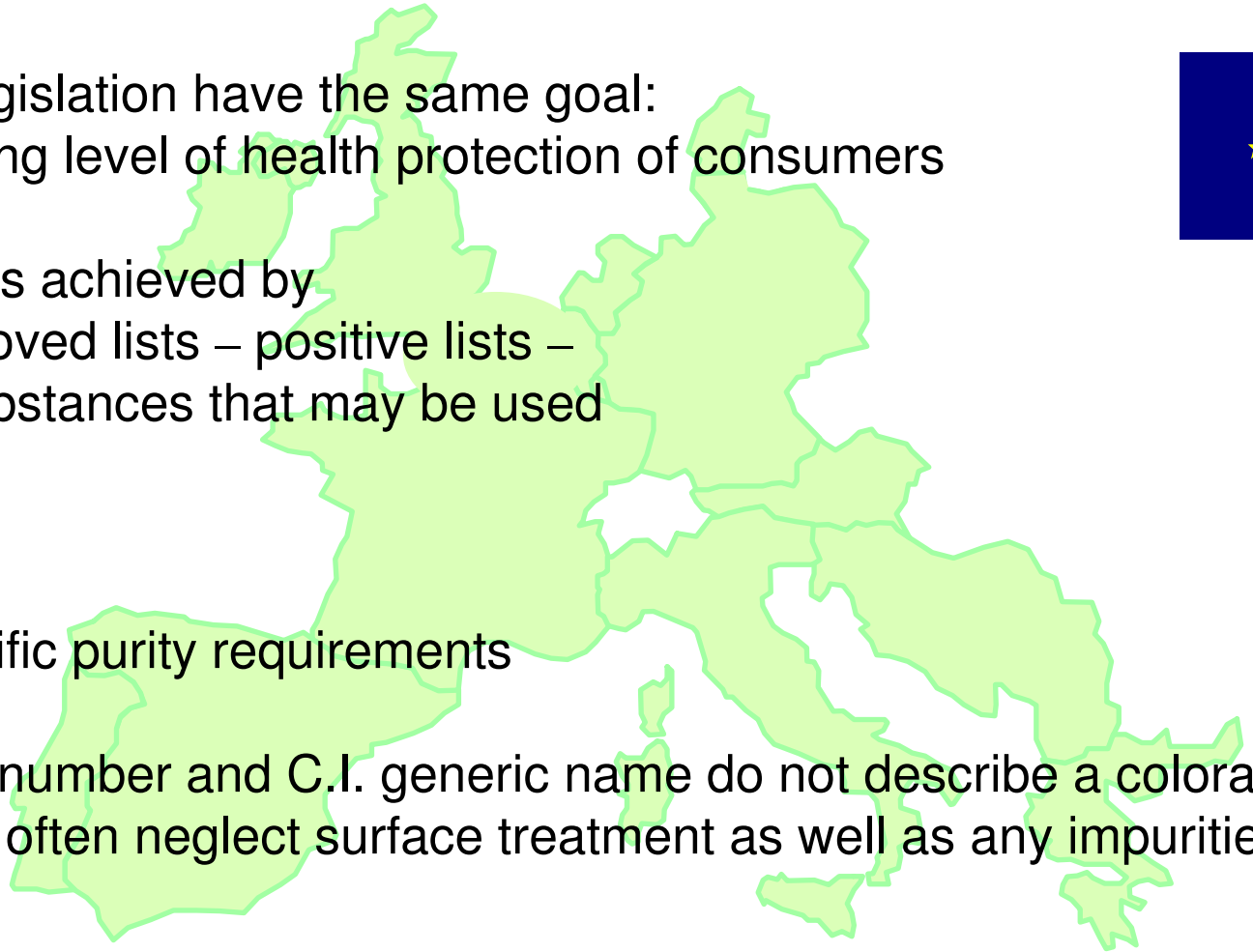
BfR (Federal Institute for Risk Assessment)

Recommendation IX defines purity criteria for

- Heavy metals
- Primary aromatic amines (PAA)
- Polychlorinated biphenyls (PCB) and
- Absence of migration

In case of preparations each component must conform to a BfR Recommendation

European Regulations
Conclusion for colorants



All legislation have the same goal:
Raising level of health protection of consumers

This is achieved by
Approved lists – positive lists –
of substances that may be used

