Topics Covered

SECTION A:

Microorganisms and their Control in Leather Industry

1. *Microorganism problems in leather production*
2. *Best practices in control of microorganisms*
3. *Importance of monitoring*

SECTION B:

Government Regulations & Market Requirements

1. *Risk assessment*
2. *Government regulations on biocides*
3. *Market restrictions on biocides*

SECTION C:

Questions and General Discussion

SECTION B:

Government Regulations & Market Requirements

1. RISK ASSESSMENT

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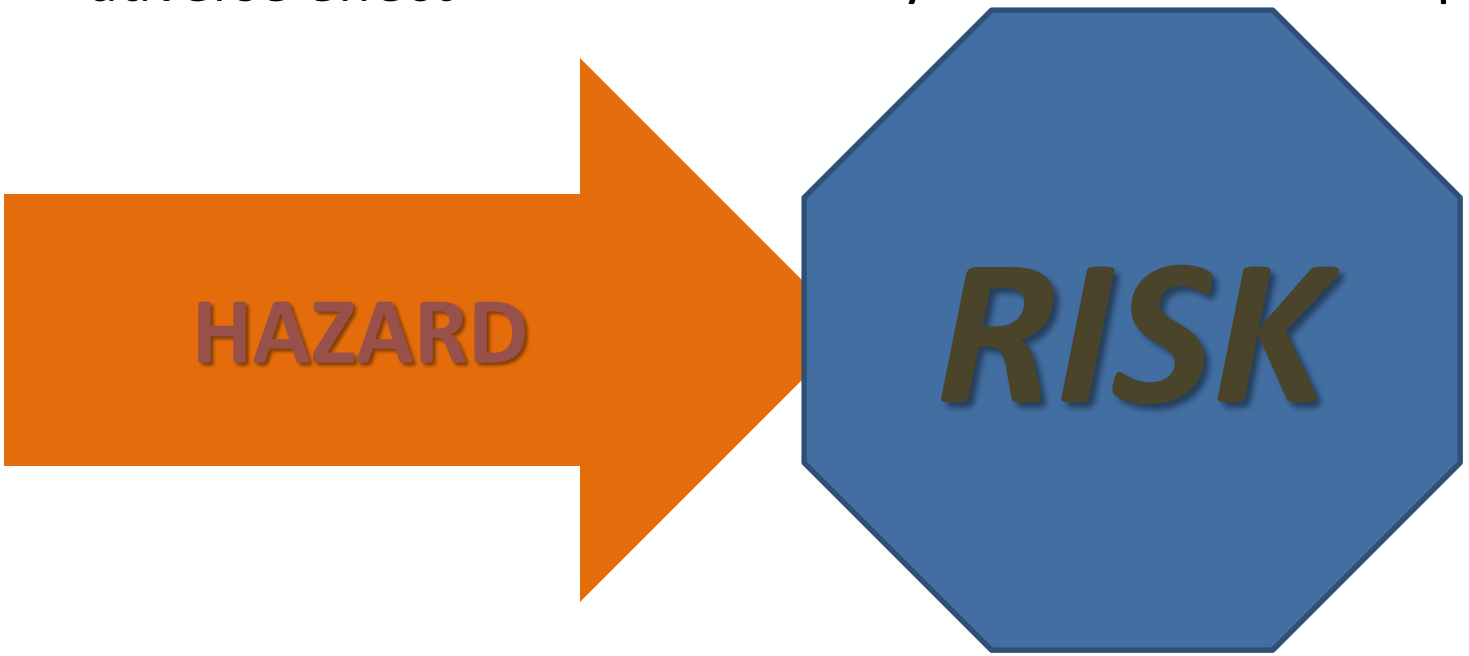
Definitions - Hazard & Risk

Hazard is the **intrinsic** capacity to produce an adverse effect

Risk is the probability of an exposure to a hazard and the likely outcome of that exposure



TOXICITY: Relative capacity of a substance (chemical) to produce harm to living things; it is an inherent property of **all** chemical substances

