ANNEX XV REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): Chromium (VI) compounds

IUPAC NAME(S): not applicable[1]

EC NUMBER(S): not applicable

CAS NUMBER(S): not applicable

INDEX NUMBER(S): not applicable

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[1] Information corrected by the dossier submitter after submission of the dossier.

CONTENT

A. Proposal

A.1 Proposed restriction(s)

A.1.1 The identity of the substance(s)

Substance name	Chromium (VI) compounds
IUPAC name	not applicable
EC number	not applicable
CAS number	not applicable

The restriction may concern the chromium (VI) substances and ions listed in Appendix 1.

A.1.2 Scope and conditions of the restriction

Based on the justifications summarised in section A.2 and discussed in the report, the following restriction is suggested for chromium (VI) (hexavalent chromium) in leather:

- Articles of leather, coming into direct and prolonged or repetitive contact with the skin, shall not be placed on the market if the leather contains chromium (VI) in concentrations equal to or higher than 3 mg/kg.

Hexavalent chromium is not intentionally used in the preparation of leather from skins and hides and in the manufacturing of articles of leather, but may be formed during the processing. Under controlled conditions chromium tanned leather and articles of chromium tanned leather have be found without hexavalent chromium.

Some studies have shown that already sensitised individuals may react at a concentration of 3 ppm of hexavalent chromium, but for practical reason to determine compliance with the restriction the limit has been chosen. The limit represent the quantitative limit of detection of the analytical method used to determine the content of hexavalent chromium is in leather in its current state. The method is the international standard EN ISO 17075:2007.

A.2 Summary of the justification

A.2.1 Identified hazard and risk

Chromium (VI) is known to cause severe allergic contact dermatitis in humans and to be able to elicit dermatitis at very low concentrations. Previously cement was a major cause of chromium dermatitis in Europe. However, the introduction of restrictions in the use of cement containing more than 2 mg/kg soluble chromium (VI) has had a significant impact of the prevalence of chromium allergy in the population.

In a recent study, the development of chromium allergy among patients with eczema was investigated from 1985 to 2007 in the region of Copenhagen in Denmark. A retrospective analysis of contact allergy to chromium in 16,228 patients was made. The frequency (the prevalence) of chromium allergy among the patients with eczema decreased significantly from 3.6% in 1985 to 1% in 1995, but increased again significantly to 3.3% in 2007.

Leather goods coming into close prolonged contact with the skin are expected to give rise to the highest exposure of consumers. Examples include shoes and gloves, clothes, hats, sports equipment, leather cover for seats, steering wheel and gearshift in cars, furniture, watch straps and straps for bags.

The risk assessment performed as part of this dossier concludes that extractable chromium (VI) from shoes and other articles of leather represents a risk for the development of contact allergy to chromium for the consumers.

Chromium (VI) is not used intentionally in the production of leather but may be formed within the leather by oxidation of chromium (III) used for the tanning of the leather. The mechanisms of the formation of chromium (VI) in the leather are today well known and measures for prevention of the formation of chromium (VI) in measureable concentrations have been developed and implemented in most tanneries in the EU.

Chromium contact allergy is a severe allergy. It is on the basis of Danish experience assumed that the number of symptom days will gradually decrease over a 20 year period from 200 to 100 days per year and then remain at 100 days per year for the rest of the patient's life. It is furthermore estimated that a person with chromium contact allergy is absent from work 7 days per year due to the allergy.

Evidence of consumer exposure

Surveys of chromium (VI) in articles of leather in Germany and Denmark in 2007-2008 have demonstrated that more than 30% of the tested articles of leather contained chromium (VI) in concentrations above 3 mg/kg.

Virtually all consumers are to some extent exposed to chromium (VI) in articles of leather such as leather shoes, straps, garments made of leather, gloves, bags, car steering wheels and furniture.

Articles of leather, when in direct and prolonged contact with the skin can result in skin sensitisation with symptoms such as contact dermatitis. The main exposure route is dermal contact and in principle all consumers across the EU are at risk of exposure to chromium (VI) in leather.

It is on the basis of the available data estimated that 0.2-0.7% of the population in the EU are allergic to chromium (VI) corresponding to approximately 1-3 million people. Chromium (VI) in leather has been demonstrated to be one of the causative exposures for development of contact dermatitis in patients. Bases on survey data from Denmark, it has been estimated that during the last 10 years about 45% of the new chromium allergy cases were due to exposure to leather.

A.2.2 Justification that action is required on a Community-wide basis

According to Industry measures for prevention of formation of chromium (VI) in leather are implemented in tanneries all over Europe. Furthermore, many importers of leather and articles of leather require that the leather does not contain chromium (VI) in measureable concentrations. The survey data, however, clearly demonstrates that the risk management measures implemented by the manufacturers and some importers are not sufficient to protect the consumers against exposure to chromium (VI) in leather. The majority of articles of leather placed on the market are imported from countries outside the EU, and a likely explanation for the high percentage of articles with chromium (VI) in measureable concentration, could be that these articles are imported. The surveys in general do not report on the origin of the tested articles and data clearly demonstrating that it is only imported articles that contain chromium (VI) are not available.

In spite of the implemented measures, a large number of consumers develop each year chromium allergy due to exposure to chromium (VI) in leather.

The proposed restriction covers articles of leather that are extensively traded among and used in all Member States; most of which have not established national restrictions.

The justification to act on a Community-wide basis origins from the need to avoid different legislations in the Member States with the risk of creating unequal market conditions:

- The proposed restriction would remove the potentially distorting effect that current national restrictions may have on the free circulation of goods;

- Regulating chromium (VI) in leather through Community-wide action ensures that the producers of the articles in different Member States are treated in an equitable manner;

- Acting at Community level would ensure a 'level playing field' among all producers and importers of the articles of leather.

A.2.3 Justification that the proposed restriction is the most appropriate Community-wide measure

The majority of manufacturers in Europe, according to Industry, have already implemented measures for prevention of chromium (VI) in leather, and the authorisation route is consequently not considered to be an efficient risk management option. As the authorisation route does not address the imported articles placed on the market, the risks to the consumers are not adequately addressed by this route.

Two other restriction options have been assessed: To widen the scope to cover all articles of leather (RMO 2) and to widen the scope and restrict chromium in any form in leather (RMO 3).

RMO 2 may provide a slightly better consumer protection, but also include technical leather used for industrial purposes like leather belts for power transmission and hydraulic packing etc. with very limited skin contact, but the costs to the benefits ratio for the extra articles are higher than the ratio for RMO 1.

RMO 3 is in practice a ban of chrome tanned leather. This RMO may provide a better consumer protection by omitting all exposure from both Chromium III and VI but with significantly higher costs than RMO 1 as especially the shoes production must be completely changed.

Effectiveness in reducing the identified risks

Based on the available data the total number of new cases of chromium allergy per year in EU is estimated at approximately 44,000. Of these, 45% is estimated to be caused by exposure to chromium (VI) in leather.

It is proposed that the EN ISO 17075 standard for determination of chromium (VI) in leather is used for compliance control. As the standard currently has a detection limit for chromium (VI) of 3 mg/kg, even leather passing the test may contain chromium (VI) in trace amounts.

It is estimated that the restriction would cover about 90% of the articles placed on the market, the remainder being articles with short-time contact with the body. The articles are to a large extent manufactured or imported by the same companies manufacturing or importing the articles covered by the restriction. For articles of chrome tanned leather, it is most likely that the manufacturers and importers of articles would apply the same procedures whether they are covered by the restriction or not.

On the basis of the available information on elicitation threshold and the limit value of the applied standard for compliance control (3 mg/kg) it is estimated that the effectiveness of the restriction in preventing new cases of chromium allergy caused by leather would likely be some 80% meaning 13,000 less cases per year[2].

Proportionality to the risks

The cost-benefit analysis performed as part of the socio-economic assessment demonstrates that the monetised health benefits are significantly higher than the costs of the restriction.

The net benefit of the proposed restriction is significant and growing over time. The health benefits will yearly initially be around 1,500 €m and gradually grow as the prevalence of chromium allergy in the EU27 population decreases. With estimated costs of the restriction proposal in the order of 100 €m the net benefit is substantial. Even when applying least-benefits assumptions for a sensitivity calculation, the benefits are significantly higher than the costs.

Practicality, including enforceability

According to the Confederation of National Associations of Tanners and Dressers of the European Community (COTANCE), measures are already applied by tanneries all across Europe and the confederation welcomes a restriction. The proposed restriction covers the same type of articles as the current restriction of azocolourants in leather and the same reporting procedures applied for the azocolourants, can be used for the chromium (VI). A standard for determination of chromium (VI) in leather has been developed and procedures for compliance with the companies' own restrictions or the current German regulation are widely applied. A large number of laboratories provide analysis of chromium (VI) in leather, which is often tested together with other hazardous substances. The enforcement of the restriction can be done concurrently with enforcement of other restriction of hazardous chemicals in leather or articles of leather.

Monitorability

The effect of the restriction of the presence of chromium (VI) in leather can be monitored by tests of chromium (VI) in articles.

The effect of the restriction on the number of new cases of chromium allergy can be monitored by the prevalence of chromium allergy among patients with dermatitis which are patch tested. At EU-level, changes in prevalence can be monitored by the use of results from the European baseline series from the European Surveillance System on Contact Allergies.

A.2.4 Summary

In summary, the available data show an unacceptable baseline situation for European consumers with respect to chromium (VI) in a variety of widely used consumer articles of leather coming into direct and prolonged contact with the skin. At present, the provisions on chemicals and the consumer protection legislation are insufficient to protect consumers, including children, from long-term adverse effect from contact allergy. Swift regulation is needed in order to adequately protect the consumers.

[2] Information corrected by the dossier submitter after submission of the dossier.

B. Information on hazard and risk

B.1 Identity of the substance(s) and physical and chemical properties

B.1.1 Name and other identifiers of the substance(s)

Chemical Name: Chromium (VI) compounds
IUPAC Name: not applicable
EC Number: not applicable
CAS Number: not applicable
Synonyms: Hexavalent chromium compounds, Cr (VI) compounds, Cr^{6+} compounds

B.1.2 Composition of the substance(s)

All substances containing chromium in oxidation state: +6

B.1.3 Physicochemical properties

The hexavalent chromium ion (CAS Number: 18540-29-9) is not registered as a "substance" under REACH or included in the ESIS database.

In the hexavalent state, chromium exists as oxo species such as CrO_3 and CrO_4^{2-} that are strongly oxidizing (US EPA, 1998).

In solution, chromium (VI) exists as hydrochromate ($HCrO_4^-$), chromate (CrO_4^{2-}), and dichromate ($Cr_2O_7^{2-}$) ionic species. The proportion of each ion in solution is pH dependent. In basic and neutral pH, the chromate form predominates. As the pH is lowered (6.0 to 6.2), the hydrochromate concentration increases. At very low pH, the dichromate species predominate (US EPA, 1998).

The aqueous solubility's of selected chromium (VI) compounds are shown in Table 1.

Hexavalent chromium is a strong oxidizing agent and may react with organic matter or other reducing agents to form chromium (III). The trivalent chromium will eventually be precipitated as $Cr_2O_3 \cdot xH_2O$. Therefore, in surface water rich in organic content, hexavalent chromium will have a much shorter lifetime (US EPA, 1998).

TABLE 1 CAS NUMBERS AND AQUEOUS SOLUBILITIES OF SELECTED CHROMIUM (VI) COMPOUNDS

Compound	Chemical formula	EC No. 2)	CAS No.	Water solubility
Ammonium chromate	$(NH_4)_2CrO_4$	232-138-4	7788-98-9	40.5 g/100 mL at 30ºC
Calcium chromate	$CaCrO_4$	237-366-8	13765-19-0	2.23 g/100 mL at 20ºC
Chromic trioxide 3)	CrO_3	215-607-8	1333-82-0	61.7 g/100 mL at 0ºC
Potassium chromate 3)	K_2CrO_4	232-140-5	7789-00-6	62.9 g/100 mL at 20ºC
Potassium dichromate 3)	$K_2Cr_2O_7$	231-906-6	7778-50-9	4.9 g/100 mL at 0ºC
Sodium chromate	Na_2CrO_4	231-889-5	7775-11-3	87.3 g/100 mL at 30ºC
Sodium dichromate dihydrate	$Na_2Cr_2O_7\ 2H_2O$ 1)	-4)	7789-12-0	230 g/100 mL at 0ºC

Source: Based on US EPA, 1998; 1): Chemical formula added in this report. 2): EC No added in this report. 3) : Chemical name or CAS No is corrected. 4): EC No of the entry of the anhydrous form: 234-190-3 (CAS No: 10588-01-9)

B.1.4 Justification for grouping

This proposal concerns chromium (VI) formed unintentionally in leather tanned by the use of chromium (III) compounds as tanning agents. The chromium (VI) may be present in the leather and in articles of leather as various chromium (VI) compounds. The allergen is the chromium (VI) ion and the proposal concerns the group of substances containing hexavalent chromium.

B.2 Manufacture and uses

B.2.1 Manufacture and import of chromium (VI)

Chromium (VI) compounds are no longer used in the production of leather. Chromium (VI) may be formed unintentionally in small amounts in leather tanned using chromium (III) compounds. This restriction proposal does not address the chromium (III) compounds used in the tanning process.

The following description of the production of the chromium salts should be regarded as a part of the framing of the discussion about chromium (VI) in leather, rather than a description of the manufacture of the substances addressed by the dossier.

Manufacturing and use of chromium

In 2009 according to the Minerals Yearbook, world chromite ore production was about 18.9 million tonnes of which 95.2% was for the metallurgical industry, 2.4% for the foundry industry, 1.6% for the chemical industry and 0.8% for the refractory industry (Papp, 2009). The production in terms of Cr content is not indicated, but a previous study indicated that in 1992, 30% of chromite ore was Cr (11.2 Mt Cr-ore contained 3.37 Mt Cr; Papp, 1995). Using these data, approximately 91,000 t Cr/year would be used globally in the chemical industry and a part of this for chromium based tanning chemicals. The production in 2009 was about 10% lower than the previous years (USGS, 2009).

Manufacturing of chromium (VI) compounds in the EU

World sodium dichromate production was about 1.2 million tonnes (Papp, 2009). A part of this is used for manufacturing of chromium tanning agents.

A range of chromium (VI) compounds are on the SVHC candidate list and Annex XV dossiers have been prepared for more than 15 chromium (VI) compounds. Data on manufactured volume and consumption are shown in Table 2.

In terms of manufactured volumes in the EU, sodium chromate, sodium dichromate, chromium trioxide, potassium dichromate, strontium chromate and two lead chromate pigments have been the most important. The total manufactured volume in the EU is of the order of magnitude of several hundred thousand tonnes.

TABLE 2 MANUFACTURED VOLUMES FOR CHROMIUM (VI) COMPOUNDS ACCORDING TO ANNEX XV DOSSIERS (ECHA, 2011)

Substance(s)	EC No	CAS No	Manufactured volume		Consumption volume		Dossier submitted by
			Tonnes /year	Year	Tonnes /year	Year	
Sodium dichromate, dihydrate	2)	7789-12-0	110,000 1)	1997	25,000 1)	1997	France 2008
Lead chromate	231-846-0	7758-97-6	Not indicated		Not indicated		France 2009
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	30,000	2008	~7700 (~2/3 of Yellow 34)	2008	France 2009
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2					France 2009
Chromium trioxide	215-607-8	1333-82-0	32,000 1) Ceased	1997 2006	17,000 1)	1997	Germany, 2010
Acids generated from chromium trioxide and their oligomers Group containing: Oligomers of chromic acid and dichromic acid Chromic acid Dichromic acid	 231-801-5 236-881-5	 7738-94-5 13530-68-2					Germany, 2010
Sodium chromate	231-889-5	7775-11-3	103,000 1)	1997	Not indicated		France 2010
Potassium chromate	232-140-5	7789-00-6	Not indicated		Not indicated		France 2010
Ammonium dichromate	232-143-1	7789-09-5	850 1)	1997	Not indicated		France 2010
Potassium dichromate	231-906-6	7778-50-9	1,500 1)	1997	Not indicated		France 2010
Strontium chromate	232-142-6	7789-06-2	4,000	2010	Not indicated		France 2011
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	10-100	2011	Not indicated (Confidential)		France, 2011
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	100-1000	2011	Not indicated (Confidential)		France, 2011
Dichromium tris(chromate)	246-356-2	24613-89-6	10-100	2011	Not indicated (Confidential)		France, 2011

1) Data from the EU RAR (ECB, 2005). 2) EC No of the anhydrous form: 234-190-3.