And

Specific purity requirements

CAS number and C.I. generic name do not describe a colorant well
They often neglect surface treatment as well as any impurities

Purity Criteria
Limits in Europe

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	EU AP(89)1	Type 8081 (BASF)	Germany BfR, IX	Nether-lands	Italy	France
Antimony, Sb	500	250	500	2000	500	500
Arsenic, As	100	50 1)	100	100	50 1)	100
Barium, Ba	100	100	100	100	100	100
Lead, Pb	100	100 1)	100	100	100 1)	100
Cadmium, Cd	100	50	100	1000	100	100
Chromium, Cr	1000	100	1000	1000	1000	1000
Selenium, Se	100	100	100	100	100	100
Mercury, Hg	50	25	50	50	50	50
Zink, Zn	*)	1000	*)	*)	*)	*)
Prim. arom. Amines	500	500	500	500	500	500
Benzidine a.o.	10	10	*)	*)	10	10
Polychlorobi-phenyls (PCB)	25	25	*)	*)	*)	25

Values as ppm *) no limits given / 1) total content

Regulation in the USA - FDA /FCN

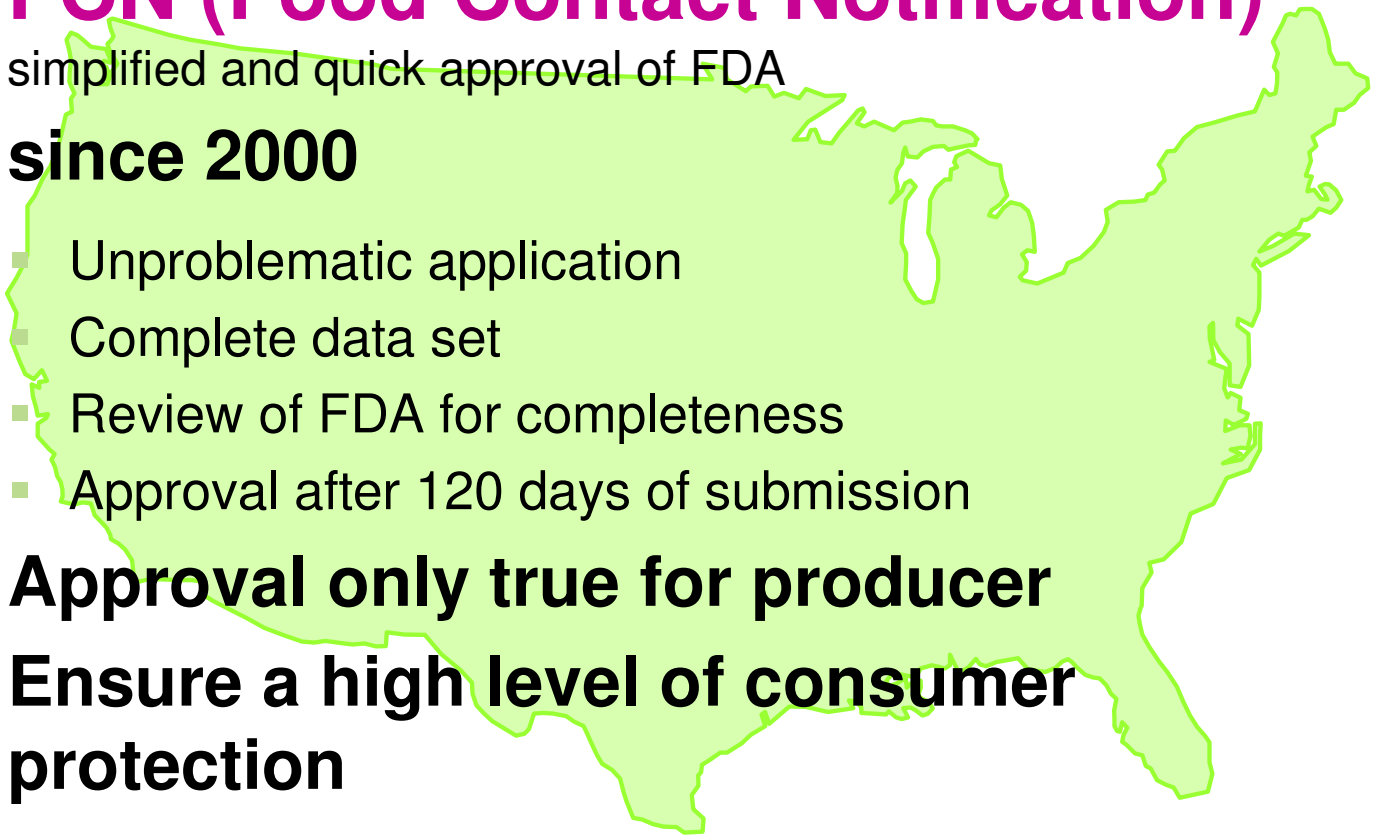
FDA = Food and Drug Administration

21 CFR §170 – 199

- **§ 178.3297 Colorants for Polymers** (Positivlist)
- § 170.39 Threshold of Regulation for Substances used in Food-Contact Articles

  Proof that there is: "No migration"
  Limit 0,5 ppb (= 0,5 µg/kg)

Regulation in the USA - FDA / FCN



- **FCN (Food Contact Notification)**
  simplified and quick approval of FDA
- **since 2000**
  - Unproblematic application
  - Complete data set
  - Review of FDA for completeness
  - Approval after 120 days of submission
- **Approval only true for producer**
- **Ensure a high level of consumer protection**

Confirmation for Food Contact Applications

- **BfR and FDA approval**
- **Purity requirements**
- Pigments Type 8081
- **For many customers a sign of quality**
- **Also for Non-Food packages**

Topics

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Toys – Regulation in Europe

- In Europe EN – Norm EN 71 harmonise toy application
- Limits given in EN 71 refer to coloured toys and not to the colourant itself!