Basic Risk Assessment Elements

Toxicity

- Inherent toxicity of the chemical

Quantity

- How much of the chemical is present

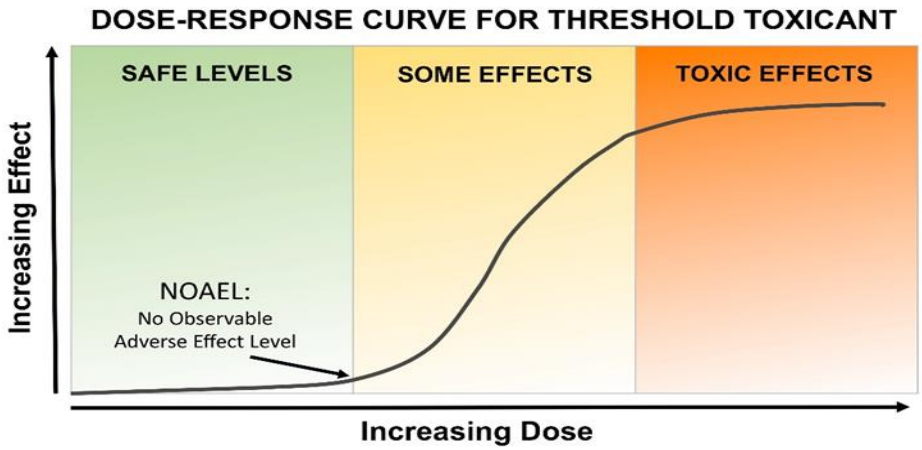
Exposure Level

- How much contact with the chemical

RISK is a function of Hazard and Exposure (Potency + Level)

Assessing Risk – Key Concepts

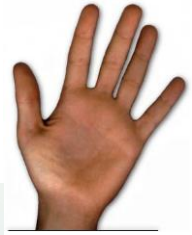
Dose-Response

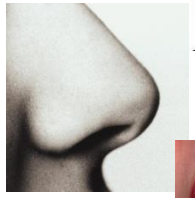


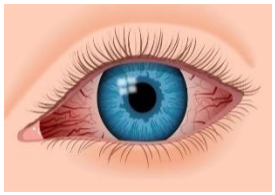
Route of Exposure

Human Exposure

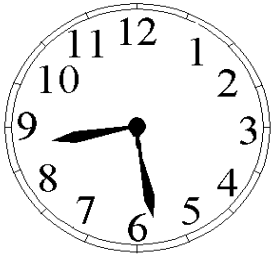
- Dermal
- Inhalation
- Ingestion
- Eyes

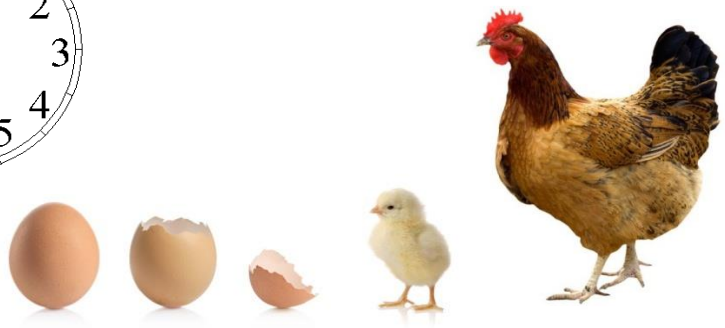




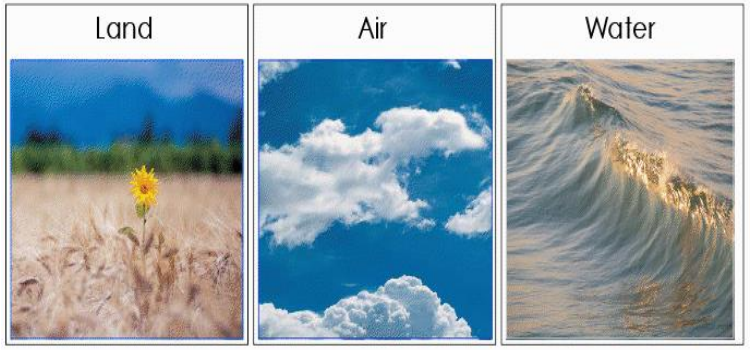


Duration & Timing





Environmental Release



Risk Assessment Process

- Hazard Testing / Endpoints:
  - Development toxicity
  - Reproductive toxicity
  - Neurotoxicity
  - Carcinogen
  - Skin Irritation / Corrosivity / Sensitization
  - Eye Irritation / Corrosivity
  - Respiratory sensitization
  - Endocrine effects
- Intensity, frequency, duration
  - Acute tests
  - Sub chronic / chronic