Manufacturing of chromium (III) tanning salts

Chromium (VI) compounds are assumed not to be used for tanning anywhere in the world today.

The main chromium compound used for tanning of leather is chromium (III) hydroxide sulphate, $Cr(OH)SO_4$ (CAS No 12336-95-7; EC No 235-595-8). The chromium (III) hydroxide sulphate is marketed under many trade names for use in leather tanning, and chromium based tanning salts are produced at several sites in the EU. The substance is not included in Annex VI of the CLP Regulation (CLP-Regulation (EC) No 1272/2008) (harmonised classification) but its classification has been notified by several companies to the C&L inventory (http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database).[3]

The chromium (III) hydroxide sulphate is made by the reduction of sodium dichromate in the presence of sulphuric acid. By varying the sulphuric acid to chromium (VI) ratio, chromium (III) sulphates of differing basicity are produced (ECB, 2005). The basicity of a chrome tanning agent is the proportion of hydroxyl groups (OH groups) in the molecule (BASF, 2007). The optimum basicity is obtained by addition of alkalis such as sodium bicarbonate or sodium ash[4] (BASF, 2007). The chromium (III) hydroxide sulphate is most often designated "basic chromium sulphate". The amount of sodium dichromate used in the production of chromium sulphate is in the EU RAR indicated at 13,500 tonnes in 1997 (corresponding to 4,333 tonnes Cr) (ECB, 2005).

According to Pocket Book for the Leather Technologist from BASF (2007), potassium dichromate may also be used as starting point for manufacturing of chromium tanning salts, however this application is not indicated in the Annex XV report for potassium dichromate (ECHA, 2011).

The basic chromium agents are often described by their content of Cr_2O_3 (typically 21-26% Cr_2O_3) and their basicity (typically 33-50 % basicity). The salts do not contain $Cr_2O_{3,}$ but according to a major supplier of tanning agents, the tanning agents are described in terms of Cr_2O_3 content because the chromium content historically has been determined by calcination of the chromium with subsequent quantification of the Cr_2O_3.

Traditionally the sodium dichromate has been converted into tanning salts either at chemical production sites or in the tanneries. At the time of the EU Risk Assessment for five chromium (VI) compounds (EU RAR), a small number of tanneries in Europe were still purchasing sodium dichromate and converting it on-site into chromium (III) salts (ECB, 2005). According to information obtained from industry for this Annex XV report, it is unlikely that any tanneries in Europe today convert sodium dichromate on site.

Basic chromium sulphate manufactured within the EU contains no measurable chromium (VI) (ECB, 2005). This has been confirmed by manufacturers of chromium tanning salts. To what extent basic chromium sulphate manufactured and used outside the EU contains chromium (VI) as an impurity is not known.

Two other chromium (III) compounds are indicated by the Pocket Book from BASF (2007) as potentially useful for tanning:

Chrome alum, chromium potassium bisulphate ($KCr(SO_4)_2$; EC No. 233-401-6, CAS No. 10141-00-1) has been used for special one-bath tannage of leather. It has not been possible to find any confirmation of actual use of this substance for tanning today.

Chromium acetate (violet) ($[Cr(H_2O)_6]$ $(CH_3COO)_3$; EC No. 213-909-4, CAS No. 1066-30-4) has been used as a special after treatment dyeing auxiliary (glove leather). It has not been possible to find any confirmation of actual use of the substance for tanning today.

[3] Information corrected by the dossier submitter after submission of the dossier.
[4] Chemical name: Sodium carbonate

B.2.2 Uses

B.2.2.1 Use of chromium in leather tanning

Chemicals used for leather production

According to the BREF draft 80-95% of the world tanneries use chromium (III) salts in their tanning process (BREF, 2011). For this Annex XV report, the German association TEGEWA e.V. has indicated that 80-85% of leather worldwide is processed using chrome tanning (TEGEWA, 2011). The percentage indicated by different sources varies and may be dependent on whether sole leather is included, but this is often not indicated. Sole leather, which is typically tanned using vegetable tanning agents, is a specific market segment and is seldom included in market statistics of leather manufacture (described later in this section).

According to the paper of Reich and Taeger (2009), about 900,000 tonnes of tanning agents are used per year globally (Table 3). Of these, basic chromium sulphate accounts for 400,000 tonnes. A major supplier of chrome tanning agent indicates that the technical quality of basic chromium sulphate may vary, but on average it contains about 17% Cr. Using this percentage, the 400,000 tonnes would correspond to approximately 68,000 tonnes Cr. Compared to the data on global consumption of Cr for the chemical industry, this seems somewhat high. Other tanning chemicals are vegetable tannins (300,000 t), aromatic syntans (150,000 t), glutaraldehyde (30,000 t) and resin tannins (30,000 t). The different types of tanning are further described in section C.3.2.

The total market value of chemicals for leather production in 2002 was 3.5 billion €. Tanning agents accounted for 28% of the value (Reich and Taeger, 2009).

Europe has 15-20% of the global production of leather (as described later) and the consumption of chromium tanning agents in the EU is estimated on this basis at 60,000-80,000 tonnes of basic chromium sulphate corresponding to 10,000-14,000 tonnes Cr.

TABLE 3 GLOBAL CONSUMPTION OF CHEMICALS FOR LEATHER PRODUCTION

Product category	**Global consumption 1000 t/year**
Water	320,000
Tensides	120
Hydrated lime	200
Sodium sulphide	150
Sodium chloride	270
Basic chromium sulphate	***400***
Vegetable tannins	300
Aromatic syntans	150
Glutaraldehyde	30
Resin syntans	30
Polymer tanning agents	150
Fatliquors	400
Pigments	90
Polymer binders	200

Source: Reich and Taeger, 2009

A significant part of the non-chrome tanning agents are used in combination with the basic chromium sulphate to produce chrome tanned leather. It is common to use the term “chrome tanned leather” instead of “chromium tanned leather” and the former term is used here. The typical consumption of chemicals for the production of 1,000 m^2 chrome tanned leather for shoe uppers and 430 m^2 split leather (in total 1,430 m^2 leather), produced from the same hides, is shown in Table 4. In total about 160 kg vegetable tannins, aromatic syntans, polymer tanning agents and resin tannins are used in combination with 175 kg chromium tanning agents (as Cr_2O_3) for the production of the indicated quantity of leather.

TABLE 4 CHEMICALS USED FOR THE PRODUCTION OF 1000 m^2 CHROME TANNED SHOE LEATHER AND 430 m^2 SPLIT

Product category	**Consumption kg**
Process chemicals	
Water	215,000
Inorganic salts (mainly sodium chloride)	570
Inorganic and organic acids	30
Calcium hydroxide	285
Sodium sulphide	175
Enzymes	20
Tenside	20
Chemicals of which 85-98 % stays permanently in the leather	
Chromium tanning agents (as Cr_2O_3)	***175***
Vegetable tannins	50
Aromatic syntans	50
Polymer tanning agents	50
Resin syntans	10
Fatliquors	150
Pigment	35
Polymer binder	30

Source: Reich and Taeger, 2009

Steps in the production of leather

Tannery operation consists of converting the raw hide or skin into leather, a stable material, which can be used in the manufacture of a wide range of products. The leather tanning industry uses hides and skins, which, except for a few types of exotic skins are by-products of the meat and dairy industry. The production of raw hides and skins depends on animal population and slaughter rate and is related mainly to meat consumption.

The whole process involves a sequence of complex chemical reactions and mechanical processes. Amongst these, tanning is the fundamental stage, which gives leather its stability and essential character. Tanning is a specific step in the processing of the raw hide into leather, but the term is sometimes used for the entire process.

The possible steps in the production of leather are shown schematically in Figure 1 based on the Reference Document on Best Available Techniques (EU BREF) for the tanning of hides and skins (which in fact covers all processes in the conversion of the hides into leather). There is considerable variation between tanneries, depending on the type of leather being produced. Chromium tanning salts may be added to the two processes indicated as “tanning” and “re-tanning”, but several of the other processes are of importance as to the formation of chromium (VI) in the leather.

The full process does not necessarily take place in one company and semi-manufactured goods are intensively traded both within the EU and imported and exported to and from countries outside the EU. The most common types of traded semi-manufactures are:

- Raw hides and skins – which typically have been salted for preparation;
- Pickled leather (or pickled pelts) which is the product output of the beamhouse operations, ready for the tanning;
- Wet-blue leather (or wet-white for chrome-free tanning) which is the leather that has undergone tanning operations and is ready for shaving and retanning;
- Crust leather, which has been retanned and dried, and is ready for finishing.

As will be discussed in the following, it is mainly the post-tanning operations that are associated with the risk of formation of chromium (VI) in the leather.

About 20-25 % of the raw (salted) bovine hide weight is transformed to leather in the tanning process; for sheep or goat skins the figure is 12-15 %, based on salted raw skins (BREF, 2011). The remainder is waste or by-product of the process. The processing of hides and skins also generates other by-products which find outlets in several industry sectors such as pet and animal food production, fine chemicals including photography and cosmetics, and soil conditioning and fertilisers (DG ENTR, 2011).

The tanning sector and trading of the various products is further described in Section B.2.2.5.

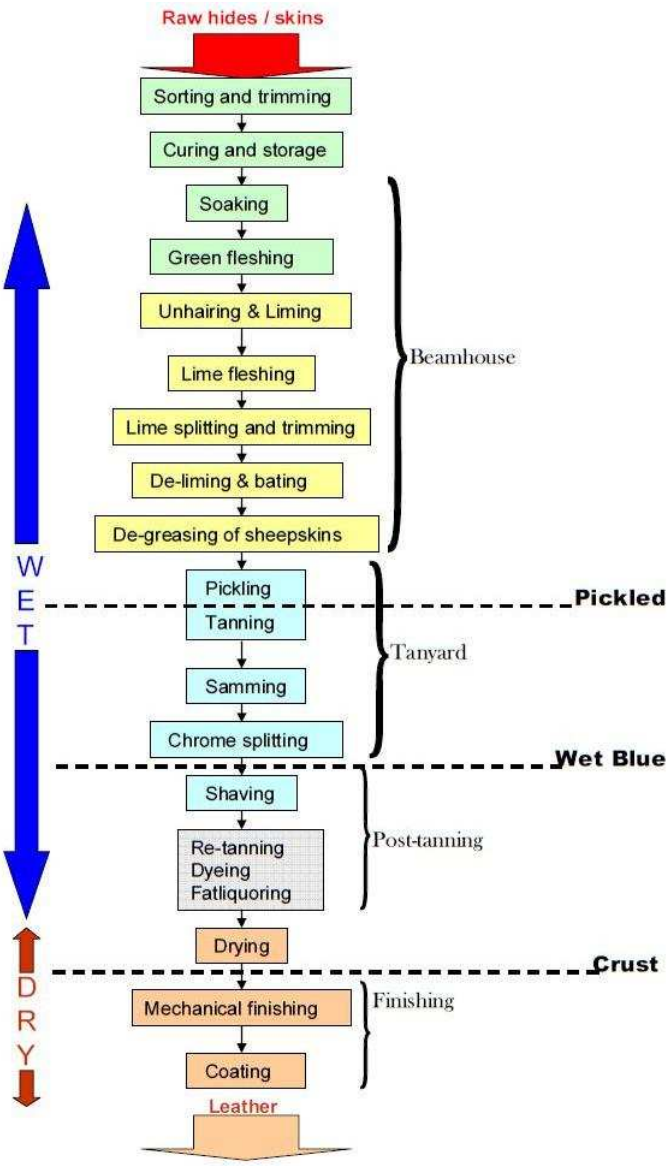

FIGURE 1 POSSIBLE STEPS IN THE PRODUCTION OF LEATHER (BREF, 2011)

The function of chromium in the tanning process

During the tanning process, the chromium tanning agent binds to the collagen in the hides and cross links the collagen subunits. The dimensional stability, resistance to mechanical action and heat resistance of the leather increases (BREF, 2011).

Different chromium tanning processes are described in the EU BREF document designated "conventional process" and "high exhaustion chrome tanning". In the context of the BREF the two processes are described because the potential environmental impact is different in each. In a conventional process, the chromium salts are mostly added as powder. For each tonne of raw materials, 80 to 120 kg of chrome tanning salts is added. Of the added chromium tanning powder only 25% is actually active tanning material (BREF, 2011). In the conventional tanning process between 60 and 80% of the chromium may be fixed in the leather the remainder being left in the water phase (BREF, 2011). In the high-exhaustion chrome tanning process only 50-60 kg chromium salts are added for each tonne of raw materials. High exhaustion tanning includes the use of specific chemical products able to increase the chromium uptake combined with an optimisation of the tanning process parameters as described by the BREF (2011). It seems not to be significant as far as the formation of chromium (VI) is concerned, whether conventional or high exhaustion tanning is used.

The chromium uptake can be increased by up to 80% through careful control of pH, float, temperature, time and drum speed. In conventional tanning (without chrome recovery) 2 - 5 kg chrome salts per tonne of raw bovine hides is released via the spent liquors. In high exhaustion chrome tanning this quantity can be reduced to 0.05 - 0.1 kg per tonne of raw bovine hides.

Despite the fact that chromium has been under pressure from some regulatory authorities, the extent of substitution of chromium tanning agents has been limited. The main reason for this is that chromium is the most efficient and versatile tanning agent available and it is relatively cheap (BREF, 2011).

Besides the use of chromium in the tanning process, chromium tanning salts may also be added by the retanning of the wet-blue leather. The purpose of the retanning includes improving the feel and handling of the leather, fill looser and softer parts in order to produce more uniform physical properties, to improve the resistance to alkali and perspiration and prepare the leather for the dyeing process. The retanning is often done in a sequence of retanning, dyeing and fatliquoring in the same tumblers. Several types of retanning agents may be combined to obtain the desired properties of the leather. The retanning, dyeing and fatliquoring steps are of great importance for the possible formation of chromium (VI) (Chrom6less, 2005).

B.2.2.2 Formation of chromium (VI) in leather

All tanning within the EU is carried out using basic trivalent chromium (III) sulphate. Basic trivalent chromium sulphate manufactured within the EU contains no measurable Cr (VI) (ECB, 2005), but chromium (VI) may be formed by oxidation of the chromium (III) within the leather.

The formation of chromium (VI) by the production of leather and techniques for the prevention of its formation have been investigated for more than a decade with some of the first studies dating back to the 1990's (e.g. Hauber and Germann, 1999; Font *et al.*, 1998). The prevention of formation was the objective of a research programme entitled "Prevention of Chromium (VI) formation by improving the tannery processes" funded by the European Community. The two-year-long research programme (2003-2005) involved 11 partners within the tanning sector from three European countries (Chrom6less, 2005). One of the outputs of the project was a quality handbook for the production of chromium (VI)-free leather.

More recently a joint research project at the German Test and Research Institute Pirmasens and the Tanning School Leather Institute Reutlingen has studied the possible formation of chromium (VI) in leather and articles of leather together with measures for the prevention of the formation (Meyndt *et al.*, 2011; PFI, 2011).

The recommended measures for the prevention of formation of chromium (VI) are further described in section C.2.1, whereas this section contains a brief description of the formation of chromium (VI) in the leather and articles made of leather.