- However customers usually require that the colourant itself should comply with EN 71 limits!
- BASF Type 8082 pigments

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Chromium, Cr	1000	100	1000	1000	1000	1000
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Mercury, Hg	50	25	50	50	50	50
Zink, Zn	*)	1000	*)	*)	*)	*)
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Polychlorobi-phenyls (PCB)	25	25	*)	*)	*)	25

Values as ppm *) no limits given / 1) total content

What‘s about the future?

- **REACh**

  Registration, **E**valuation, **A**uthorisation **o**f **C**h**emicals**

  starts 2008 (in force June 2007)

- **GHS**

  Global **H**armonized **S**ystem

  starts 2007, 2008 (?)

- **Superregulation**

  EU-directive for plastic materials coming in contact with food (colorants will not be regulated)

Topics

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Sustainable Development

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Since the 1992 World Summit in Rio de Janeiro a key issue in global development

Sustainable enterprise now stands for conducting business through

Combining, Balancing policy of

- **economic growth and success,**
- **Ecological / environmental protection and**
- **social responsibility**

Sustainable Development

Secure the future and long-term success

- **of the chemical companies,**
- **that of their employees,**
- **Customers and**
- **Shareholders**

Sustainable Development – Contribution by Responsible Care

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Voluntary global initiative of the chemical industry
Respond to public health and environmental concerns

Goals:
to achieve continuous improvements in the areas of

- Environmental protection
- Product stewardship
- Occupational health
- Occupational safety
- Process safety
- Distribution safety
- Communications and
- Emergency respons