- Chemical, physical effects
- Ecological impacts
- Environmental Fate
- Bio-concentration
- Life Cycle assessment
- Weight of evidence; level of confidence
- Uncertainty & extrapolation
- Epidemiology
- Occupational vs consumer exposures
- Cost Benefit Analysis
- Sex & Politics

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Risk Categorization & Management

Hazard Classes

- Corrosive to skin
- Cancer
- Endocrine disruptor
- Aquatic toxicity

Hazard Categories

- Category 1 – 5 based on standardized testing
  e.g. Acute Tox Cat. 3

Exposure

- How much contact, what, who, when, where, how?

"There are no poisons, only poisonous doses…"

Paracelsus (1493-1541)

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Biocides & Sustainability

All biocides are hazardous substances …they need to be, as they are required to control living things.

Perception:	Reality:	
"Less is more" - it is more sustainable to use less biocide	**"Use the RIGHT amount of biocide to adequately control growth"** - Uncontrolled microorganism growth causes financial damage and potential worker health problems	People – Planet - Profits
"Greener is cleaner" - it is more sustainable to use a biocide with a lower hazard categorization	**"Use a product that is risk-assessed & registered for the application"** • It is typical that biocides with a less hazardous profile need to be applied in much larger quantities to achieve control	Dose -Response Principle

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SECTION B:

Government Regulations & Market Requirements

2. GOVERNMENT REGULATIONS ON BIOCIDES

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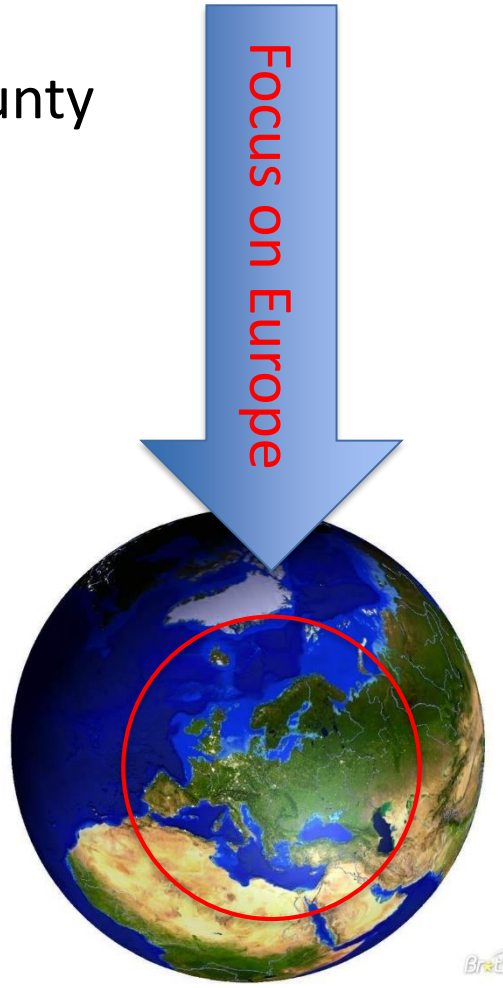
Government Regulations

Many Laws & Regulations apply globally. For example:

- **USA EPA**: TSCA, FIFRA, CPSC, Proposition 65 etc.
  - Laws & Executive orders - federal, state, & county
- **Europe ECHA**: REACh, BPR, Directives, BfR, etc.
  - Regulations, Directives, National laws
- **China MEP**: Complex regulations, GB standards
- **Japan**: CSCL, ISHL, Law 112 – formaldehyde, etc.
- **Many others…**

EPA = Environmental Protection Agency
TSCA = Toxic Substances Control Act
FIFRA = Federal Insecticide, Fungicide, Rodenticide Act
CPSC = Consumer Product Safety Commission
ECHA = European Chemical Agency
BPR = Biocidal Products Regulation
Bfr = Federal Institute for Risk Assessment
REACh = Registration, Evaluation, Authorization & Restriction of Chemicals
MEP = Ministry of Environmental Protection
CSCL = Chemical Substances Control Law
ISHL = Industrial Safety & Health Law