Formation mechanism

As mentioned, chromium (VI) in the leather is formed by an oxidation of the chromium (III) added to the leather during the tanning or the retanning processes. By the oxidation of trivalent chromium, Cr $(III)^{3+}$ to hexavalent chromium, Cr $(VI)^{6+}$, the chromium atom donates three electrons, which can be accepted by an electron acceptor as shown in the illustration below:

$$Cr^{3+} \underset{\text{Reduction}}{\overset{\text{Oxidation}}{\rightleftarrows}} Cr^{6+} + 3\ e^-$$

The oxidation of chromium (III) in the leather seems to be favoured by:

- Conditions that increase the tendency of the chromium atom to donate electrons (e.g. alkaline pH values).
- The presence of suitable electron acceptors (e.g. oxidizing fatty acids).
- Conditions that brings the electron acceptors into a state where their tendency to accept the electrons is increased (e.g. by the formations of free radicals at high temperatures or by UV light).

The main mechanism of the formation of chromium (VI) in the leather seems to be the oxidation of the chromium (III) by oxidizing fatty acids.

A guideline from UNIDO (United Nations Industrial Development Organization) on the prevention of chromium (VI) in leather manufacture explains the mechanism of UV light on the formation of chromium (VI) as follows: "*Free radicals are formed by UV light from a molecule whose normal covalent bond was split to create two unstable moieties. These free radicals react with oxygen developing very reactive derivates such as peroxides, and radicals such as HO•, LO• and LOO• which are strong oxidants. Probably, this is the reason for chromium oxidation in light*" (Hauber and Buljan, 2000).

Process parameters
The oxidation by air may be favoured by high pH during the neutralisation or dyeing processes, photo-ageing and thermal ageing (Hauber and Buljan, 2000).

The extent to which the natural fat content influences the formation of chromium (VI) has been discussed. In the Chrom6less project it was suggested that skins with a high content of natural fat should be subjected to a conventional degreasing process in order to diminish the possible formation of Chromium (VI). The possible effect of the natural fat has not been confirmed by newer results of a study undertaken by two German research institutes which found that the animal hide constituents present in leather had no influence on the chromium (VI) values (PFI, 2011).

Both studies found that the choice of fatliquoring agent was crucial for the formation of chromium (VI) during leather production (Crom6less, 2005; PFI, 2011). Some types of fatliquoring agents of natural origin, such as fish oil, have been demonstrated to highly favour the formation of chromium (VI). Also some type of natural waxes used for the finishing may influence the formation of chromium (VI) (Chrom6less, 2005).

Use of greater quantities of chrome tanning agent led to high contents of total chromium and soluble total chromium in leather. No correlation however, could be seen between high total chromium content or high soluble total chromium content and the chromium (VI) content of the leathers (PFI, 2011). Contrary to this, a study from India found that the quantities of chromium salts used in the tanning and retanning had an influence on the quantities of chromium (VI) in the leather, with higher levels of chromium (VI) with higher levels of basic chromium sulphate in the process (Basaran *et al.*, 2008).

Available data indicate that chromium (VI) is mainly formed after the tanning process. This means that the chromium (VI) content in the raw hides and skins, as well as the content in wet blue (which has not been further processed after the tanning step) is usually below the detection limit. Consequently chromium (VI) is not present in raw hides, skins or wet blue imported from countries outside the EU. If chrome tanning agents with high levels of chromium (VI) as impurity is used in some countries outside the EU this may result in measurable concentrations of chromium (VI) in the wet blue. This source cannot be discounted although no actual examples have been identified.

Formation of chromium (VI) by further processing of the leather and in articles made of leather

If the chromium (VI) can be formed by the finishing of the leather it may equally well be formed later during the processing of the leather for manufacturing of footwear and other products and it may be formed within the finished articles of leather.

According to a recent research project, tests for contaminants in footwear and leather goods repeatedly reveal the presence of chromium (VI). In a laboratory study of 60 shoes of various kinds, some of which contained several different kinds of leather, six were found to contain high levels of chromium (VI) (PFI, 2011). Among the other 54 shoes without conspicuous initial chromium (VI) values, chromium (VI) could be detected in 11 shoes after they had been subjected to an ageing process in which the shoes were incubated for 24 hours at 80°C (PFI, 2011).

A considerable influence on the formation of chromium (VI) in leather could be attributed to ageing and UV irradiation. After ageing and UV irradiation, the chromium (VI) content proved to be higher in the outer layers directly exposed to the environment than in the inner layers (PFI, 2011).

One of the data-set showing the effect of UV irradiation is shown in Table 5. The data are illustrative of some of the parameters of importance when discussing the formation of chromium (VI) in leather. The samples were prepared for the purpose using three different loadings of chromium tanning salts specified in units of % Cr_2O_3 of the pelt weight ranging from 0.5 to 2.5% resulting in a total Cr content of 0.7 to 3.6% of the leather weight. Most of chromium (III) in the leather is hardly soluble and the concentration of soluble chromium is in the range of 275 to 1,186 mg/kg and is slightly different depending on the extraction method applied. The percentage of the total soluble chromium content before the UV treatment, was in the range of 2-4% using EN ISO 17072-1[5] and 3-7% using EN ISO 17075[6]. There was a slight tendency to increased content at lower chromium level. Before the UV irradiation all samples had a chromium (VI) concentration below 3 mg/kg as measured in accordance with EN ISO 17075. After UV irradiation four of the samples had a chromium (VI) concentration above 3 mg/kg, whereas the concentration of soluble chromium did not increase. It should be noted that EN ISO 17075 has a quantification limit of 3 mg/kg. In-house tests of reproducibility resulted in a lower detection limit of 0.75 mg/kg (Meyndt *et al.*, 2011). For research purposes only, it was possible to use this lower in-house detection limit to establish tendencies (Meyndt *et al.*, 2011).

[5] EN ISO 17072-1 Leather - Chemical determination of metal content - Part 1: Extractable metals
[6] EN ISO 17075 Leather - Chemical tests - Determination of chromium(VI) content

TABLE 5 EFFECT OF UV-IRRADIATION ON THE CONCENTRATION OF CHROMIUM (VI) IN LEATHER

V-Nr	Chrome tanning	Original air-dried state				After UV irradiation		
		Chrome (VI)	Total chrome	Total soluble chrome		Chrome (VI)	Total soluble chrome	
	% Cr_2O_3 of raw weight			ISO 17075	ISO 17072-1		ISO 17075	ISO 17072-1
		(mg/kg TS)				(mg/kg TS)		
Upper leather (crust)								
2.1.1	0.5	0.88	7,335	496	275	1.16	406	257
2.1.2	1.5	< 0.75	21,919	898	754	1.50	781	744
2.1.3	2.5	< 0.75	29,406	935	995	1.92	840	1,007
2.1.4	1.5 with fixation	< 0.75	22,444	667	534	1.94	314	557
Leather lining (crust)								
2.1.1	0.5	< 0.75	10,339	687	383	3.58	300	325
2.1.2	1.5	< 0.75	26,532	1,010	847	6.58	461	800
2.1.3	2.5	< 0.75	36,004	951	1,186	7.32	437	1,049
2.1.4	1.5 with fixation	0.90	28,597	843	663	11.44	374	606

Source: Meyndt *et al.,* 2011

The effect of three different adhesives on the formation of chromium (VI) was also examined. Application of adhesive led to significantly higher chromium (VI) contents in some of the tested lining leathers, whereas upper leathers showed hardly any increase in chromium (VI) levels. The effects of some types of glue on the formation of chromium (VI) have previously been demonstrated by Nickolaus (2000).

The study also demonstrated that adoption of specific measures can minimise the risk of the formation of chromium (VI) in articles of leather. Methods for reduction of the formation of chromium (VI) during leather processing and in the final articles are further described in section C.2.

B.2.2.3 Other sources of chromium (VI) in leather

Some pigments contain chromium (VI). Table 6 shows some of the pigments that might be used in leather. Two of the pigments, lead sulphochromate yellow and lead chromate molybdate sulphate red, are produced in the EU in quantities of 30,000 tonnes (ECHA, 2011). The listed potential applications include paints and varnishes, printing inks, vinyl and cellulose acetate plastics, textile printing, leather finishing, linoleum and paper.

Although the pigments are almost insoluble in water the low quantities of soluble chromium (VI) released are enough to result in detectable concentrations of chromium (VI). A chromium (VI) concentration of 10 mg/kg may easily be exceeded using the amount of 8 grams of finishing solution with chromate pigments per square feet or higher (Chrom6less, 2005). It has been proved that in vegetable tanned leathers that are free from chromium (III) compounds, but finished with Pigment Yellow 34 (which of the two types of Pigment Yellow 34 is not specified), chromium (VI) could be detected (Chrom6less, 2005).

The use the chromate pigments in the processing of leather is not recommended today, but their use is not restricted and the presence of chromate pigments in imported leather cannot be ruled out. The pigments are on the candidate list of Substances of Very High Concern (SVHC) for authorisation.

TABLE 6 CHROMIUM (VI) PIGMENTS THAT MAY BE USED IN LEATHER (BASED ON CHROM6LESS, 2005)

Pigment	EC N°	Colour	Reference colour index
Lead chromate	231-846-0	Yellow	C.I. 77600 Pigment Yellow 34
Lead sulphochromate yellow	215-693-7	Green yellow	C.I. 77603 Pigment Yellow 34
Lead chromate molybdate sulphate red	235-759-9	Orange	C.I. 77605 Pigment Red 104

B.2.2.4 Methods for prevention of the formation of chromium (VI) in leather

Methods for prevention of chromium (VI) in leather are further described in Section C.2.1. According to COTANCE, the umbrella organisation for national associations of tanners in 13 Member States (with equivalent associations from Norway and Switzerland as associate members), the techniques for prevention of the formation of chromium (VI) are currently applied all over the EU. The same has been indicated by suppliers of chemicals for the tanning sector. According to COTANCE and the contacted research institutions the introduction of the German restriction on chromium (VI) in articles of leather placed on the market had no major impact on the sector as the tanneries had already implemented measures to prevent the formation of chromium (VI).

B.2.2.5 Manufacturing and trade of articles of leather

Applications of chrome tanned leather

Globally, approximately 6.0 million tonnes of raw hides on a wet salted basis were processed to yield about 522,600 tonnes of heavy leather and about 1,185 million square metres of light leather, including split leather (BREF, 2011). In comparison, Europe produced about 71,700 tonnes of heavy leather and about 230 million square metres of light leather (BREF, 2011). European production of light leather corresponds to about 19% of world production. Approximately 85% of the heavy leather is sole leather while the remaining 15% is leather for saddles and technical leather (Reich and Taeger, 2009). The heavy leather is a specific market area, and this leather is in general not tanned using chromium, because the leather is not intended to be soft.

The global use of light leather by product sector is shown in Table 7 and is based on statistics from the International Council of Tanners (ICT, 2011). According to COTANCE, no detailed statistical data on leather in circulation as such and in articles of leather in the EU exist. The breakdown by application areas of leather produced in the EU is most likely quite similar to the global situation (COTANCE, 2011).

A less detailed breakdown of European leather output by application area from the EU BREF document is shown in Table 7 as well. The main product sector is footwear which represents about half of the leather use, both at global and European level.

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TABLE 7 GLOBAL LEATHER USE BY APPLICATION AREA IN 2007 AND DESTINATION OF EUROPEAN LEATHER OUTPUT

Application area	**Global leather use** (ICT, 2011)		**European leather output** (BREF, 2011)
	Million square feet	**Percentage of total**	
Footwear	11,925	52 %	50 %
Furniture	3,210	14 %	17 %
Auto	2,340	10.2 %	
Garments	2,290	10 %	20 %
Gloves	1,010	4.4 %	13 %
Other articles of leather	2,155	9.4 %	
Total	22,930	100 %	100 %

The tanning sector in the EU

The basis for the tanning sector in the EU is hides and skins either produced in the EU or imported mainly from developing countries. Hides and skins are imported in a raw state (wet-salted or dry-salted) or as partly processed products, for example wet blues. EU imports of raw hides and skins have fallen significantly since 2000. The trend in the trading of bovine hides and skins is toward the EU changing from being net importer to being net exporter. This reflects an expansion in tanning capacity, especially in the Far East and Latin America. A concurrent increase in the use of imported intermediate materials means that certain steps of the leather-making process are transferred to other countries, particularly to developing countries (BREF, 2011).

TABLE 8 RAW HIDES AND SKINS 2006-2010 (CN 4101-4103): OVERVIEW (MILLION €)

	2006	**2007**	**2008**	**2009**	**2010**
Imports	482	484	394	276	424
Exports	445	406	399	402	631
Balance	-36	-78	4	126	207

Source: Eurostat, Comext database

Structural data for the sector "tanning and dressing" (Nace Rev 1 code DC 19.1) in the EU is shown in Table 9. The total number of persons employed in the sector decreased from 65,000 in EU25 in 2000 to 50,700 in EU27 in 2008. During the same period, the number of enterprises decreased from about 4,300 to 4,000.

TABLE 9 EU27 STRUCTURAL DATA 2000-2008 FOR THE SECTOR "TANNING AND DRESSING OF LEATHER"

	EU25					**EU27**			
	2000	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**
Number of enterprises	4,294	4,284	:	4,069	3,883	3,780	3,710 (e)	:(c)	4,000
Number of persons employed	65,000	63,600	61,900	60,900	56,000	54,000 (e)	51,900	50,800	50,700
Production value (€m)	:	11,484	11,205	10,661	10,097	9,000 (e)	10,699	10,365	9,228
Value added at factor cost (€m)	2,231	2,080	2,813	1,995	2,043	1,800 (e)	1,957	1,975	1,728

Source: Eurostat; SBS - industry and construction (sbs_ind_co) NACE Rev.1.1 D

Products covered: 2000-2007; Nace Rev 1 code DC 19.1 "Tanning and dressing of leather". 2008 Nace Rev 2 code C 15.11. "Tanning and dressing of leather" – data obtained from DG ENTR (2011).

Flags used: Not available; :(c): confidential; (e): estimated by Eurostat.

The trend in the number of employees in the sector by Member State is shown in Table 10. Italy represents about half of the total number of employees. In most Member States the number of employees is decreasing. For those countries with reported data, the highest decrease is reported in Lithuania, Slovakia and the UK, whereas the number of employees in Italy in 2008 was still at 85% of the 2000 level whilst in Germany it was at 73%. In Austria and Bulgaria the number of employees has increased. According to the BREF, most of the loss in industrial capacity over the last decade has been in Northern European countries. Southern European countries like Italy and Spain are now also losing enterprises in the leather sector (BREF, 2011).

TABLE 10 NUMBER OF EMPLOYEES IN THE SECTOR "TANNING AND DRESSING OF LEATHER" 2000-2008

	Number of employees								
	2000	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**
EU27					:(c)	54,000	51,900	50,800	50,700
EU25	65,000	63,600	61,900	60,900	56,000	:	:	:	:
Austria	2,070	2,090	2,257	2,343	2,274	2,279	2,139	2,227	2,292
Belgium	256	225	:	209	217	197	189	:	:
Bulgaria	967	993	1,125	744	510	817	1,148	1,030	:
Cyprus	113	119	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)
Czech Republic	1,263	977	890	777	556	386	334	:	:
Denmark	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)
Estonia	:(c)	:(c)	:(c)	:(c)	141	131	140	:	:
Finland	247	224	214	190	162	147	145	130	143
France	2,936	3,081	3,098	2,680	2,473	2,346	2,097	2,050	:
Germany	3,285	3,698	3,367	3,237	2,950	2,948	2,638	2,795	2,412
Greece	:	:	:	531	609	467	457	441	:
Hungary	:	599	407	325	280	157	174	141	131
Ireland	:	:	:	:	:	0	:	:	:
Italy	30,757	30,786	31,004	31,086	29,329	27,933	27,682	27,313	26,068
Latvia	:(c)	:(c)	89	83	80	73	56	56	55
Lithuania	808	756	693	639	454	406	294	173	161
Luxembourg	0	0	0	0	0	0	0	0	0
Malta	:(c)	:(c)	:(c)	:(c)	:	:	:	:	:
Netherlands	585	454	370	421	370	329	359	370	477
Poland	:	:	2,966	3,229	2,892	2,333	2,348	2,246	1,856
Portugal	3,105	2,845	2,747	2,734	:	2,283	2,181	:	2,012
Romania	2,143	1,796	1,649	:	:	1,275	1,132	936	:
Slovakia	1,233	852	935	1,140	972	996	443	409	322
Slovenia	:	:	1,450	1,348	:	954	:	:	928
Spain	7,396	7,858	7,398	6,824	6,105	5,592	5,072	4,840	3,989
Sweden	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)	:(c)
United Kingdom	3,323	3,184	2,640	2,254	1,802	1,457	1,438	1,345	:

Source Eurostat; SBS - industry and construction (sbs_ind_co) NACE Rev.1.1 D.