BASF lives this goals and is therefore a reliable partner for you

Topics

1. Registration
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Thank you for your attention!

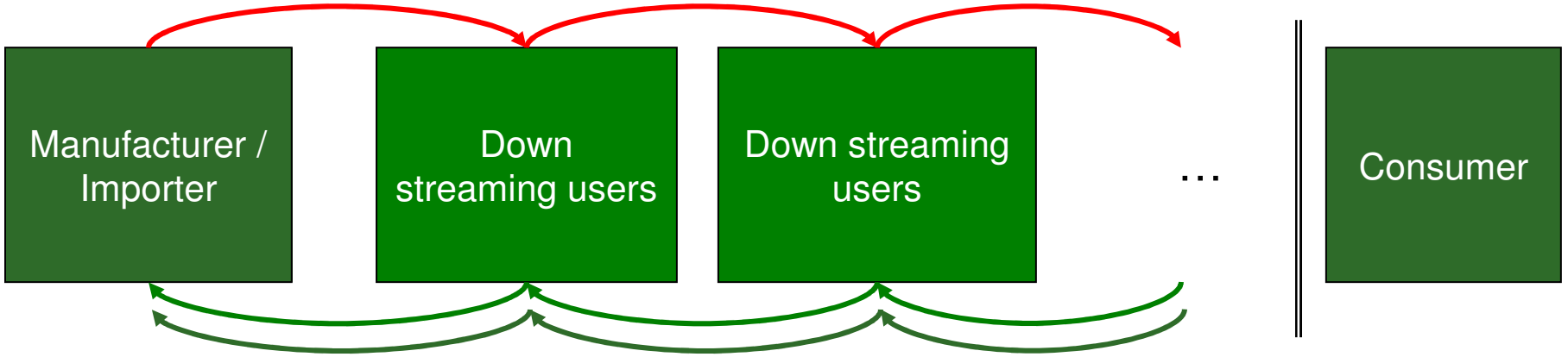
Back up

Introduction of REACH (continued)

Information flow along the supply chain

For each product, each customer, each application:

Duty to inform about risks and appropriate risk reduction measures



Right to inform about uses
Need on exposure information

Introduction of REACH (continued)

Reach will be the dominant European Chemical law in future.

It replaced 40 existing legislation in a single system. So, what was regulated before you will find in REACH from 'restriction list' again!

ANNEX XVII

RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

Impact of REACH in the industry

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No Data, No Market!

Article 5
No data, no market

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

- For many firms, **REACH** registration will be the most costly and time-consuming part of compliance.

Zeitplan der REACh Gesetzgebung

gemäß des Gemeinsamen Standpunktes vom 12.06.2006

REACH - Be aware of and act properly

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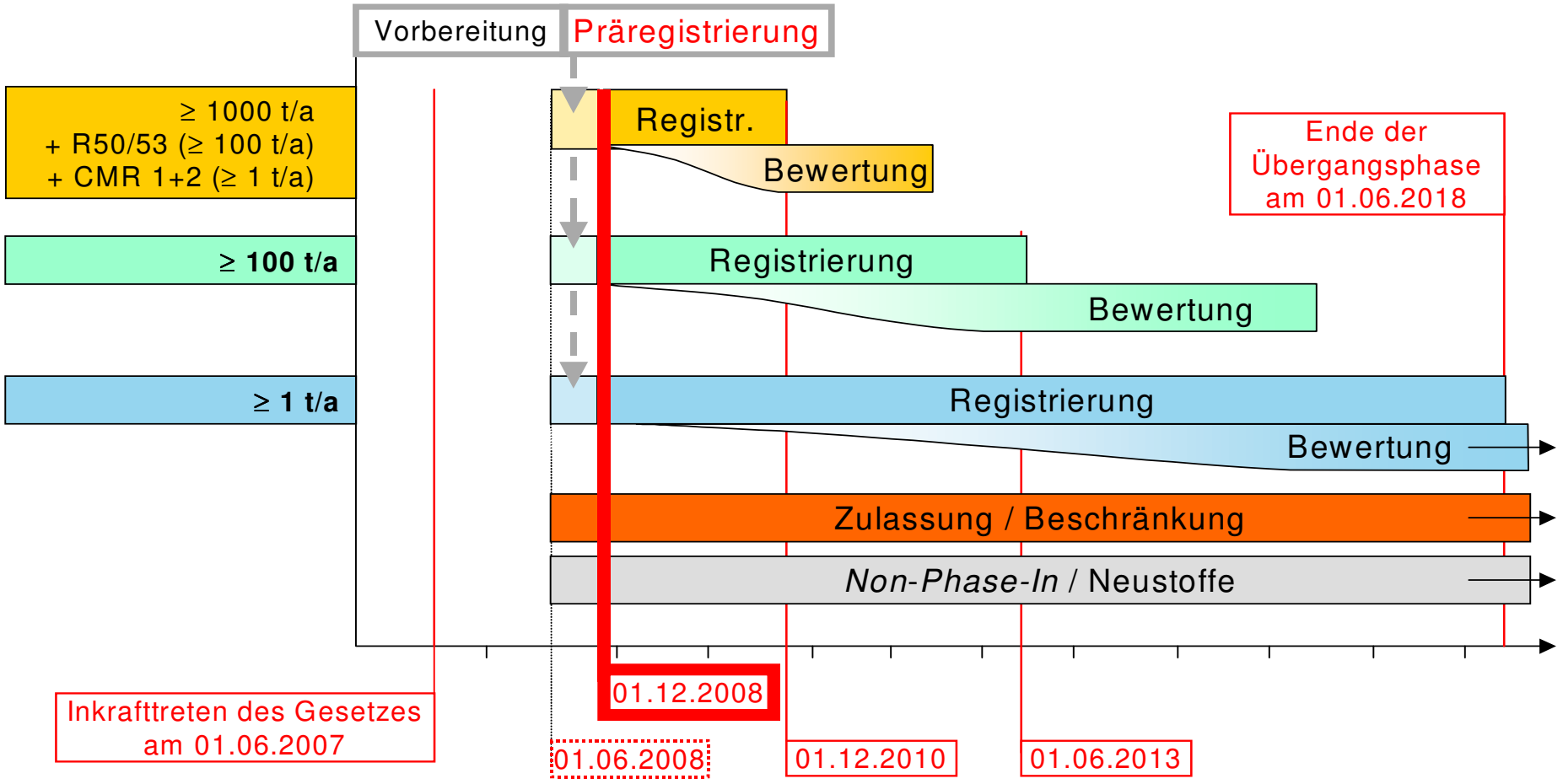