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Regulatory Affairs “Jungle”

BPR

EU

CLP

REACH

Local

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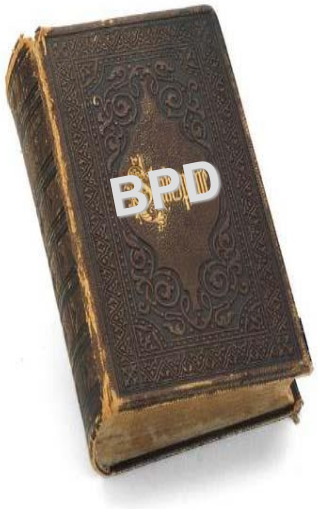
Biocidal Products Directive BPD 98/8/EC



Entry into force: 14th of May 2000

Article 1: **Scope**

1. This Directive concerns:

(a) the authorisation and the placing on the market for use of biocidal products within the Member States

Goal :

- ✓ To **harmonise** the European market for biocidal products and their active substances
- ✓ To provide a **high level of protection** for **humans** and **the environment** through **risk assessment**

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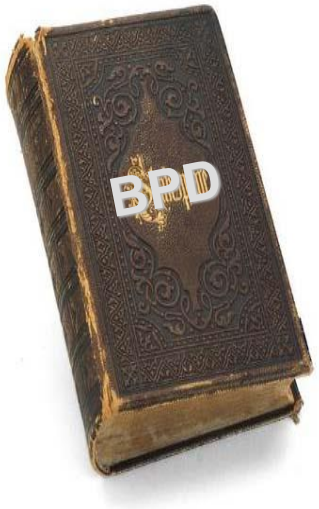
Biocidal Products Directive BPD 98/8/EC



Annex V :

MAIN GROUP 2 : Preservatives

=> Product Types related to leather applications :

PT 6 : Preservatives for products during storage *

PT 9 : Fibre, leather, rubber and polymerised materials preservatives

PT 11 : Preservatives for liquid-cooling and processing systems **

* Chemical products are sometimes treated with biocides

** Soaking biocides may be considered treatment of the process water

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Biocidal Products Directive BPD 98/8/EC

Existing active substances & biocides => placed on the market before14 May 2000

New active substances & biocides => placed on the market from 14 May 2000

Review Program existing active substances
BPD dossiers for Leather submitted by October 2008

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Biocidal Products Directive BPD 98/8/EC

Biocidal Products Regulation – BPR 528/2012/EC

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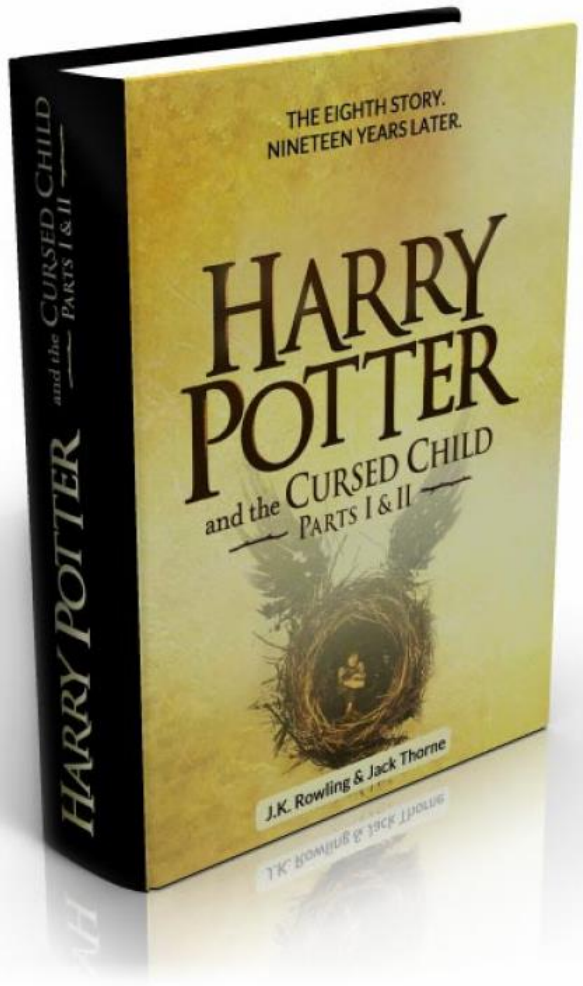
Biocidal Products Regulation – BPR 528/2012/EC



Entry into force: 17th of July 2012
Implementation as of 1st of September 2013

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Biocidal Products Regulation – BPR 528/2012/EC

- **Regulation** : immediately enters into force in all Member States (⇔ Directive)

- Maintains **2-tier authorisation process**:
  Active substance + Biocidal Products

- **Review program of existing active biocides** continues under BPR !