EU27, 2005 data are estimated by Eurostat.

Products covered: Nace Rev 1 code DC 19.1 "Tanning and dressing of leather" .EU27 total for 2008 based on Nace Rev 2 code C 15.11. "Tanning and dressing of leather"

Flags used: : Not available; :(c): Confidential

Another overview of the tanning sector and the production of leather in EU Member States represented by COTANCE, Norway and Switzerland are shown in Table 11 based on statistics from COTANCE. According to COTANCE, the statistics probably cover about 90% of the total EU leather manufacture. Poland and Austria are the only Member States with significant manufacture that are not covered by the statistics. The data for some Member States are based on actual reported data from the tanneries (e.g. Germany) whereas for others (e.g. Italy) it is estimated on the basis of the number of hides and skins produced and imported.

According to Table 11 in 2009 a total of about 25,000 people were employed in about 1,600 tanneries in Member States with a total turnover of 5.2 billion €. These figures are about half of those from Eurostat. According to COTANCE this is due to a narrower definition of the sector in their statistics.

Italy represents about 60-65% of the production of leather in the EU. Tanneries in Europe are small and medium sized enterprises (SMEs) and are generally family businesses with long traditions (BREF, 2011). Production units in Italy are generally smaller than in the other countries with an average of 12 employees (Table 11). The many small tanneries reflect the structure of the sector with many small companies specialising in very specific processes.

According to data from COTANCE provided as part of the stakeholder consultation in 2010 the total number of employees in the tanning sector in EU27 was 34,637 in 1,741 tanneries. The total turnover of the tanning industry in EU 27 was 7,119 €m and the leather production was 225 million m^2.

According to COTANCE, techniques for prevention of the formation of chromium (VI) are already applied by tanneries all over Europe and the organisation does not expect any major changes within the sector as a consequence of an EU-wide restriction of chromium (VI) in leather along the lines of the existing German restriction.

TABLE 11 OVERVIEW OF THE TANNING SECTOR IN EU MEMBER STATES REPRESENTED BY COTANCE, NORWAY AND SWITZERLAND IN 2009

Country	Employment	Companies	Turnover (1000 €)	Exports %	Leather production (1,000 m^2)	
					Cattle/calf [1)]	Sheep/goat [2)]
Belgium	n.i.	n.i.	n.i.	n.i.	n.i.	n.i.
Finland	n.i.	n.i.	n.i.	n.i.	n.i.	n.i.
France	1,529	53	217,792	33.0	2,663	2,306
Germany	1,925	18	286,968	60.0	7,000	450
Greece	n.i.	n.i.	n.i.	n.i.	n.i.	n.i.
Italy	16,717	1,378	3,800,000	68.0	96,921	29,295
Netherlands	325	5	100,000	71.0	4,000	n.i.
Portugal	1,980	63	180,000	31.0	n.i.	n.i.
Spain	2,689	118	602,830	44.9	14,414	7,686
Sweden	260	4	40,000	90.0	1,100	30
UK	1,000	23	180,000	70.0	5,000	1,500
Lithuania	n.i.	n.i.	n.i.	n.i.	n.i.	n.i.
Romania (east)	900	15	13,250	n.i.	300	1,250
Bulgaria	190	17	2,900	90.0	55	176
Total EU MS	**25,535**	**1,631**	**5,246,740**		**131,453**	**42,693**
Norway	78	2	n.i.	n.i.	n.i.	n.i.
Switzerland	n.i.	n.i.	n.i.	n.i.	n.i.	n.i.
Grand total	**25,613**	**1,633**	**5,246,740**	**-**	**131,453**	**42,693**

[1)] Including deer, elks, buffaloes, etc. The data represent light leather only.

[2)] Including pig leather

n.i. Not indicated

Source: COTANCE, 2011

Exports account for some 40 to 90 % of the turnover of the tanning sector in the different EU Member States. Asia's growing economies, in particular the Far East, have become increasingly important markets for EU tanners (BREF, 2011).

EU tanners are adjusting their production towards higher quality output and high fashion content leathers. In certain cases they specialise in some particularly demanding niche markets requiring careful technological control of the process (e.g. automotive leather) or innovation in fashion. The transition from quantity to quality has swept through much of the leather industry in Western Europe during the past few decades and continues to do so (BREF, 2011).

Leather tanning is a raw materials and capital intensive industry. Raw materials account for 50 to 70 % of production costs, labour 7 to 15 %, chemicals about 10 % and energy 3 %. Environmental costs are estimated at about 5 % of the turnover of EU tanners. The remaining 5 to 15 % are other production costs. These figures refer to Europe in general (BREF, 2011).

Manufacturing of articles of leather and extra-EU import/export of articles
Although pure leather may be considered articles, the term "articles of leather" is used here to refer to leather goods, which have been shaped further.

EU27 structural data for the three sectors "Manufacture of luggage, handbags and the like, saddler", "Manufacture of footwear" and "Manufacture of leather clothes" are shown in the table 12.

In 2004, the total number of employees in the three sectors was close to 442,000 with 74% employed in the manufacture of footwear, 4% in manufacture of leather clothes and 22% in the manufacture of other leather goods. For the period after 2004 the data on total number of employees in the manufacture of leather clothes have been confidential.

The two sectors "Manufacture of luggage, handbags and the like, saddler" and "Manufacture of footwear" were until 2008 subgroups of the Nace Rev 1, group DC: "Manufacture of leather and leather products ". As no specific group is used for footwear and bags made of other materials, the figures also include manufacture of footwear and bags from other materials than leather. This is one of the reasons that the total production value in this table is significantly higher than the value of the production of footwear shown in Table 13 on the basis on the production statistics from the Prodcom database. In the data from the Prodcom database, only commodity codes specifically indicating "leather" are included.

Production value for the manufacture of footwear and other leather goods has increased during the period, whereas it has decreased slightly for the manufacture of leather clothes.

The total production value in 2007 was 41,454 €m. Manufacture of footwear represented 70% of the total value whilst the manufacture of leather clothes represented 2% of the total.

TABLE 12 EU27 STRUCTURAL DATA 2005-2008 FOR THE PRODUCTION OF LEATHER GOODS

	EU25		EU27			
	2003	**2004**	**2005**	**2006**	**2007**	**2008**
Manufacture of luggage, handbags and the like, saddler; Nace Rev 1 DC 19.2						
Number of enterprises	15,564	14,878	14,507	14,158	13,924	12,561 [1)]
Number of persons employed	102,200	98,500	110,000	:c	108,800	97,800 [1)]
Production value (€m)	8,338	8,474	9000 (e)	9,828	11,514	10,650 [1)]
Value added at factor cost (€m)	2,576	2,564	:c	3,028	3,465	3,154 [1)]
Manufacture of footwear; Nace Rev 1 DC 19.3						
Number of enterprises	27,860	26,963	27,125	26,624	26,100 (e)	n.a.
Number of persons employed	358,100	326,800	404,500	388,100	368,600	n.a.
Production value (€m)	25,368	24,346	24,854	24,853	28,927	n.a.
Value added at factor cost (€m)	7,062	3,268	6,793	6,944	7,631	n.a.
Manufacture of leather clothes; Nace Rev 1 DB 18.1						
Number of enterprises			3,490	3,302	3,000 (e)	n.a.
Number of persons employed	18,200	17,200	;c	;c	;c	n.a.
Production value (€m)	1,230	943	900 (e)	;c	1,012	n.a.
Value added at factor cost (€m)	318	172	;c	;c	;c	n.a.

[1)] 2008 data from DG ENTR (2011) Nace Rev 2 code C 15.12. The Nace Rev 2 code includes the same articles as Rev 1 DC 19.2 but includes also harness.

n.a. The Eurostat database does not include EU27 total for Nace Rev 1 codes or Nace Rev 2 codes. Date available for some Member States, but the dataset is incomplete.

: c: Confidential; (e): Estimated by Eurostat.

External trade

An overview of the production and extra EU27 trade of hides and skins and selected articles of leather are shown in Table 13. The table is based on Eurostat's Prodcom Database which provides the data in monetary units only.

The data are supplemented by external trade data in € and in tonnes from Eurostat's Comext database in Table 14. The two databases do not use exactly the same nomenclature and the data in the table are presented somewhat differently. As a consequence, the import and export figures in Euros differ between the two tables. Information on the commodity codes that are grouped in the tables is shown in Appendix 2: "Production and trade statistics". In the data collected on finished leather and semi-manufactured leather (e.g. wet blue) the category "processed leather" includes those commodity groups where the word "leather" is included in the commodity description.

The commodity group G42 of the external trade statistics specifically covers "*Articles of leather; saddlery and harness; travel goods, handbags and similar containers; articles of animal gut (other than silkworm gut)*". Table 13 and Table 14 do not include leather garments and furniture, as the commodity codes covering clothing and furniture do not specifically state that they include articles of leather. As shown in the previous section, manufacturing of leather clothing represents a few percent of the total value of manufactured articles of leather. Import and export of leather in vehicles is also excluded. The total for footwear (boots, shoes, soles etc.) may include articles made of other materials as many of the commodity groups include both leather footwear and footwear of other materials.

The tables show that in monetary terms, the import of hides and skins and processed leather more or less balances the export. In some of the commodity groups it may be unclear whether they are semi-manufactures (pickles, wet blue and crust) or finished leather. In this report, the term "leather" covers all commodity groups using the designation "leather". The EU production in monetary terms is approximately 2/3 of the EU consumption. The same is the situation comparing the quantities in tonnes.

When it comes to higher value processed articles such as shoes, bags and accessories, the picture is quite different. Whereas in monetary terms imports are only slightly higher than exports, the tonnage of imports is in the range of 5-10 times that of the tonnage of exports (Table 14). Expensive, high-end articles of leather are exported from the EU while less expensive articles are imported.

Data on production in tonnage are not available from Prodcom. If it is assumed for the data in Table 13 that the tonne/€ for the production and export are the same as the tonne/€ of export in Table 14 and the tonne/€ for import is the same for the two tables a rough approximation can be obtained. Using this approximation, the import can be estimated to account for 99% of the consumption of the travelling goods, 79% of the footwear and 91% of the accessories (in tonnage). Although uncertain, it demonstrates that a majority (in tonnage) of the articles of leather placed on the market are imported from countries outside Europe. Technical leather goods account for approximately 1% of the total.

Data on import and export for the period 2006 to 2010 are shown in Appendix 2. Both import and export have decreased slightly in tonnage during the period.

According to data from COTANCE provided as part of the stakeholder consultation, in 2010 the extra-EU export of finished leather was 2,131 €m (30% circa of turnover) whereas import of finished leather from outside the EU was 1.043 €m. Apparent consumption of leather in EU27 for manufacture of articles of leather had a value of 6,030 €m (production+import-export). The difference between these data from COTANCE and the data provided in Table 14 is a consequence of differences in the aggregation of the groups "hides and skins" and "processed leather".

TABLE 13 EU27 PRODUCTION, IMPORT AND EXPORT OF RAW HIDES AND SKINS AND SELECTED LE LEATHER ARTICLES IN 2010

Product types	2010 (€m)		
	Production	**Import**	**Export**
Hides and skins (all animals included)	1,067	358	591
Leather articles:			
Processed leather (all animals included)	6,287	2,019	2,437
Travelling goods and bags: bags, cases, wallets etc.	3,493	3,464	3,114
Accessories: Gloves, belts, watch straps etc.	792	674	434
Footwear: Boots, shoes, soles etc. [1)]	11,429	8,344	4,065
Technical leather: Conveyor, transmission belts,	240	6	9
Saddlery, textile fabrics laminated with leather, inflatable leather balls, others	1,917	1,124	714
Total leather articles	**24,158**	**15,631**	**10,773**

Source: Eurostat, Prodcom annual sold 1.1

[1)] Also includes footwear where leather only is a smaller part of the product

TABLE 14 IMPORT AND EXPORT OF HIDES AND SKINS AND SELECTED LEATHER ARTICLES IN 2010

Product types	CN codes	2010, €m		2010, 1000 tonnes	
		Import	**Export**	**Import**	**Export**
Hides and skins and semi-manufacturers (all animals included)	4101-4106	1,518	1,003	548	589
Leather articles:					
Processed leather (all animals included)	4107-4115	1,050	2,184	79	140
Travelling goods and bags: bags, cases, wallets etc.	4202	6,633	4,600	858	57
Accessories: gloves, belts, watch straps etc.	4203 +9113.9010	1,605	771	83	7
Footwear: boots, shoes, soles etc. [1)]	6403-6406	6,638	4,046	449	80
Technical leather: conveyor belts, transmission belts	4204-4205	6	9	0.35	0.35
Saddlery, textile fabrics laminated with leather, inflatable leather balls, others	4201+5911.1000 +9506.6210	481	539	49.8	49.8
Total articles of leather		**16,414**	**12,149**	**1,518**	**334**

Source: Eurostat (EU27 Trade since 1995 by CN8 (DS_016890))

[1)] May includes some footwear not made of leather or where leather is a small part of the product.

B.2.2.6 Leather chemicals production and market

Chromium tanning agents constitute a part of a wide range of leather chemicals. The global chemical consumption for the leather industry is approximately 1.8 million tonnes (TFL, year not indicated) or 2.5 million tonnes (Reich and Taeger, 2009).

According to a presentation in the context of REACH, available on the website of one of the major suppliers of chemicals for the tanning sector (TFL, year not indicated), leather chemicals to a value of 1.8 billion € are manufactured within the EU. Of these, the production for demand within the EU is 0.6 billion € while the rest is exported. Five chemical suppliers BASF, Lanxess (BAYER), CLARIANT, STAHL and TFL hold a combined market share of approx. 40 % of the global market.

The remaining 60 % is covered by some 100-200 other suppliers many of whom are local (TFL, year not indicated).

Of the five major leather chemicals suppliers, some manufacture and supply both chromium tanning chemicals and non-chrome tanning chemicals whereas some supply only the non-chrome tanning chemicals.

B.2.2.7 Presence of chromium (III) and chromium (VI) in articles of leather

In spite of the implementation of measures to prevent the formation of chromium (VI) in leather in the European tanning sector, product control of marketed articles of leather demonstrates that a significant part of the articles contain chromium (VI) in measureable quantities.

Surveys of chromium (VI) in articles of leather marketed in Germany
The regulatory authorities of the federal states in Germany examined the chromium (VI) levels in leather goods between 2000 and 2006. Chromium (VI) was detected in more than half of 850 samples; in one sixth of the samples, the levels were higher than 10 mg/kg leather (BfR, 2007a). The leather goods contaminated with chromium (VI) also included items worn next to the skin, for instance gloves or shoes and leather watch straps.

