



**Ministry of Environment  
and Food of Denmark**  
Environmental  
Protection Agency

# Restriction on Chromium (VI) in leather

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Leather articles, or leather part of articles, coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) in concentrations > than 3 mg/kg chromium(VI) of the total dry weight of the leather.

What you will hear:

- Background - Cr(VI), allergy, symptoms
- Cr(VI) in leather – exposure, alternative techniques, substances and raw materials
- Impacts – Benefits – quantification – valuation  
- Costs – Industry - Authorities
- General considerations on performing the SEA

# Cr(VI) known to cause severe allergic contact dermatitis

Symptoms:

Inflammation of the skin

Sensitized persons react on very low levels

Long periods of illness for some people



2.5 – 5.9 % of patients with dermatitis are sensitized towards Cr(VI)

0.2 – 0.7 % of population allergic to Cr(VI) – 1-3 million people in EU



# Why has only sensitisation been included?

Carcinogenic Cat. 1B or 1A

Mutagenic, cat. 1B

Reproductive toxic, cat. 1B

Respiratory sensitiser, cat. 1

Specific target organ toxicity - STOT RE 1

Aquatic Acute 1, Aquatic Chronic 1

**Skin sens 1:**



Leather articles counted for app. 45% of chromium allergy cases (Other causes for chromium allergy: Cement, plywood, cosmetic, graphic work and paint, great group of unknown causes)

Global leather use:

- shoes 52%
- furniture 14%
- auto 10%
- garments and gloves 14%
- other uses 9%

$\frac{1}{4}$ - $\frac{1}{3}$  of leather articles found to contain Cr(VI) above 3 mg/kg (ppm)

Typical range of chromium content in leather shoes between 1 and 3%.  
Content of Cr(VI) is much lower.

# Why is chromium in leather?

- Added during the tanning process
  - Cr binds to collagen (tessuto conettivo) in hides – gives dimensional stability, resistance to mechanical action and heat resistance. Also used in pigments.
- 80-85% of leather worldwide produced using Cr(III) salts
- Cr(VI) is unintended – formed by oxidation of Cr(III) in leather

# Tanning agents

- Chromium tannage - Basic sulphate complex of trivalent chromium
- Non Chromium mineral tannages - Aluminium, zirconium, and titanium salts
- Vegetable tannage - Polyphenolic compounds leached from vegetable material (e.g. quebracho, mimosa, oak, etc.)
- Aldehyde tannage - Glutaraldehyde and modified aldehydes and di-aldehydes

## Cr(VI) can be avoided by optimizing the tanning process

- Avoid use of Cr(VI) salts
- If use of Cr(III) salts
  - Finish wet part of the tanning process under low pH
  - Use 1-3% vegetable tanning extract to provide antioxidant protection(or phenolic and amine)
  - Avoid use of ammonia prior to dying process
- Avoid yellow and orange inorganic pigments



## Risk Management Options considered

1. Leather articles coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) above 3 mg/kg chromium(VI)
2. Restriction of chromium (VI) content in all articles of leather
3. Restriction of total chromium content of leather (both Cr(III) and Cr (VI))

## Effectiveness of the proposed restriction

- 90% of all leather articles covered
- Nearly 100% of Cr(VI) exposure to humans from leather covered
- 80% of all cases related to Cr(VI) in leather is avoided
- 36% of all cases related to Cr(VI) is avoided
- 10,800 cases avoided annually (not including Germany)

# Impacts - benefits

Total annual cost per case of allergy :

Direct cost – health care and medication, Euro:	472	(15%)
Production loss – (7 days per week), Euro :	1,190	(28%)
Welfare loss (125 days/year), Euro:	1,875	(57%)
Total cost, Euro	3,537	

A restriction will also reduce provocation of already sensitized persons.

Loss of consumer surplus - €50 -

		1 <sup>st</sup> year	Year 20
<b>Number of allergy cases avoided per year</b>		10,800	10,800
<b>Number of existing cases</b>		1,320,000	1,280,000
<b>Saved costs for cases after restriction entry</b>	Million €	38	764
<b>Saved costs for existing cases</b>	Million €	66	56
<b>Total Health benefit</b>	Million €	104	820

First 20 years, accumulated, discounted: € 5,282 million

## Costs (Germany not included)

Tanneries: Cost increase of 0.2 – 1% of production cost for leather.