- BPR authorisations mainly for wood preservatives & rodenticides

⇒ Review program is running late
Extended until 2024 !

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Biocidal Products Regulation – BPR 528/2012/EC

Important Difference between the BPR and the former BPD

- **Nominative Listing** of official applicants, incl. participants under Review Program (known as **Art 95 BPR List**)
  = list of "official sources" of active substances to be used only

As of **September 1, 2015** , a biocidal product can only be used if **sources of active substances are listed**

→ end of free-rider concept

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Biocidal Products Regulation – BPR 528/2012/EC

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BPR Article 95 LIST

Example of list using TCMTB as reference:

ECHA
EUROPEAN CHEMICALS AGENCY

Article 95 List
Prepared as of 16 December 2016

Active Substance Name	EC number	CAS number	PT	Entity Name	Country	Supplier Type	Inclusion Reason	Inclusion Date
(benzothiazol-2-ylthio)methyl thiocyanate (TCMTB)	244-445-0	21564-17-0	9	nv Buckman Laboratories	Belgium	Substance Supplier	RP Participant	24-Sep-14

https://echa.europa.eu/information-on-chemicals/active-substance-suppliers

- You can obtain information on the active substances, the Product Type (PT), and nominative suppliers from the ECHA website.
- Ensure that the biocides you are using are listed under the correct PT (e.g. PT 9), AND that the correct use application is covered.
- You should also obtain a compliance letter from your supplier

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BPR Compliance Letter

We XXX, confirm that the biocidal product XXX is in compliance with the European Biocidal Products Regulation **528/2012/EC** concerning the making available on the market and use of biocidal products.
Furthermore, the active substance **(benzothiazol-2-ylthio)methyl thiocyanate (CAS: 21564-17-0; EINECS: 244-445-0)** is listed on Annex II of Commission Delegated Regulation (EC) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council for the following Product Types:
- 9 : Fibre, leather, rubber and polymerized materials preservatives
…
Furthermore, we also confirm the above mentioned active substance is listed on the Art. 95 list published on the ECHA website.

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nv Buckman Laboratories
Wondelgemkaai 159
9000 Gent, Belgium
europe@buckman.com

+32 9 257 92 11 Tel
+32 9 253 62 95 Fax
buckman.com

BPR Article 95 compliance

We, nv Buckman Laboratories, Wondelgemkaai 159, B-9000 Ghent, Belgium, confirm that the biocidal product **Busan 30WB** is in compliance with the European Biocidal Products Regulation **528/2012/EC** concerning the making available on the market and use of biocidal products.

Furthermore, the active substance **(benzothiazol-2-ylthio)methyl thiocyanate (CAS: 21564-17-0; EINECS: 244-445-0)** is listed on Annex II of Commission Delegated Regulation (EC) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council for the following Product Types:

- 9 : Fibre, leather, rubber and polymerized materials preservatives
- 12 : Slimicides

Furthermore, we also confirm the above mentioned active substance is listed on the Art. 95 list published on the ECHA website.

Ghent, December 16, 2016

Coppens

Tamara Coppens
Regulatory Affairs Coordinator - Biocides

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Biocidal Products Regulation – BPR 528/2012/EC

Important Difference between the BPR and the former BPD

Introduction of new concepts :

Treated Articles

means any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products

(Definition - Art 3.1(l)-BPR)