Surveys by the German Federal Ministry of Food, Agriculture and Consumer Protection undertaken in 2008 and 2009 before the new German restriction went into force, found that many leather goods like gloves, shoes or watch straps, that come directly in contact with skin, contained high levels of chromium (VI) (BVL 2011; BVL, 2010).

In the 2008 survey, 588 samples from ten federal states were examined for the presence of chromium (VI) (Table 15). In 250 of the 588 samples (43%) the chromium (VI) concentration was above the level of quantification. The limit of detection and quantification of the applied method is not indicated. The results show that in 85 (14%) of the samples, the chromium (VI) level was in the range 3-10 mg/kg and in 52 (9%) of the samples, chromium (VI) level was above 10 mg/kg. In 23% of the total samples the chromium (VI) concentration was above 3 mg/kg.

As part of the 2009 survey, a total of 504 samples from ten federal states were examined for the presence of chromium (VI) (Table 16). In 227 of the 504 samples (45%) chromium (VI) was above the limit of quantification. In 163 (32%) of the samples, the chromium (VI) level was above 3 mg/kg and in 81 (16%) of the total samples, chromium (VI) level was above 10 mg/kg.

The highest chromium (VI) concentrations found in the 2009 survey were 141 mg/kg in work wear, 137 mg/kg in footwear and 112 mg/kg in gloves.

The data do not indicate any decrease in the percentage of the articles with high chromium (VI) content. The origin of the articles is not indicated in the report, so on the basis of the data, it is not possible to estimate whether the percentage of articles with quantifiable chromium (VI) content were higher in imported products than in products produced in the EU.

The fact that about 1/4 - 1/3 of the articles in the two surveys contained more than 3 mg/kg chromium (VI) clearly demonstrates the high potential for exposing consumers to chromium (VI) in leather.

TABLE 15 CHROMIUM (VI) IN SAMPLES OF LEATHER ARTICLES FROM THE GERMAN MARKET IN 2008

Group	**Number of positive samples**	**Number of samples with a chromium content of:**		
		> not quantifiable < 3 mg/kg	**3-10 mg/kg**	**> 10 mg/kg**
Commodities with the body contact and body care	1	1	0	0
Leather outerwear	2	0	1	1
Outerwear, material combinations	1	1	0	0
Stockings of material combinations	1	0	0	1
Headgear of material combinations	1	1	0	0
Shawl/scarf/bow tie of leather	1	0	0	1
Footwear material without differentiation	2	1	0	1
Plastic footwear	2	0	0	2
Leather footwear	93	63	26	4
Footwear made of material combinations	64	25	22	17
Gloves/finger cots made of leather	25	8	10	7
Gloves/finger cots made of material combinations	13	3	6	4
Work wear/uniforms material without differentiation	1	0	0	1
Work wear/uniforms leather	1	1	0	0
Work wear/uniforms of material combinations	16	1	6	9
Braces/belts	2	1	1	0
Backpack/suitcase/bag/pouches made of leather	2	0	1	1
Backpack/suitcase/bag/neck pouch material combinations	11	7	3	1
Watches and other leather strap	5	0	4	1
Jewellery made of leather	4	0	3	1
Other commodities with body contact	2	0	2	0
Sum [1)]	**250 (43%)**	**113 (19%)**	**85 (14%)**	**52 (9%)**

Source: BVL (2011)

1) The percentages indicate the percentage of the total 588 samples. 43% of the samples were below the level of quantification while 62% were below 3 mg/kg.

TABLE 16 CHROMIUM (VI) IN SAMPLES OF LEATHER ARTICLES FROM THE GERMAN MARKET IN 2009

Group	Number of samples	Number of samples with a chromium (VI) content in indicated range				
		Not detectable 1)	Not quantifiable 1)	> not quantifiable < 3 mg/kg	3-10 mg/kg	> 10 mg/kg
Outerwear and clothes	34	12	8	4	5	5
Footwear	204	50	67	23	36	28
Gloves/finger cots	106	17	16	11	24	38
Work wear	63	18	29	9	4	3
Belts/straps	11	2	6	0	3	0
Watch straps	31	6	8	10	3	4
Jewellery	27	0	17	3	4	3
Backpack/suitcases etc.	7	5	2	0	0	0
Material for the manufacture of apparel	9	6	2	1	0	0
Other Commodities	12	2	5	2	3	0
Total 2)	504	118 (23 %)	160 (32 %)	63 (13 %)	82 (16 %)	81 (16 %)

Source: BVL (2010)

1) Limit of quantification is not indicated in the study but a minimum value of 0.1 mg/kg is shown for one group.

2) The percentages indicate the percentage of the total 504 samples. 53% were neither detectable nor quantifiable, while 66 % were below 3 mg/kg.

Chromium (VI) in articles of leather marketed in Denmark

A recent study of leather shoes marketed in Denmark in 2008 found that the chromium (VI) concentration in 8 pairs of leather shoes out of 18 pairs tested, exceeded the detection limit of 3 mg/kg as analysed according to EN ISO 17075 (Johansen *et al.*, 2011). Hence, 44% of the tested products contained chromium (VI) in a concentration above 3 mg/kg. The highest chromium (VI) concentration found was 62 mg/kg. The concentration of soluble chromium (III) in the 8 pairs of shoes with chromium (VI) concentration above the detection limit ranged from 36 to 303 mg/kg with an average of 140 mg/kg. Sandals seemed to be over-represented among the shoes with detectable chromium (VI). This is of concern as sandals are more likely to be worn with bare feet and thus direct exposure of the skin to chromium (VI) is likely to be higher. On average the soluble Cr (III):Cr (VI) ratio was 8. Retailers did not know the country of origin of half the shoes sold and the study does not report any differences between chromium (VI) content of shoes produced in the EU and outside the EU.

A total of 60 pairs of shoes were tested for total chromium content by XRF analysis and the majority of the shoes had a content of 1-3% Cr in both the uppers (upper leather parts) and in the inner soles. No significant differences in total chromium content between different types of shoes or price ranges were found.

In a previous study carried out in 2002, 15 out of the 43 tested articles of leather (35%) contained chromium (VI) in levels above the detection limit of 3 mg/kg (Rydin, 2002). In the 15 products where chromium (VI) was detected, the concentration ranged from 3.6 to 14.7 mg/kg as analysed according to DIN 53315. The total chromium content expressed as percentage Cr_2O_3 (but not necessarily present as Cr_2O_3) ranged from 2.0 to 5.6 % corresponding to a Cr content of 1.4 to 3.8 %. No correlation between chromium (VI) concentration and total Cr content was found. Additionally 10 pair of baby-shoes were analysed for their content of chromium (VI), but in all the shoes the chromium (VI) concentration was below the detection limit. The total Cr content in the baby shoes ranged from 3.7 to 5.2 % Cr_2O_3, corresponding to a Cr content of 2.5 to 3.6 percent. The report states with reference to UNIDO that the chromium content should generally not be below 2.5% Cr_2O_3 for chrome tanned leather in order to receiving a good quality of leather.

Possible environmental impact of chromium (VI) in leather

In order to have an early indication of the extent to which the total content of chromium (VI) in leather could also have environmental implications, a rough estimate of the total content of chromium (VI) in marketed articles has been completed.

The average chromium (VI) content of leather in the articles from the German surveys is in the order of 5-10 mg/kg if samples below detection limit are assumed (worst case) to be at the detection limit. The total content of leather in articles placed on the market in the EU is not known, but is likely about 500,000 tonnes per year. Based on these assumptions, the total chromium (VI) content of the articles sold in one year would be in the order of magnitude of 2.5-5 tonnes. Considering the uncertainty, a rough estimate of the total would be in the range of 1-10 tonnes chromium (VI) per year. Compared to the quantities of chromium (VI) compounds used in the EU, this quantity is very small (see Table 2), and possible direct releases of chromium (VI) from the articles of leather to the environment are considered insignificant.

The main issue associated with environmental releases of chromium (VI) from leather for the entire life cycle is the possible release of chromium (VI) from incineration of the leather. The chromium (VI) is formed from chromium (III) in the leather by the incineration. Chromium (III) is typically present in the leather in concentrations more than 1000 times the concentration of chromium (VI). The releases are thus a consequence of the use of chromium (III) in the tanning process, and not a consequence of the unintentional formation of chromium (VI) in the leather. For this reason, the possible formation of chromium (VI) due to incineration has not been addressed further.

B.2.2.8 Articles of leather that may come into prolonged contact with the skin

Investigations of exposures of patients with dermatitis and chromate allergy treated in Denmark show for the period 1995 through 2007 that most of the cases were caused by contact with leather shoes and leather gloves (Thyssen *et al.*, 2009). In both female and in male patients, leather footwear was the main cause of the dermatitis in 39% and 28% of the cases, respectively. The paper indicates the following other clinically relevant exposure sources: Furniture, watch straps, jewelleries, jackets, bags, belts and covers for car steering wheels. The results of the study show that the dermatitis may be caused by many types of product which under normal conditions of use are only in contact with the skin for brief periods.

Most articles of leather are to some extent in contact with the skin, at least when they are handled e.g. when a leather belt is taken on off.

Furthermore, many products may be in contact with the skin under certain conditions e.g. if the user wear shorts or short dresses. For many products e.g. leather coats, only a small part of the product is in prolonged direct contact with the skin.

The existing German restriction on chromium (VI) in leather (See section B.9.1.1) specifically addresses articles which are meant not only to be in contact with the human body for a short time and mentions in particular the following articles: clothing, bracelets, bags and backpacks, chair covers, purses and leather toys.

Annex XVII to the REACH Regulation specifies that azocolourants “shall not be used in textile and articles of leather which may come into direct and prolonged contact with the human skin or the oral cavity, such as:”

- clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags,
- footwear, gloves, wristwatch straps, handbags, purses wallets, briefcases, chair covers, purses worn round the neck,
- textile or leather toys and toys which include textile or leather garments.
- yarn and fabrics intended for use by the final consumer.

The definition of “prolonged contact” will depend on the actual substance and the possible effect of the contact. In the “Questions and Answers on the Restrictions in Annex XVII of REACH” by the European Commission of October 2010, the concept of “prolonged” contact with the skin is discussed in the context of the restriction of nickel (DG ENV, 2010). According to the Commission, in the implementation of the restriction on nickel, the term “prolonged” should be understood as covering a daily overall contact with skin of more than 30 minutes continuously or 1 hour discontinuously. According to the Commission, this clarification takes, into account the recent scientific information on nickel allergy and therefore is only applicable to provisions pertaining to nickel. It does not provide an interpretation of the term of "direct and prolonged contact with the skin" as it may appear in other entries of Annex XVII (DG ENV, 2010).

Based on the current knowledge of the effects of chromium (VI) in leather it is suggested that “prolonged and direct contact” in the context of the current restriction proposal should be understood as covering a potential daily contact with a part of the articles of leather of more than 30 minutes continuously or 1 hour discontinuously. For some products the potential contact will depend on the clothing of the user, and the potential for contact should be determined on the basis of normal use conditions of a user wearing summer dress with shorts or short dresses.

Table 17 lists articles of leather for which at least a part of the product is considered to be in prolonged contact with the skin under normal use conditions.

TABLE 17 LEATHER ARTICLES FOR WHICH PART OF THE SURFACE MAY BE IN PROLONGED CONTACT WITH THE SKIN UNDER NORMAL USE CONDITIONS

Product group	**Application**
Footwear	Leather shoes, sandals and boots. When used without stocking the skin is in prolonged contact with both the leather i.e. sole and the uppers.
Gloves	Many leather gloves (apart from protective gloves) have inner lining which reduces the direct exposure to the leather. Some types of thin soft leather such as suede and gloves used for riding, driving, cycling, etc. are not equipped with a lining. All types of gloves usually leave a small part of the leather in contact with the wrist. Leather is widely used in protective gloves for personal protection which often do not have inner lining. Gloves have been more common as causative exposure in male patients than in female, which may be due to the males' more common use of protective gloves. Today regulated at < 3 mg/kg Cr (VI)).
Underwear	The leather is probably in direct contact with the skin although some products may have lining.
Watch straps and other wrist straps/bands/braces	Commonly used for watches but also for braces and bracelets. The straps or braces are in direct contact with the skin. Some wrist straps e.g. used as bandages have a lining.
Neck straps	Commonly used as small straps used for necklaces. The strap is in direct contact with the skin.
Covers for car steering wheels	Prolonged contact with the hands.
Jackets and coats	Jackets and coats usually have inner lining, but the leather will be in direct contact with the skin around the wrist and the neck.
Trousers	Most leather trousers have inner lining, but trousers do often not have lining below the knee. A small part of the skin below the knee may be in prolonged contact with the leather.
Hats	Leather hats may have inner lining, but usually a part of the leather is in contact with the head.
Auto seats	The contact between the auto seats and the skin highly depends on the clothing of the user. During summer where many users of the cars wear shorts or short dresses, the legs are in prolonged contact with the leather.
Other furniture	The contact between the other furniture and the skin highly depends on the clothing of the user. During summer where many people wear shorts or short dresses, the legs are in prolonged contact with the leather.
Bags	For most types of bags contact between the handle and the skin of the hand when the bag is carried or opened/handled. Small handbags may be in prolonged contact with the hand. Shoulder bags may be in prolonged contact with the shoulder if the user wears a dress with bare shoulders.
Toys	E.g. leather dolls and animals. Prolonged contact with hand when playing with the toy.
Riding gear	In contact with the hand when handled. Prolonged contact with the reins when riding.
Dog leashes	Prolonged contact between the leash and the hand when the dog is taken out.

In a number of product groups, the leather is not generally in prolonged contact with the skin under normal conditions of use, but would be in contact with the hand when handled e.g. when a belt is taken on or off.

Examples of consumer products are listed in Table 18 together with different technical/industrial articles of leather. In some of the consumer products the products may be in prolonged contact with the hand under certain conditions of use and the distinction between the consumer products included in Table 17 and Table 18 are not clear-cut. Many of the products would typically be manufactured by the same manufacturers and share the same supply chain.

The technical/industrial articles of leather are a specific market area which can easily be distinguished from the consumer products. Leather in very small quantities is used for such purposes as conveyer belts, gaskets and seals and stropping. According to Prodcom statistics the technical leather represent less than one percent of the EU manufacturing of articles of leather as discussed in section B.2.2.5. These articles are typical in contact with the hand for short time e.g. when the leather parts are mounted in the machinery.

TABLE 18 LEATHER ARTICLES FOR WHICH THE LEATHER IS ONLY IN CONTACT WITH THE SKIN FOR SHORT TIME WHEN HANDLED

Product group	**Application**
Consumer products:	
Belts	In contact with the hand when taken off and on
Purses, credit card holders, key rings, spectacle cases, etc.	In contact with the hand when opened/handled
Tools and nail holders, pistol holsters, etc.	In contact with the hand when handled
Collars for dogs and other pets	In contact with the hand when handled
Dice cups	In contact with the hand when handled
Carpets	In contact with the ball of the foot
Book covers	In contact with the hand when handled. Books with leather cover are typically handled for relatively short time.
Aprons	In contact with the hand when taken off and on
Automotive interior parts apart from seats	May be touched by hand e.g. by cleaning
Technical products: [1)]	
Flat leather belting for power transmission	In contact with hand when mounting
Round leather belting for industrial sewing machines	In contact with hand when mounting
Hydraulic leathers for packing, gaskets and seals	In contact with hand when mounting
Frictions leathers for use by certain stamping presses	In contact with hand when mounting
Stropping leathers used for honing / sharpening razor blades and knives	In contact with hand when applied

1) Source: TWS (2011) and Cheshire (2011)

B.2.3 Uses advised against by the registrants

Not relevant as the chromium (VI) ion addressed here is unintentionally formed in the leather and is not registered by any registrants.

B.2.4 Description of targeting

This restriction proposal targets chromium (VI) in articles of leather which can be in direct and prolonged contact with human skin. The chromium (VI) in articles of leather may lead to effects on human health, in particular sensitisation of the consumers or elicitation of contact allergy for already sensitised consumers.