If 1/3 of tanneries in EU have to change:

EU tannery extra cost: 8-15 mill € annually

For 2/3 (or more) of tanneries that have already changed:

Positive impact on competition

Importers of leather and leather articles:

More expensive goods: 70 mill. € annually

Further testing: 5-15 mill € annually (both imported and EU produced)

Accumulated costs first 20 years, discounted: € 1,400,000

End user: below 0.5 % increase in price of leather articles

Accumulated benefits, first 20 years, discounted: € 5,282 million

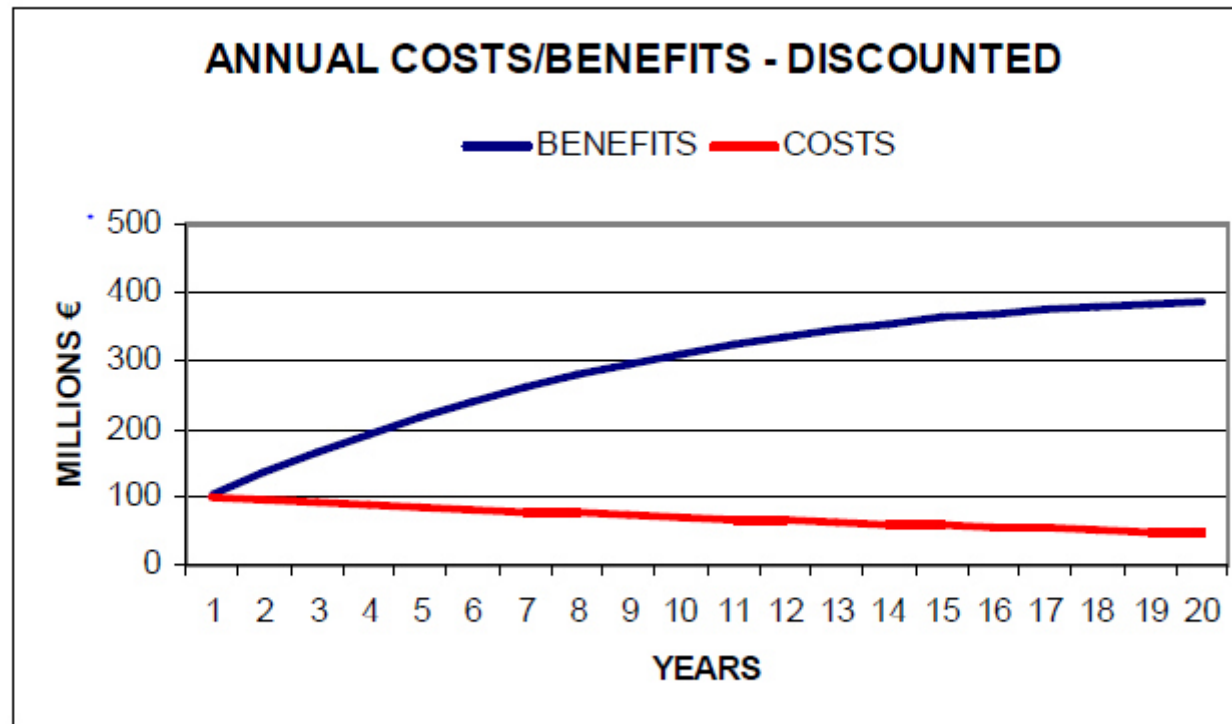


FIGURE 6: DEVELOPMENT OF DISCOUNTED ANNUAL COSTS AND BENEFITS (DISCOUNT RATE 4%)