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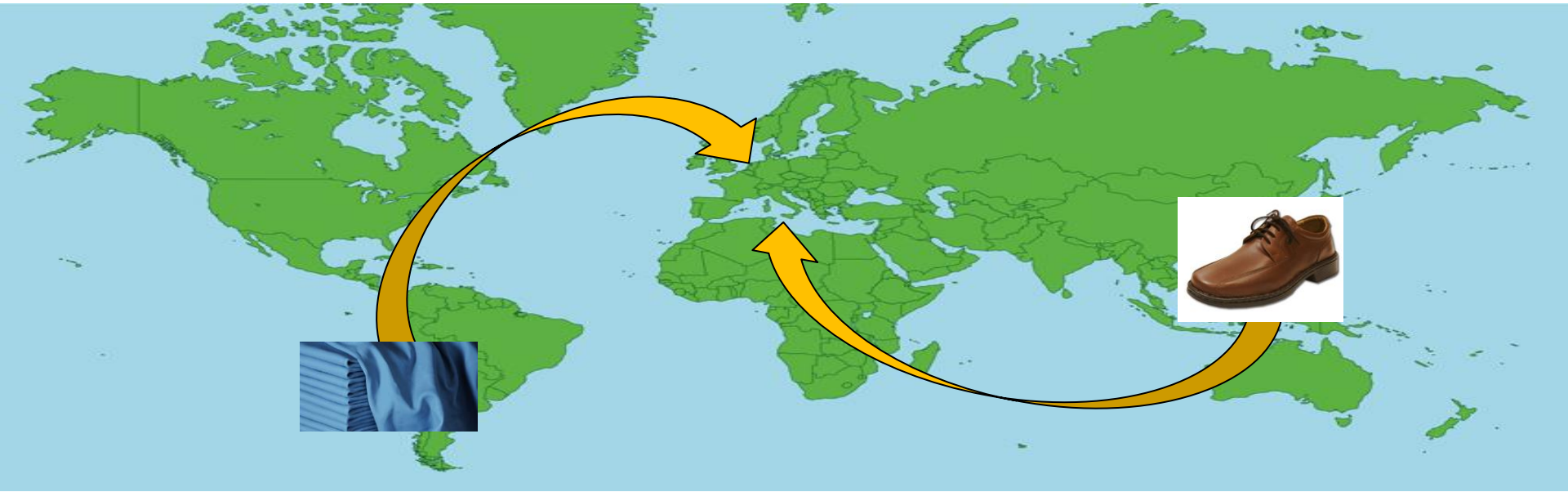
Treated Articles Provision

- **Leather articles cannot** be placed on the EU market unless treated with biocidal products containing active substances on the **Art 95 BPR List**



Impact on leather industry:

Affects imports of wet blue, finished leather and leather articles into Europe, where the leather was treated outside of the EU

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Treated Articles Provision

Biocides used in treated articles that were available on the EU market on September 1, 2013, can remain on market until EU decision on Active Substance is completed:

- ***where the article (e.g. leather) is treated with a biocide, and***
- **if application/dossier was submitted at latest by September 1, 2016**

Example for leather industry:

Fungicide CHED

BPR dossier submitted by Buckman to Norway (Rapporteur Member State)