As described in section B.2.2.7 the total quantity of chromium (VI) in articles of leather sold in a single year can be roughly estimated at 1-10 tonnes. The main release route of the chromium (VI) from the articles of leather to the environment is releases from shoes in wet weather and releases to waste water when articles of leather are washed off or wiped off. A worst case estimate of the total releases would be in the range of 1-10 t/year of chromium (VI).

Compared to the quantities of chromium (VI) compounds used in the EU, this quantity is very small. As shown in Table 2, the total quantities of chromium (VI) compounds manufactured are more than 200,000 t/year.

Chromium (VI) is released to the environment from a number of other sources. The EU risk assessment report (ECB, 2005) describes the sources of releases of chromium (VI) to the environment as consequence of the use of chromium trioxide, sodium chromate, sodium dichromate, ammonium dichromate and potassium dichromate. The production of chromium (VI) compounds and "metal treatment formulation" represent the major sources of chromium emissions to the air of 12 t/year and 6.2 t/year, respectively, on the continental level. The major source of chromium releases to water is "metal treatment use" which is estimated at 2,342 t/year (worst case). Compared to this, other sources are relative small with the major sources being chrome tanning salt production (38 t/year), chromium (III) oxide production (22 t/year) and metal treatment formulation (12 t/year). According to the risk assessment report, it is not possible from the available information to estimate how much of the released chromium is in the form of chromium (VI) and the risk assessment for the environmental exposure prepares the calculations assuming as a worst case that all chromium is in the form of chromium (VI) and as a best case that all chromium is in the form of chromium (III).

Based on this it is considered that the releases of chromium (VI) from the leather to the environment would be a minor source compared to other sources and the environmental effects of chromium (VI) released from the leather to the environment and the environmental exposure is not further described in the report.

The indirect exposure of humans to chromium (VI) released from leather via the environment is considered insignificant compared to the direct exposure to the chromium (VI) in the leather.

Chromium (VI) formed from chromium (III) by the waste disposal of chrome tanned leather would not be affected by the proposed restriction. Chromium (VI) may be formed from chromium (III) in the leather by incineration. Chromium (III) is typically present in the leather in concentrations more than 1000 times the concentration of chromium (VI). The releases are thus a consequence of the use of chromium (III) in the tanning process, and not a consequence of the unintentional formation of chromium (VI) in the leather. The EU Risk Assessment of five chromium (VI) compounds concludes that it is not possible to assess emissions from the disposal route, but it is considered based on the evidence that they will be minor (ECB, 2005).

On this basis this restriction proposal focuses on the effects of chromium (VI) in the leather on human health, in particular sensitisation of the consumers or elicitation of contact allergy for already sensitised consumers.

B.3 Classification and labelling

The classification and labelling of the chromates was agreed at technical levels to be listed in Annex I to Directive 67/548/EEC following the adoption of the 29th Adaptation to Technical Progress, the minimum translations according to the CLP-criteria are listed in Annex VI (part 3, Table 3.1) of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

B.3.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

The classifications according to part 3 of Annex VI, Table 3.1 (the list of harmonised classification and labelling of hazardous substances from Annex I to Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008 for the majority of hexavalent chromium compounds are shown in Table 19.

TABLE 19 CLASSIFICATION OF THE MAJORITY OF HEXAVALENT CHROMIUM COMPOUNDS

		Potassium dichromate[1)] Ammonium dichromate[2)] Sodium dichromate[3)]	Potassium chromate	Chromium trioxide	Sodium chromate	Zinc chromates Zinc potassium chromate	Chromium (VI) compounds with the exception of barium chromate and of compounds specified elsewhere in Annex VI
Classification	Hazard class and Category Code	Ox. Sol. 2 Carc. 1B Muta. 1B Repr. 1B Acute Tox. 2 * Acute Tox. 3 * STOT RE 1 Acute Tox. 4 * Skin Corr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	Carc. 1B Muta. 1B Eye Irrit.. 2 * STOT SE 3 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	Ox. Sol. 1 Carc. 1A Muta. 1B Repr. 2 Acute Tox. 2 * Acute Tox. 3 * Acute Tox. 3 * STOT RE 1 Skin Corr. 1A Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	Carc. 1B Muta. 1B Repr. 1B Acute Tox. 2 * Acute Tox. 3 * STOT RE 1 Acute Tox. 4 * Skin Corr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	Carc. 1A Acute Tox. 4 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	Carc. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
	Hazard statement Code(s)	H272 H350 H340 H360-FD H330 H301 H372** H312 H314 H334 H317 H400 H410	H350i H340 H319 H335 H315 H317 H400 H410	H271 H350 H340 H361f*** H330 H311 H301 H372** H314 H334 H317 H400 H410	H350 H340 H360-FD H330 H301 H372** H312 H314 H334 H317 H400 H410	H350 H302 H317 H400 H410	H350i H317 H400 H410
Labelling	Pictogram, Signal Word Code(s)	GHS03 GHS06 GHS08 GHS05 GHS09 Dgr	GHS08 GHS07 GHS09 Dgr	GHS03 GHS06 GHS08 GHS05 GHS09 Dgr	GHS06 GHS08 GHS05 GHS09 Dgr	GHS08 GHS07 GHS09 Dgr	GHS08 GHS07 GHS09 Dgr
	Hazard statement Code(s)	H272 H350 H340 H360FD H330 H301 H372 ** H312 H314 H334 H317 H410	H350i H340 H319 H335 H315 H317 H410	H271 H350 H340 H361f*** H330 H311 H301 H372** H314 H334 H317	H350 H340 H360-FD H330 H301 H372** H312 H314 H334 H317 H410	H350 H302 H317 H410	H350i H317 H410

				H410			
	Specific Conc. Limits, M-factors	STOT SE 3; H335 : C ≥ 5%[1,2,3)] Resp. Sens.; H334: C ≥ 0,2%[2,3)] Skin. Sens.; H317: C ≥ 0,2%[2,3)]	Skin. Sens. 1; H317: C ≥ 0,5%	STOT SE 3; H335 : C ≥ 1%	Resp. Sens.; H334: C ≥ 0,2% Skin. Sens.; H317: C ≥ 0,2%		
	Notes	3 G[2)]	3			A	A
Key	Ox. Sol. 2: Oxidising solid Carc. 1 B: Carcinogenicity; Muta. 1B: Germ cell mutagenicity; Repr. 1B: Reproductive toxicity; Acute Tox. 2, Tox. 3, Tox. 4: Acute toxicity ; STOT SE: Specific target organ toxicity - single exposure; Resp. Sens. 1 : Respiratory/skin sensitization ; Skin Sens. 1: Respiratory/skin sensitization Aquatic Acute 1, Aquatic Chronic 1: Hazardous to the aquatic environment H271: May cause fire or explosion; strong oxidizer H272: May intensify fire; oxidiser H301: Toxic if swallowed H311: Toxic in contact with skin H312: Harmful in contact with skin H314: Causes severe skin burns and eye damage H317: May cause an allergic skin reaction H319: Causes serious eye irritation H330: Fatal if inhaled H335: May cause respiratory irritation H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled H350: May cause cancer H340: May cause genetic defects H360-FD: May damage fertility. May damage the unborn child H361: Suspected of damaging fertility or the unborn child H372**: Causes damage to organs through prolonged or repeated exposure H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects GHS03: Flame over circle GHS05: Corrosion GHS06: Skull and crossbones GHS08: Health hazard GHS09: Environment Dgr: Danger Note 3: The concentration stated is the percentage by weight of chromate ions dissolved in water calculated with reference to the total weight of the mixture. An asterisk (*) indicates: Minimum classification for a hazard class Asterisks (**) indicate: Route of exposure cannot be excluded						

B.3.2 Classification and labelling in classification and labelling inventory

No industry self classification(s) and labelling are publically available ultimo October 2011.

B.4 Environmental fate properties

Not relevant; see section B.2.4.

B.5 Human health hazard assessment

Toxicity of certain chromium (VI) compounds is discussed thoroughly in the European Union Risk Assessment Report (RAR) on chromium compounds published by the ECB in 2005 (ECB, 2005). The RAR covers chromium trioxide, sodium dichromate, sodium chromate, ammonium dichromate and potassium dichromate. Information from the RAR is also included in the Annex XV dossiers for potassium chromate and potassium dichromate prepared by France (ECHA, 2011).

Information about toxicity, other than sensitisation described in the following in section B.5.5, is primarily taken from the RAR if not otherwise indicated and further details can be obtained from the RAR.

B.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

There is a reasonably good database available on the toxicokinetics of the chromium (VI) compounds under review, although there are relatively few human data. The available data indicate that chromium (VI) compounds are generally likely to behave in a similar manner with respect to toxicokinetics, and that the kinetic behaviour of these substances would be similar in those species studied, including humans (ECB, 2005).

Following inhalation exposure, animal studies have shown that 20-30% of the administered chromium (VI) is absorbed via the respiratory tract. Highly water-soluble chromium (VI) is poorly absorbed via the gastrointestinal tract (only 2-9% of the dose was absorbed in human studies) due to reduction to the relatively poorly absorbed chromium (III) (ECB, 2005).

Only limited dermal absorption takes place through intact skin, with 1-4% chromium (VI) from an aqueous solution crossing the skin in guinea pig studies.

Part of chromium (VI) becomes reduced to chromium (III) after entering the body due to the influence of reducing agents, for example glutathione (discussed further in B.5.5). Distribution is widespread even after a single dose and includes transfer of absorbed chromium (VI) across the placenta. Excretion occurs in urine and faeces. Repeated exposure leads to accumulation of chromium in several tissues, particularly the spleen because of uptake of senescent erythrocytes (ECB, 2005).

B 5.2 Acute toxicity

Highly water-soluble chromium (VI) compounds are very toxic by inhalation and toxic by ingestion. The respiratory tract and the kidney are damaged by these compounds following inhalation and oral exposure respectively. Although, acutely harmful or toxic by the dermal route, more severe responses may be observed due to greater uptake via the skin if there is any prior or simultaneous damage to the skin. Depending upon the pH of the chromium (VI) solution, corrosive effects can occur on contact (see section B.5.4 on corrosivity) (ECB, 2005).

Available acute toxicity values for potassium dichromate (ECB, 2005):

- $LD_{50,\ oral}$: 74 mg/kg bw (26 mg Cr(VI)/kg bw)
- $LD_{50,\ dermal}$: 1150 mg/kg bw (410 mg Cr(VI)/kg bw)
- $LC_{50,\ inhal}$: 99 mg/m^3 (35 mg Cr(VI)/m^3), 4 hours

B 5.3 Irritation

Skin irritation

Single application of a low concentration of highly water-soluble chromium (VI) in solution to undamaged human skin resulted in only a mild irritant response around the hair follicles. Animal data indicate that irritation occurs following single application to the skin for 4 hours. It is not possible to determine a clear concentration-response relationship for human skin irritation from the single exposure animal or occupational data available. Repeated-exposure skin responses are considered under corrosivity (ECB, 2005).

No information on the applied concentrations levels are provided in the RAR.

Eye irritation
Significant damage to the eye can occur upon accidental exposure to highly water-soluble chromium (VI) compounds. Severe and persistent effects occur when there is contact with the low pH aqueous chromium (VI) trioxide or chromium (VI) solutions at high temperature. A number of case reports have detailed both inflammation of the cornea and conjunctivae and in more severe cases, corneal erosion and ulceration. The severity of response is increased by low pH or high temperature. Accidental eye contact with the corrosive aqueous chromium (VI) trioxide results in conjunctival congestion and necrosis and corneal oedema and opacity. It is not possible to determine a clear concentration-response relationship from the data available (ECB, 2005).

Respiratory irritation
Symptoms of sensory irritation of the respiratory tract are known to occur among chrome plating workers exposed to a mist of aqueous chromium (VI) trioxide. Since this is corrosive, such symptoms are to be expected. No quantitative data on such irritation are available from studies of workers. No studies reporting symptoms of sensory irritation are available for the other chromium (VI) compounds. Overall, it is not possible to determine a reliable concentration-response relationship for respiratory tract irritation using the available data. In a very poorly-reported volunteer study, 10 subjects were apparently exposed to chromium (VI) trioxide at concentrations of 10-24 mg/m^3 (5-12 mg $Cr(VI)/m^3$) for "brief periods of time". It was claimed that this exposure caused nasal irritation. According to the authors, exposure to lower but unspecified concentrations produced slight (if any) irritation of the upper respiratory tract. Given the poor reporting in this study the results cannot be considered to be reliable (ECB, 2005).

B 5.4 Corrosivity

Highly water-soluble chromium (VI) compounds can cause very severe skin effects under certain conditions. In workers repeatedly exposed to highly water-soluble chromium (VI), where there is some slight initial damage to the skin, ulcers can develop which constitute a serious and persistent effect. Animal data are consistent with the observations made in humans. It is not possible to determine a clear concentration-response relationship for repeated-exposure human skin effects from the occupational data available and quantitative data could be misleading given the potential for severe effects resulting from repeated contamination of slightly damaged skin. Overall, highly water-soluble chromium (VI) compounds should be regarded as corrosive (ECB, 2005).

B 5.5 Sensitisation

B 5.5.1 Sensitisation to chromium (VI)

Skin sensitisation resulting from contact with chromium (VI) compounds is well-known from both occupational exposures and consumer exposures.

Mechanisms of contact allergy
Allergic contact dermatitis (ACD) is a delayed type of induced sensitivity (allergy) resulting from skin contact with a specific allergen to which the patient has developed a specific sensitivity. This

allergic reaction causes inflammation of the skin manifested by varying degrees of erythema, edema, and vesiculation.

Metals, such as nickel, cobalt, chromium, gold, palladium and aluminium may result in contact allergy and allergic contact dermatitis (Thyssen and Menné, 2010). Before the metal ions can cause an immune response they must enter the viable epidermis and bind to protein. In contrast to chromium (III), hexavalent chromium has poor protein binding capacity and may easily pass through the epidermis. It is believed that chromium (VI) after passing through the epidermis is reduced to chromium (III) which can then form stable conjugates with protein to become able to provoke an immune response. Metal absorption is influenced by a number of exogenous factors including dose, size, counter ions, polarity, valence and pH and endogenous factors like age of skin, anatomical site, oxidation and reduction (Thyssen and Menné, 2010).

Contact allergy develops in two phases:

- A first phase, called the **induction** phase or sensitisation, where the changes in the immune system are induced. This phase is without symptoms.

- On subsequent exposure to sufficient amounts of the allergenic substance, the immune system will react to the substance and symptoms will develop. This phase is called **elicitation** and the symptoms of elicitation are eczema.

Induction

During the induction phase of contact sensitivity the immune system reacts to the exposure, and the hapten-protein complexes which are formed result in an activation of T-lymphocytes in the lymph nodes draining the sites of exposure. The cells divide forming clones of differentiated T-cells which are distributed to the bloodstream and the lymph system. Here they are able to recognise the hapten-protein complexes upon subsequent exposure to the allergen. At this stage the allergy is developed. The induction phase may take between one and three weeks of skin contact with soluble chromium ions and the quantity of chromium (VI) required to induce sensitivity varies with the individual. Factors influencing the susceptibility and the time it takes to develop the condition include temperature, presence of other allergic conditions (e.g. atopic dermatitis), sex and age. In addition, the skin condition and simultaneous exposure to skin irritants may also influence the development of ACD (Diepgen and Coenraads, 1999).

Recent studies have suggested that repeated low-dose exposure to an allergen has at least the same induction capacity as one single high dose (Fischer *et al.,* 2011). This is a potentially very important observation as most cases of contact allergy related to occupational exposure and exposure to consumer products are caused by repeated exposures to low or moderate concentrations of chemicals as is e.g. the case with chromium (VI). However, further elaboration of the significance of these findings in relation to chromium allergy and threshold doses has not been identified.