Polycyclic Aromatic Hydrocarbons (PAHs)

- Benzo(a)anthracene
- Benzo(b)fluoranthene
- Benzo(k)fluoracene
- Benzo(ghi)perylene
- Benzo(a)pyrene
- Chrysene
- Dibenz(a,h)anthracene
- Indeno(1,2,3-cd)pyrene
- Acenaphtene
- Acenaphtylene
- Anthracene
- Fluoranthene
- Fluorene
- Naphtalene
- Phenanthrene
- Pyrene

List of Aromatic Amines (1)
2002/61/EG

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	CAS-Nummer	Index-Nummer	EG-Nummer	Stoffname
1	92-67-1	612-072-00-6	202-177-1	Biphenyl-4-ylamin 4-Aminobiphenyl Xenylamin
2	92-87-5	612-042-00-2	202-199-1	Benzidin
3	95-69-2		202-441-6	4-Chlor-o-toluidin
4	91-59-8	612-022-00-3	202-080-4	2-Naphthylamin
5	97-56-3	611-006-00-3	202-591-2	o-Aminoazotoluol 4-Amino-2',3-dimethylazobenzol 4-o-Tolylazo-o-toluidin
6	99-55-8		202-765-8	5-Nitro-o-toluidin
7	106-47-8	612-137-00-9	203-401-0	4-Chloranilin
8	615-05-4		210-406-1	4-Methoxy-m-phenylendiamin
9	101-77-9	612-051-00-1	202-974-4	4,4'-Methylendianilin 4,4'-Diaminodiphenylmethan

List of Aromatic Amines (2)

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	CAS-Number	Index-Number	EG-Number	Stoffname
10	91-94-1	612-068-00-4	202-109-0	3,3'-Dichlorbenzidin 3,3'-Dichlorbiphenyl-4,4'-ylendiamin
11	119-90-4	612-036-00-X	204-355-4	3,3'-Dimethoxybenzidin o-Dianisidin
12	119-93-7	612-041-00-7	204-358-0	3,3'-Dimethylbenzidin 4,4'-Bi-o-Toluidin
13	838-88-0	612-085-00-7	212-658-8	4,4'-Methylendi-o-toluidin
14	120-71-8		204-419-1	6-Methoxy-m-toluidin p-Cresidin
15	101-14-4	612-078-00-9	202-918-9	4,4'-Methylen-bis-(2-chloranilin) 2,2'-Dichlor-4,4'-methylendianilin
16	101-80-4		202-977-0	4,4'-Oxydianilin
17	139-65-1		205-370-9	4,4'-Thiodianilin
18	95-53-4	612-091-00-X	202-429-0	o-Toluidin 2-Aminotoluol
19	95-80-7	612-099-00-3	202-453-1	4-Methyl-m-phenylendiamin
20	137-17-7		205-282-0	2,4,5-Trimethylanilin
21	90-04-0	612-035-00-4	201-963-1	o-Anisidin 2-Methoxyanilin
22	60-09-3	611-008-00-4	200-453-6	4-Amino-azobenzol