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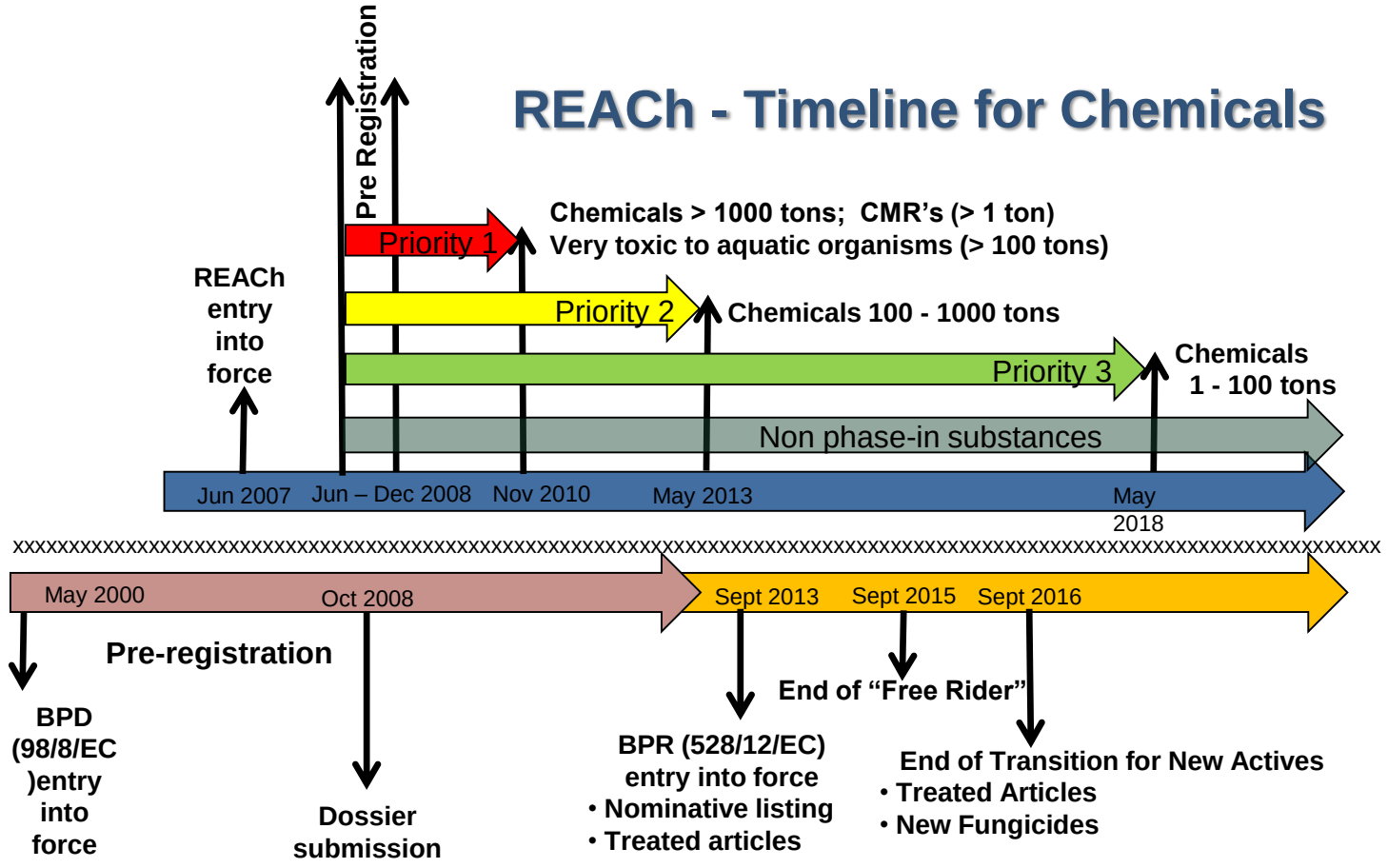
BPR and Reach

- BPR is similar to REACh in concept, but was enacted earlier and has higher standards for substance review
- For commercial biocide Products, REACh also applies in that the solvents, emulsifiers, etc. need to comply with REACh



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SECTION B:

Government Regulations & Market Requirements

3. MARKET RESTRICTIONS ON BIOCIDES

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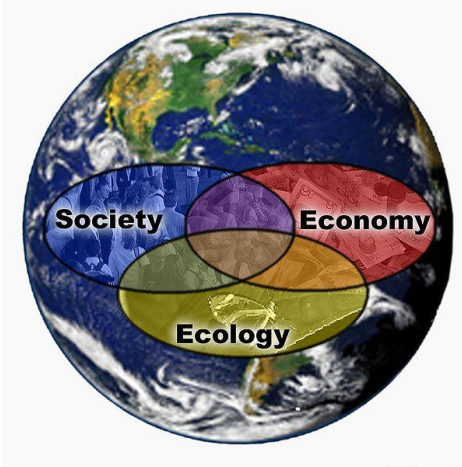
Market Restrictions on Biocides

Governments control biocides because they have an obligation to protect the health of their people and the environment.

Who else seeks to restrict use of biocides?

- Brands and retailers
- Industry organizations
- Environmental organizations
- Activist groups

Non-Government Organizations



Why do NGO's restrict biocides?

- Corporate risk
- Industry reputation
- Sharing of best practices / raise standards
- Concern for environment or consumers

Market Restrictions on Biocides

Approach to mitigate perceived risks represented by biocides is by restriction.