Elicitation

Over the past decades, a large number of dose-response patch test studies by various methods have been conducted in an attempt to identify the minimum elicitation threshold (MET) concentration of chromium (VI) that produces an allergic response in chromium (VI) sensitive subjects. Because of the variability in the patch testing techniques and the variability in diagnostic criteria, older data may not be adequate to provide an accurate estimate of the MET, and furthermore they are not always reported in terms of mass of allergen per surface area of skin (mg Cr/cm^2-skin) (Nethercott *et al.*, 1994). Nethercott *et al.* (1994) therefore conducted a study to determine the MET for chromium (VI) using a patch test method that delivers a controlled amount of the allergen per surface area of skin. The results indicated that the $MET_{10\%}$ for chromium (VI) based on the cumulative response was 0.089 μg/cm^2 (Nethercott *et al.*, 1994).

A Danish survey and health assessment of chromium in leather shoes was issued by the Danish Environmental Protection Agency in 2011 (Johansen *et al.,* 2011) and a substantial part of the following information has been extracted from this survey report.

An individual who has become sensitized to a substance will react to this particular substance upon re-exposure. Whether a sensitized individual will get symptoms depends on exposure, in particular concentration i.e. dose of allergen. This concentration is different from person to person. However, when a group of individuals is studied dose-response curves can be drawn, which represent the group of sensitized individuals (Johansen *et al.*, 2011).

The dose-response curves are based on testing with different concentrations of the allergen in a small (0.5 cm^2) aluminium chamber under occlusion for two days on the back of the patient with allergy. The reaction is observed at each test site and the signs of allergic contact dermatitis are noted. This gives data on the threshold responses. Based on dose-response curves, the dose, which will elicit a reaction in 10% of sensitized individuals, is estimated and often called $MET_{10\%}$ (minimum elicitation threshold) (Fischer *et al.,* 2009). The results of such dose-response investigations employing allergic individuals have been shown to be fairly reproducible even when these are performed in different clinics and in different European countries (Fischer *et al.,* 2005, Hansen *et al.*, 2002). Even though no general model for the use of data yet has been accepted, such data has been the basis of several regulatory decisions regarding allergens. (Johansen *et al.*, 2011).

The limitations of patch testing are discussed by Thyssen *et al.,* (2007b). A positive reaction is not necessarily an indicator of a clinical disease in the form of ACD, because the patch test only measures whether the individual is sensitised or not. Furthermore, patch test concentrations are not age adjusted and equally optimised for all age groups and identification of weak reactions may be based on different criteria. As an example it can be difficult to distinguish between irritative and allergic reactions. In spite of false positives and negatives it has however been estimated, as concluded in the Danish survey (Johansen *et al.*, 2011), that the reproducibility in general is high.

Threshold values of chromium allergy

Dose-response relationships are observed for both the induction (e.g. LLNA data) and elicitation phases of skin sensitisation and both phases are considered to be threshold phenomena. Thresholds for a given allergen are, however, not absolute values and may as such not be applicable to a population (Gerberick, 2008).

An important factor influencing on induction thresholds is the inherent potency of the allergen. Other factors influencing the thresholds include the vehicle matrix, and exposure conditions like the duration and frequency of contact, and the occlusion. Skin conditions like inflammation can also have an impact on the thresholds (Gerberick, 2008).

As described in the section above, a typical way of presenting threshold values related to allergenic effects is in terms of $MET_{10\%}$ values.

It is not possible to predict the exact induction level for a sensitising substance based on knowledge of elicitation thresholds e.g. $MET_{10\%}$ values. But values protecting sensitized individuals will be sufficient to protect against induction also (Basketter *et al.*, 2001; SCCP, 2008).

Threshold values:

MET (Minimal Elicitation Threshold): The $MET_{10\%}$ value represents the concentration at which 10% of sensitized individuals elicit a reaction. The $MET_{10\%}$ is derived from one occluded exposure to a dose of allergen at 0.5 cm^2 area for 48 hours. (Johansen *et al.,* 2011).

ED (Elicitation Dose): The $ED_{10\%}$ is the dose required to elicit a reaction in 10% of sensitized individuals. This value therefore expresses the same as the $MET_{10\%}$ value.

Induction thresholds are difficult to define, but from experience in the construction industry and among cement workers it is well known that levels of 10-20 mg/kg soluble chromium (VI) in the cement is causing sensitization with a prevalence around 4-5 % (Shelnutt *et al.*, 2007).

In a review on metal allergy, Thyssen and Menné (2010) refer to chromium elicitation studies suggesting that between 0.6 and 1,770 ppm chromium (VI) in the occlusion solution may elicit chromium dermatitis in sensitised individuals.

The following information from the literature regarding threshold values for chromium (VI) are summarized in Johansen *et al.* (2011): Data from several studies in humans exists concerning the elicitation thresholds for chromium (VI). The $MET_{10\%}$ from a single 48 hour occluded exposure has been estimated to be between 0.02-0.9 µg/cm^2 (see Table 20). The most recent study is Danish and estimates the $MET_{10\%}$ to be 0.03 µg/cm^2, which corresponds to 1 ppm chromium (VI) in the occlusion solution over a period of 2 days (Hansen *et al.*, 2003). This is in line with the results from the largest published study where the $MET_{10\%}$ was 3 ppm (Nethercott 1994). However, variations exist and both lower and more than 10 times higher $MET_{10\%}$ values have been identified (Hansen *et al.*, 2002). The US EPA has based their risk assessment of allergy to chromium in wood on the study by Nethercott *et al.* (1994) as it was the largest study (Johansen *et al.*, 2011).

TABLE 20 ESTIMATED MINIMAL ELICITATION THRESHOLD FOR 10% OF SENSITIZED INDIVIDUALS ($MET_{10\%}$)

$MET_{10\%}$ µg Cr(VI)/cm^2/2 days	$MET_{10\%}$ ppm[2)]	Number of test subjects	Reference
0.09	3	54	Nethercott *et al.,* 1994
0.35	11.67	14	Allenby and Goodwin, 1983
0.90	30	17	Kosann *et al.,* 1998
0.02	0.67	5	Wass and Wahlberg, 1991
0.03[1)]	1	18	Hansen *et al.,* 2003

Source: Based on Johansen *et al.*, 2011; Column 2 is added as part of this report.

1) Corresponded to 1 ppm in the occlusion solution (15 µl of a solution with 1 mg/kg (ppm) =0.0001% chromium (VI) applied at 0.5 cm^2 area of skin; see Robinson *et al*., 2000)

2) Concentration in the occlusion solution. Calculated based on the same conditions as described under 1) (15 µl of a solution applied at 0.5 cm^2).

Fischer *et al.* (2011) searched the literature up to May 2010 for patch test elicitation studies that fulfilled six criteria regarding vehicle, test methods, patch test solutions, number of participants, possibility to calculate the applied µg/cm^2 and sufficient data to calculate the dose-response relationships. Sixteen studies covering eight different allergens including chromium were identified. The logistic dose-response curves for each allergen were drawn. For chromium the necessary concentration to elicit a patch test reaction in 10% of 17 allergic individuals ($ED_{10\%}$) with 95% confidence interval (0.0033 - 5.55 µg/cm^2) was 1.04 µg/cm^2. The median $ED_{10\%}$ for all eight substances was 0.835 µg/cm^2.

Comparison between EC_3 (LLNA induction data) and ED_{10} (human elicitation)

The EC3 for chromium was 10 µg/cm2 (area dose) and the relationship between EC3 (induction potency) and ED10% patch test (elicitation potency) was 9.6. In conclusion, the authors found small variations in the elicitation doses between allergens for the most sensitive part of the allergic population, and no clear relationship between induction potency and elicitation threshold for a range of allergens. They therefore conclude that individuals already sensitised will not be protected by exposure limitations based on sensitisation thresholds as derived from animal assays (Fischer et al., 2011). This conclusion also applies to chromium based on the identified EC3/ED10% relationship.

EC_3 value: The EC_3 value represents the effective concentration required to stimulate of a 3-fold increase in lymph node cell proliferation in the murine local lymph node assay (LLNA).

Effective concentration (EC): Concentration of a substance that causes a defined magnitude of response in a given system. (IUPAC glossary)

Chromium in leather and induction of dermatitis

In a study to determine the relation between the content of chromium (III) and chromium (VI) in leather and to elicit leather dermatitis in chromium (VI) positive patients, fifteen chromium-allergic patients with past or present foot eczema and suspected leather relevance were patch tested with 14 chromium-tanned leather samples and a vegetable-tanned control leather sample. The content of chromium (VI) in the samples was in the range of < 3 mg/kg and 16.9 mg/kg determined using the DIN 53314 method. The leather sample eliciting a reaction in the highest number of patients was the one with the lowest content of chromium (VI) and soluble chromium (III) (Hansen *et al*., 2006).

Results of the patch tests are shown in Table 21

TABLE 21 RESULTS FROM PATCH TESTING OF 15 CHROMIUM-ALLERGIC PATIENTS WITH LEATHER SAMPLES CONTAINING CR (III) AND CHROMIUM (VI) (HANSEN ET AL., 2006)

Leather sample	Cr(III) content mg/kg	Cr(VI) content mg/kg	Number of patients reacting
1	12	< 3	3
2	93	< 3	-
3	124	< 3	-
4	139	< 3	-
5	151	< 3	-
6	187	< 3	-
7	200	< 3	-
8	201	< 3	2
9	90	4.1	2
10	156	4.3	-
11	591	4.6	2
12	112	9.2	1
13	157	15.5	-
14	209	16.9	-
15 (control)	5.8	< 3	-

Additional patch testing with aqueous solutions of chromium (III) and chromium (VI) corresponding to the highest concentrations measured in the leathers were performed. A total of 5 patients reacted to either 591 ppm chromium (III) or 16.9 ppm chromium (VI) or both. Among these patients, 2 reacted to at least one of the samples (Hansen *et al.*, 2006). No relation was found between the reactivity to at least one of the chromium solutions and reactivity to leather. A possible explanation of the absence of a relation between reactivity to the chromium (III) and chromium (VI) solutions and reactivity to leather samples was considered to be the low chromium (III) and chromium (VI) concentrations in the solutions used (Hansen *et al.*, 2006).

The study showed that elicitation of chromium allergy can occur at low levels of chromium in leather and even below existing detection limits in standard analysis.

The same study also tested the effect of prolonged exposure from leather samples. Of the 12 patients participating in the prolonged study, 3 developed eczema during the 14-day exposure period. None of the patients had positive reaction to the leather samples in the 48-hour exposure study. Prolonged exposure may therefore reveal allergenic potential not otherwise identified using an ordinary 48-hour exposure period (Hansen *et al.*, 2006).

The authors emphasize that the study results do not reject a connection between the content of chromium (VI) and soluble chromium (III) in leather and the development of chromium dermatitis. It only demonstrates that the measures given by the test method used, the DIN 53314, do not reflect the relevant bio available chromium (III) and chromium (VI) pools (Hansen *et al.*, 2006).

Prevalence and incidence of chromium (VI) allergy

Various estimates for prevalence of chromium sensitivity in different populations are available. Most estimates for chromium (VI) are based on patch test studies in patients with eczema or to a more limited extent on cross-sectional studies involving patch testing and questionnaires performed in the general population. Data from the general population can also be used to compare and verify estimates based on patient populations.

Prevalence among eczema patients

Extensive research in the area of contact allergy to chromium is carried out in Denmark and several studies include such estimates based on information and surveillance data from dermatological clinics and from the literature.

Data on the incidence of chromium allergy is scarcer in the literature but is the preferred parameter for analysis of risk factors and risk assessment.

Prevalence: The prevalence in the general population is calculated based on the estimated number of chromium sensitive individuals in the population divided by the size of the population in a given year. More data are available regarding prevalence in groups of patients tested at dermatological clinics where the number of positive responses is divided by the number of patients. Such figures can be used to estimate the prevalence in the general population.

Incidence: The incidence of chromium allergy refers to the number of new cases of the disease during a defined period in a specified population and is calculated as the number of new cases during a time period (usually a year) divided by the size of the population under consideration who are initially disease free.

The National Allergy Research Centre in Denmark has established a National Database for Contact Allergy, which monitors the prevalence of contact allergy in Denmark among eczema patients patch tested at selected dermatological clinics. Surveillance data for chromium allergy from the database for the period 2004 to 2010 are shown in Table 22 (National Allergy Research Centre, 2011).

TABLE 22 SURVEILLANCE DATA FOR CHROMIUM ALLERGY IN DENMARK. OCCURRENCE OF CHROMIUM ALLERGY AMONG PATIENTS WITH ECZEMA.

Year	Women	Men	Both sexes
2010	3.6 %	2.8 %	3.4 %
2009	3.7 %	3.0 %	3.5 %
2008	2.5 %	2.8 %	2.6 %
2007	2.6 %	3.1 %	2.8 %
2006	3.4 %	3.0 %	3.2 %
2005	2.4 %	2.2 %	2.3 %
2004	2.9 %	2.8 %	2.9 %

Source: National Allergy Research Centre, 2011.

The overall mean for both sexes calculated from Table 22 is 2,96% used for the socio-economic evaluation.

The network of involved clinics in Denmark included 9 out of 86 specialist clinics and 3 out of 5 university dermatology departments distributed across the country. In 2010, the surveillance database included information from 5,107 patients who were tested with the European baseline series[7].

Based on the number of sold allergy tests it is estimated that 25,000 patients are tested for allergy every year and the degree of coverage is therefore estimated at 20% overall and 75% for patients referred to hospital clinics. It should be noted that patients can potentially be included in data from more than one clinic (National Allergy Research Centre, 2011). It is discussed whether the latest increase in 2009 (and 2010) may reflect a real increase caused by exposure to chromium in leather especially among women or whether they are just random fluctuations. It should be noted that an increase of the same size was also observed in 2006.

In 16,228 patients with dermatitis (63.7% females and 36.3% males) patch tested between 1985 and 2007 the overall prevalence of chromium allergy was 2.5% (Thyssen *et al.,* 2009). The prevalence of chromium allergy among women was 2.1% during 1997-2001 compared to 1.4% among men ($p<0.02$) and the overall prevalence was higher among middle-aged patients. Similar prevalence patterns are reported from the North American Contact Dermatitis Group and from Singapore where an increase is also observed after year 2000 (Thyssen *et al.,* 2009).

The MOAHLFA index (Male, Occupation, Atopic dermatitis, Hand eczema, Leg dermatitis, Facial dermatitis, Age above 40 years) in patients with dermatitis who were metal patch tested at Gentofte Hospital during 1994-2009 indicated that 14.1% of chromate-allergic patients (275) had occupational allergy (Thyssen *et al.*, 2010).

Results with the European baseline series from the European Surveillance System on Contact Allergies (ESSCA) based on clinical patch testing in 2005/2006 in 10 European countries showed significant differences in the contact allergy prevalence for chromate. Estimated prevalence was significantly lower in the UK (Western region) compared to the Southern region (ES/IT), Central region (DE/AT/CH/NL) and Northeast region (FI/LT/PL). Numbers are standardized for age and

[7] The European baseline series is the guideline minimum set of allergens to which all patients should be tested. It should form a basis for developing an appropriate more extensive allergen set to investigate an individual with allergic contact dermatitis (European Society of Contact Dermatitis at. http://www.escd.org/aims/standard_series/).

sex. 8,537 individuals in the UK were tested and 211 were positive. The results for all regions are shown in Table 23 (Uter *et al.*, 2009).

TABLE 23 PREVALENCE DATA USING THE EUROPEAN BASELINE SERIES IN FOUR EUROPEAN REGIONS; 2005/2006

Prevalence of allergy to potassium dichromate among patients from participating departments							
Western region UK		**Southern region ES/IT**		**Central region DE/AT/CH/NL**		**Northeast region FI/LT/PL**	
No. tested	% positive	No. tested	% positive	No. tested	% positive	No. tested	% positive
8,537	2.4	2,666	4.5	5,737	5.9	1,606	5.3

Source: Uter *et al.*, 2009.

