

Restriction on Chromium (VI) in leather

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Chemical division

CR(VI) – hazard endpoints

Carcinogenic Cat. 1B or 1A

Mutagenic, cat. 1B

Reproductive toxic, cat. 1B

Respiratory sensitiser, cat. 1

Specific target organ toxicity - STOT RE 1



Cr(VI) known to cause servere 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





Leather articles count 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%

1/4-1/3 of leather articles found to contain Cr(VI) above 3 mg/kg (ppm)

Typical range of Cr(III) content in leather shoes between 1 and 3%.

Why is chromium in leather?

- Added during the tanning process
 - Cr binds to collagen 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

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

Restriction

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 equal to or higher than 3 mg/kg chromium(VI) of the total dry weight of the leather.

Effectiveness of the restriction

- 90% of all leather articles covered
- 80% of all cases related to Cr(VI) in leather are avoided
 Potential release at the limit value is up to 22 times higher than the
 MET10 value (minimum elicitation threshold where 10 % of
 sensitized individuals reacts)
- 36% of all cases related to Cr(VI) are avoided
- 13,000 cases avoided annually (not including Germany)

Costs – € 100 million

Tanneries: 0.2 - 1% of leather production cost

If 1/3 of tanneries in EU have to change:
EU tannery extra cost: €8-15 million annually
For 2/3 (or more) of tanneries that have already changed:
Positive impact on competition (equal playing field)

Importers of leather and leather articles:

More expensive goods: €70 million annually

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

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

Impacts – benefits

10 800 – 13 000 cases avoided annually (3 000 cases in Germany not included)

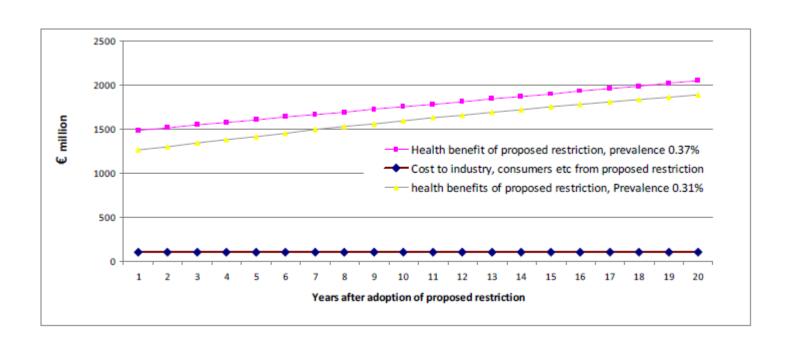
0.11	-	Discounted annual
Cost per case of allergy :	annual	lifetime
Direct cost – health care and medication, €:	472	9700
Production loss – (7 days per week), € :	1190	18600
Welfare loss (125 days/year – €15/day), € :	1875	37900
Total cost, €	3537	66100

A restriction will also reduce provocation of already sensitized persons (1.3 – 1.5 million)

Danish view: Welfare loss (63 days/year), €: 940

	Effects in year 1	Effects in year 20
Saved cost of avoided new cases (million euro)	46	920
Saved cost of avoided symptom days for existing cases (million €)	1437	1120
Total health benefits (= saved costs) (million euro)	1483	2040

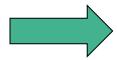
Dossier Submitter estimations — health benefits and costs to industry and consumers



How to evaluate welfare loss due to risk of Cr(VI) in leather – existing cases

Approach 1 (DS)

Assumption – 63 symptom days per year – 15 € per day (WTP) – 940 €/y



Accumulated net benefits (20 y): € 20 billion

Approach 2 (SEAC)

Possible to avoid leather and thereby exposure – loss in consumer surplus when buying leather products – assumed to be €50 per year.



Accumulated net benefits (20 y): € 4.4 billion



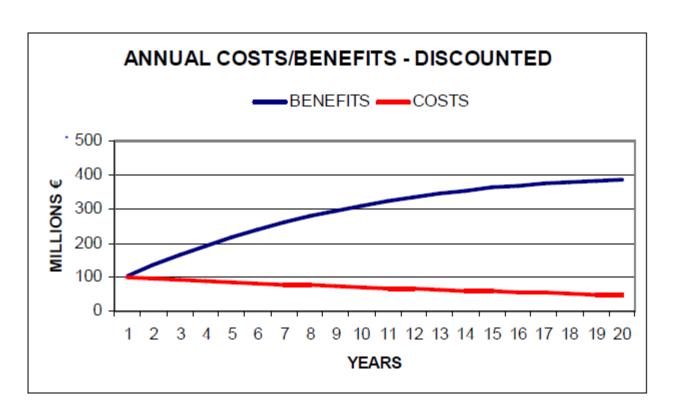


FIGURE 6: DEVELOPMENT OF DISCOUNTED ANNUAL COSTS AND BENEFITS (DISCOUNT RATE 4%)

Sensitivity analysis

- 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%



Accumulated net benefits: € 0.8 billion SEAC approach

SEA limitations

Not the whole story Countable elements dominate Dynamics not taken into account Affordability

Acceptability

Discounting – especially on long term health and environmental impacts Questions whether consumers and industry behave rationally Distributional issues (starting point and effects)

Many uncertainties

Wording (framing) is important - e.g. benefits do not cover all elements.