Use of RSL's (Restricted Substances Lists) or an Ecolabel:

A. Biocide to be compliant with prevailing legislation (e.g. BPR) → **No issues**
B. Arbitrary limits on commonly used biocides → **Some issues**

Many NGO's might have the best intentions, BUT:

- May not understand leather industry and its specific needs well
- May not have expertise in toxicology; might not use risk assessment approach; processes may not be well defined.
- Some limits are "cut-and-paste" from other industries or other ecolabels
- Limits can be secretive / competitive / open to interference
- Once in place, limits can be hard to change
- Unrealistic limits create unnecessary technical barriers to trade

Market Restrictions on Biocides

Key Points:

- Leather is different to textiles - process sequence & material requirements vary significantly:

Leather	Natural, renewable Three dimensional
Textiles	Synthetic, oil origin Two dimensional

- It is very rare that tanners overdose biocides:
  - Biocides (fungicides) are very expensive and market is highly competitive.
  - Almost all industry problems - too little active substance is present
- Difference in the amount of biocide (fungicide) needed:
  - Depends on raw material, process parameters, end product.
  - Level of nutrients (e.g. natural sugars & fats)
  - Level of contamination – e.g. fungal spores present
  - Ambient conditions – temperature
  - Technical issues related to analytical method and expression of results

Market Restrictions on Biocides

Some specific examples of NGO imposed limits on industry:

- Ecolabels:
  - EU Ecolabel for footwear – to meet EU BPR requirements
  - German Blue Angel - specifies major fungicides with workable limits
  - Oeko-Tex Leather Standard –major fungicides with workable limits
  - Bluesign – Unworkable limits on OPP and OIT
- Industry Organizations:
  - GADSL – to meet EU BPR requirements
  - CADS / DSI - specifies all major fungicides with workable limits
- RSL's:
  - AFIRM – Specifies OPP but with workable limits
  - Individual brands – some significant differences, most limits are workable

BEST PRACTICE: Biocides should be used in accordance with EU BPR requirements. This represents the highest standard for comprehensive review using scientific Risk Assessment approach.

Evolution of RSL's

Over the last decade or so, there has been a lot of activity among NGO's to develop RSL's - some of these include limits on biocides.

Good news!

Most of the more restrictive limits on commonly used fungicides have been raised over the last few years to more workable limits.

But: biocides remain under review by some brands.

Be Pro-active: There is a need for the industry to continue to advocate against limits that are not scientific or are too restrictive for practical tannery operations.

Best Practice for Tanners

So, what do I need to do?

1. Work with a good Supplier

One that has the products, processes, and knowledge to ensure performance

2. Optimize your applications

Based on your specific raw materials, processes, and preservation requirements

3. Document Biocide Compliance with BPR

Ensure the active substances applied are supported under the BPR - specifically the appropriate Product Type and for the intended use (EU No.528/2012 - Art 95 List). **Request Documentation.**

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Best Practice for Tanners

So, what do I need to do?

4. Confirm Compliance for imported articles

Confirm that wetblue, crust or finished leather, if intentionally treated with a biocide, complies with BPR Art. 95 Treated Article provision. **Document.**

5. Determine customer RSL requirements

Determine if there are any restrictions on presence of biocide residuals in leather articles sourced by your customer.

6. Pro-actively engage on biocide restrictions

Work with your biocide supplier and industry organizations if RSL limits on the existing biocides are too restrictive or not workable.

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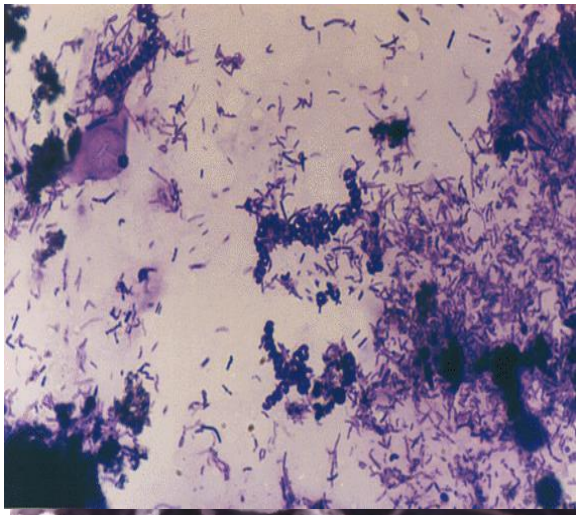
Seminar on Microorganism Control



Thank You!

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