## Comparison between Risk Management Options

Criterion	Parameter	RMO 1	RMO 2	RMO 3
		<b>Chromium (VI) in articles of leather with direct and prolonged contact with the human skin</b>	<b>Chromium (VI) in all articles of leather</b>	<b>Chromium in all articles of leather</b>
		<b>Score</b>	<b>Score</b>	<b>Score</b>
Effectiveness	Risk reduction capacity	2	2	3
	Proportionality	3	3	1
	Overall	3	3	2
Practicability	Implementability	3	2	1
	Enforceability	2	2	3
	Manageability	3	3	2
	Overall	3	2	2
Monitorability	Availability of indicators	3	3	3
	Ease of monitoring	3	3	3
	Availability of monitoring mechanisms	3	3	3
	Overall	3	3	3

# Sensitivity analysis of Proposed Restriction

- Reducing prevalence of chromium allergy from 0.37% to 0.2% in population
- Reducing the effect of the proposed restriction on leather related Cr(VI) allergy from 80 % to 40%
- Reducing the welfare cost element by 50% (e.g. if symptom days are 63 instead of 125 days)
- Increasing estimated industry costs by 100%

# Sensitivity – alternative assumptions

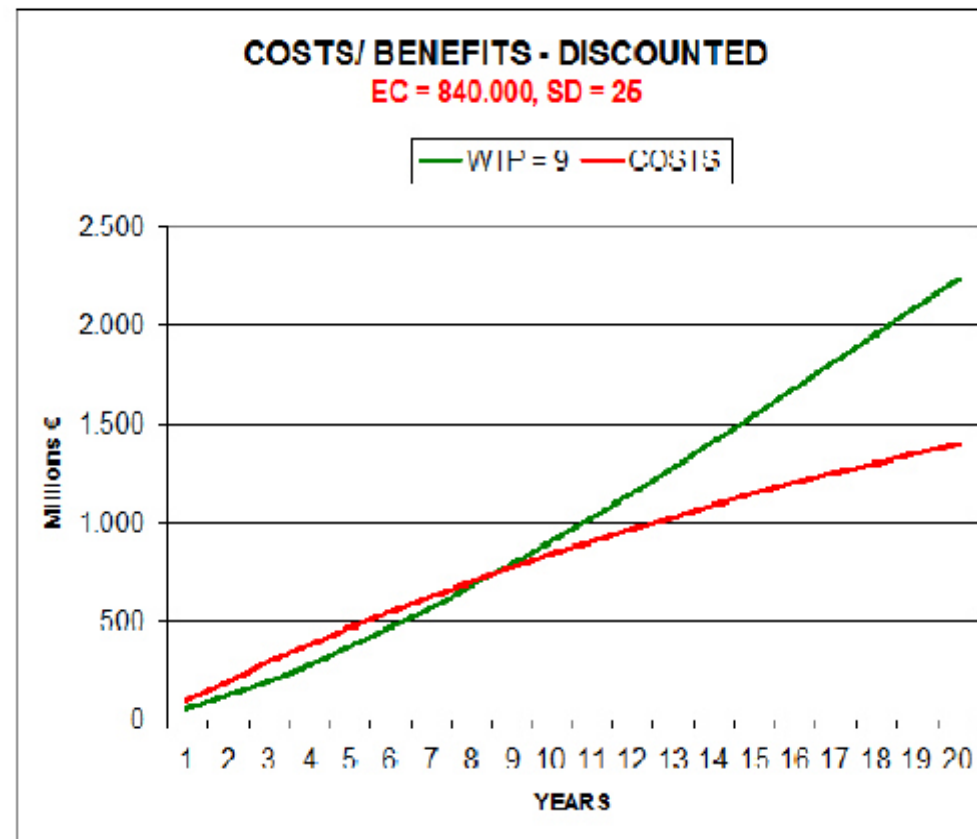


FIGURE 8 COST/BENEFITS WITH REDUCED NUMBER OF EXISTING CASES, REDUCED SD AND REDUCED WTP



## Some SEA considerations

Always keep in mind – Who is the receiver – what is necessary to take a decision

Basis scenario – what would happen without a restriction - Focus on the changes . Targeted approach

Relationship between exposure and impacts – Often tricky – but in this case more straightforward

Distributional effects – affordability – geographical scope.

Discounting – controversial issue - especially on long term health and environmental impacts

Relying on input – consultation crucial – Stakeholder involvement – Otherwise analysis will be based on assumptions.



<https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1906/term>