Differences may be a result of differences in exposure pattern, but no concrete explanation is offered as a result of the investigation.

Thyssen and Menné (2010) also concluded based on the data from the 19,793 patients tested at the 10 European patch test centres that the age- and sex-standardised prevalence of chromium allergy was 2.4-5.9% for the period 2005-2006. They also concluded that the results indicate that the prevalence is increasing in both genders, presumably due to leather exposure (Thyssen and Menné, 2010).

For Germany alone, the Bundesinstitut für Risikobewertung, reports a prevalence of chromium (VI) allergy among patients at dermatological clinics to be 5.3% based on data from 2004 (BfR, 2007a). During the last few years, the frequency of chromium sensitization has decreased from 6.1% in 2007, via 4.9% in 2008 to 3.3% in 2009 (Geier *et al.*, 2011).

Time trends in Swedish patch test data from 1992 to 2000 did not indicate a change in the prevalence of chromate allergy among men during the time period investigated. Among women there was a trend towards increasing prevalence (Lindberg *et al.*, 2007).

Prevalence in the general population

The prevalence of metal allergy in the general population is high and it is estimated that up to 17% of women and 3% of men are allergic to nickel whereas only 1-3% are allergic to cobalt and chromium (Thyssen and Menné, 2010). Two consecutive cross-sectional patch-test studies from the same general population in Glostrup, Denmark showed that the prevalence of chromium allergy decreased significantly between 1990 and 2006 (studies carried out in 1990, 1998 and 2006). This is mainly explained by the effect of the Danish chromium regulation introduced in 1983, which required the amount of water-soluble hexavalent chromium to be reduced in cement to <2 mg/kg and to generally improved work hygiene. Similar effects on the prevalence of nickel allergy in the general population have been observed following the introduction of regulation in Denmark and later in the EU restricting the content of nickel in certain consumer products (Thyssen and Menné, 2010).

Among 424 Norwegian school children aged 7-12 years who were patch tested using the Epiquick test, 1.2% showed positive reactions to chromium (Dotterud and Falk, 1994). The children were selected based on responses to a questionnaire distributed to parents of all 575 schoolchildren aged 7-12 years in the community of Sør-Varanger in Northern Norway.

Estimation of the prevalence of chromium allergy using the CE-DUR method (clinical epidemiological drug utilisation research), which estimates the number of diseased individuals in a population based on information about specific drug prescription and consumption, was used to estimate the prevalence in the general population and compare it with the prevalence estimates from the Danish Glostrup allergy studies. The Glostrup allergy studies from 1990 to 1998 estimated the prevalence of contact allergy in a general population in Denmark considered representative for the whole country with regard to age and sex distribution, and occupation (except for fisheries). The CE-DUR estimates used for comparison were based on the total annual patch test sales adjusted for the estimated proportion of discarded tests, the proportion of previously tested individuals and the proportion of diseased individuals seeking medical consultation. The study estimated the 10-year prevalence of contact allergy in Denmark to be between 5.5 and 9.7% for all age groups and to be between 7.3 and 12.9% for adults >18 years. For comparison with the Glostrup allergy studies showing a contact allergy prevalence in Denmark of 15.2% in 1990 (age 15-69 years) and 18.6% in 1998 (age 15-41 years), the estimate of 12.9% for adult Danes should be used (Thyssen *et al.*, 2007a). It is concluded that the CE-DUR method might be slightly inaccurate but that it produces prevalence estimates that are adequately realistic.

Prevalence related to the strength of the positive response in patch tests for specific allergens were also estimated and the 10-year prevalence, tested over a five year period (2001-2005) for potassium dichromate in the Danish Contact Dermatitis Group (n=14,284), was estimated to be between 1.20% (++/+++)[8] and 3.30% (+/+++)[9] for clinical patients. In the general population the worst case prevalence estimate of chromium allergy was between 0.26% (++/+++) and 0.73% (+/+++) and the medium case prevalence was estimated to be between 0.20% (++/+++) to 0.54% (+/+++) (0.37% average) related to the total Danish population of 5,400,000 (Thyssen *et al.*, 2007b).

For comparison the 10-year prevalence (1992-2002) for potassium chromate in Germany estimated a prevalence among clinical patients (n=78,067) to be between 1.6% (++/+++) and 4.2% (+/+++). In the general population the worst case prevalence estimate of chromium allergy was between 0.7% (++/+++) and 1.7% (+/+++) and the medium case prevalence was estimated to be between 0.2% (++/+++) and 0.7% (+/+++) related to the total German population of 82,000,000 (Thyssen *et al.*, 2007b).

Concluding from this the prevalence of chromium allergy in the general population (2001-2005) in Denmark was estimated at 0.2%-0.54% (0.37% average) as a medium case prevalence corresponding to 20,000 individuals.

For comparison the estimated medium case prevalence in Germany was 0.2-0.7% (Thyssen *et al.*, 2007b).

The prevalence of chromium allergy in eczema patients in 2005/2006 was found to be between 2.4% and 5.9% in four European regions including 10 countries as shown in Table 23 (Uter *et al.*, 2009). The prevalence data for eczema patients cannot be directly used to estimate the prevalence of chromium allergy in the general population. A comparison of the prevalence of chromium allergy among eczema patients in Denmark and the four European regions does not indicate that the prevalence is particularly high in Denmark, and extrapolations made on the basis of Danish prevalence data are not considered likely to overestimate the extent of the problem at EU level.

[8] ++/+++: Only unequivocal/strong positive reactions
[9] +/+++: All positive reactions

Using the German data of the estimated medium case prevalence of 0.2-0.7% for the EU27 this corresponds to a calculated estimate of 1-3.5 million individuals sensitised.

Incidence of chromium allergy in the general population

The incidence of chromium allergy refers to the number of new cases of the disease during a defined period in a specified population. Regular incidence studies are not performed and incidence data for chromium allergy in the general population have not been available.

The incidence of chromium allergy in the general population is below estimated by two methods:

1) Estimated from the prevalence among those patients who are patch tested and information about the number of purchased patch tests and relevant correction factors.

2) Estimated from the prevalence of chromium allergy in the general population and the average age when the allergy is diagnosed and the expected years of life after the diagnosis.

In Denmark, the national surveillance data provide a good background for calculating the incidence using method 1 combined with information on the annual number of purchased patch tests of 25,000. Stepwise estimation of the number of patients eligible for patch testing based on the number of patch tests sold annually and published evidence concerning the selection process is shown in Table 24 (Thyssen *et al.*, 2007b).

TABLE 24 STEPWISE ESTIMATION OF NUMBER OF PATIENTS ELIGIBLE FOR PATCH TESTING IN DENMARK (THYSSEN ET AL., 2007B)

Corrections	**Model I** **Worst case scenario**	**Model II** **Best case scenario**	**Model III** **Medium case scenario**
Number of sold patch tests per year Correction factor 1: the proportion of discarded patch tests (0-5%)	25,000 (0%)	25,000 (-5%)	25,000 (-2.5%)
Number of sold patch tests per year Correction factor 2: the proportion of previously tested persons (5-15%)	25,000 (-5%)	23,750 (-15%)	24,375[1)] (-10%)
First time patch tests Correction factor 3: the proportion of diseased persons who seek medical consultation (20-30%)	23,750 /20%	20,188 /30%	21,938[2)] /25%
Persons eligible for patch testing per year	118,750	67,290	87,750[3)]

[1)] 25,000 corrected by correction factor 1; [2)] 24,375 corrected by correction factor 2 and corresponding to 25% (correction factor 3) of persons eligible for patch testing; [3)] Persons eligible for patch testing ~ 100%.

Using this stepwise estimation specifically for chromium, the following correction factors have been used in this report to estimate the number of persons eligible for patch testing based on the 25,000 patch tests annually sold in Denmark:

Correction factor 1: - 2.5% (medium case)

Correction factor 2: - 25%; expert judgement based on information from Gentofte University Hospital (Menné, 2011)

Correction factor 3: 100% ; expert judgement, based on information from Gentofte Hospital based on the assumption that persons with chromium allergy will seek medical consultation due to the severity of the disease (Menné, 2011)

From the Danish surveillance data for chromium allergy, the average occurrence of chromium allergy among patients with eczema in the period 2004 to 2010 was 2.96% (Table 22), and this figure will be used to calculate the number of new cases of chromium allergy per year (the incidence).

The incidence for chromium (VI) in Denmark can be estimated at 0.01% ((25,000*0.975*0.75*2.96) / (1.0*5,500,000)). This figure is the result of all chromium exposure. This corresponds to 550 new cases in Denmark per year. Extrapolated to the EU this would correspond to approximately 50,000 new cases per year.

Alternatively, the incidence may be calculated from the prevalence of the chromium allergy in the general population using method 2. The incidence for Denmark could be estimated from on the average medium case prevalence of chromium allergy in the general population of 0.37% (0.2-0.54%) as estimated by Thyssen *et al.* (2007b). It is assumed that the onset of allergy happens on average at 40 years of age (expert estimate on the basis of Danish experience (Menné, 2011)) and that 40-year old people have a 42-year life expectancy (Statistics Denmark, 2011). This gives an estimated number of new cases per year of 485 (0.0037*5,500,000)/42). The estimate on this basis is slightly lower than the estimate based on method 1.

It is considered that this method gives the most transparent estimate at EU level, as each of the parameters may be re-evaluated as further data becomes available.

The key assumptions applied are shown in Table 25. The calculation is based on an estimate of the prevalence of chromium allergy in the EU27 population of 0.37%.

It is assumed that the allergy is diagnosed in the age of 40 and that EU citizens 40 years old have a 42-year life expectancy[10] (incidentally the same as for Denmark used above). On this basis, the average annual number of cases is estimated at about 44,000. It is also assumed that the prevalence is constant, which means that without further restriction the number of new cases is that same as the number of people with the allergy who die from other causes.

[10] Eurostat: 2008 data for EU27 average life expectancy at birth 79.4 and life expectance at age 65 it is 19.1 year. Interpolation for life expectance at age 40 is approximately 42.

TABLE 25 ASSUMPTIONS FOR ESTIMATION OF THE NUMBER OF CASES WITH CHROMIUM ALLERGY IN EU27 POPULATION

Assumption	Value	Unit
EU population	500	Million inhabitants
Prevalence in the EU population	0.37	%
Total number of existing cases	1.85	Million cases of chromium allergy
Age groups with chromium allergy 40 years to 82 years	42	Years
Number in each age group	44,000	Cases
New cases each year assuming constant population and constant prevalence	44,000	New cases

On the basis of the experience from Denmark it is estimated that 45% of the new chromium allergy cases are due to exposure from leather or articles of leather (Thyssen *et al.*, 2009). With 44,000 new cases of chromium allergy each year in the EU, 45% of which are due to exposure to leather, the total number of cases caused by leather would be approximately 20,000 per year. This number will be used as a basis for the assessment of the socio-economic impact of the proposed restriction in Chapter F.

B 5.5.2 Sensitisation to chromium (III)

Trivalent chromium, chromium (III) is also reported to play an important role in elicitation of dermatitis in chromium sensitised patients although chromium (III) is less potent than chromium (VI). Based on a study in 18 patients, Hansen *et al.* (2003) conclude that chromium allergy may very well be considered a combined chromium (III) and chromium (VI) allergy.

Hansen et al. (2006) found an increased risk of foot dermatitis in chromium (VI) positive patients with a concomitant positive or doubtful reaction to chromium (III), compared with chromium (VI) positive patients with no reactions to chromium (III). They therefore conclude that a positive reaction to chromium (VI) in combination with a positive or doubtful reaction to chromium (III) increases the risk of foot dermatitis. The increased risk was not due to a higher degree of sensitivity to chromium (VI) in the patient population, because the raised risk was also observed when the patch test reactions were stratified into chromium (VI) (+) or (++) reactions. The authors also conclude that chromium (III) positive patients represent a group with multiple shoe allergies, and chromium (VI) in leather was the main suspected chromium exposure source. Furthermore, they emphasise the ability of both chromium (III) and chromium (VI) to elicit dermatitis at low concentrations (Hansen *et al.*, 2006).

Only two studies on threshold levels for chromium (III) have been identified. In both studies the threshold levels for chromium (III) were higher than for chromium (VI). In the study by Nethercott *et al.* (1994), only 1 out of 54 patients reacted to chromium (III) corresponding to a threshold concentration of 33 $\mu g/cm^2$ (1,099 ppm in the occlusion solution). It should, however, be stressed that this patient did not react to the same concentration upon retest.

In the study by Hansen *et al.* (2003) based on patch testing of 22 chromium allergic patients with chromium trichloride hexahydrate in concentrations between 5 and 25,350 ppm the estimated Minimal Elicitation Threshold ($MET_{10\%}$) deducted from the dose-response curve for chromium (III) to be 6 ppm corresponding to 0.18 $\mu g/cm^2$/2 days (6 ppm in the occlusion solution). This is at least 6 times higher than for chromium (VI).

Trivalent chromium has a high protein binding capacity and easily binds to non-specific proteins to form stable complexes within the epidermis. The result is that only little chromium (III) penetrates the skin (Thyssen and Menné, 2010).

Few cases of potential primary sensitisation to chromium (III) are reported in the literature. The latest identified article on this issue by Estlander *et al.* (2000) refers to a case report of two tannery workers with work-related dermatitis of the hands, arms and legs. Patch testing revealed that both patients had become sensitised to chromium chromium (III) and it was argued that only chromium (III) in the form of chromium sulphate was used in the tannery. The two tannery workers were involved with handling of wet hides coming directly from the tanning department and were not exposed to chromium from other sources at work (Estlander *et al.,* 2000). No measurements of chromium species in the hides are reported. This opens the question of whether the actual exposure is in fact from chromium (III) alone, or possibly also from chromium (VI) formed by oxidation of chromium (III) in the leather after the tanning process. As no details are provided regarding the process carried out by the tanning department and at which stage in the process the two tannery workers handle the hides, the possibility of chromium (VI) being involved in the sensitisation cannot be overlooked.

Patch testing was carried out with five different concentrations of chromium (VI) ranging from 0.032 to 1% and four different concentrations of chromium (III) ranging from 0.5 to 2.0%. Positive reactions (++) were observed for both patients to all four chromium (III) concentrations whereas the allergic response to chromium (VI) differed among the two patients where one reacted to all concentrations (+/++ or +++) and the other reacted positively to the three highest concentrations (+ or ++) (Estlander *et al.,* 2000).

B 5.6 Repeated dose toxicity

With respect to repeated exposure, a large number of studies are available relating to exposure of workers to highly water-soluble chromium (VI), specifically sodium or potassium chromate/dichromate and chromium (VI) trioxide. The main effects reported are irritant and corrosive responses in relation to inhalation and dermal exposure. These include inflammation in the lower respiratory tract, and nasal septum perforation in the upper respiratory tract. It is not possible to relate these effects to reliable measures of chromium (VI) exposure. Although in principle a threshold dose should be identifiable, in practice the location of such a threshold is not possible from the data available. Some evidence of kidney damage has also been found among chromate production and chromium plating workers. No exposure-response data or no-effect levels are available. It appears however, that the exposure levels at which kidney toxicity occurs overlaps the atmospheric concentrations at which respiratory tract effects have been reported (ECB, 2005).

Only limited animal repeated dose toxicity testing is available. In general, the effects seen are consistent with those found in humans. Although in principle a threshold dose should be identifiable, in practice the location of such a threshold is not possible from the data available. Inhalation of sodium chromate dust for 8 months caused deaths in mice exposed to 0.3-3.7 mg/m^3 (0.1-1.2 mg Cr(VI)/m^3). Rats appeared to be less sensitive (no deaths occurring after 16 months). Chromium (VI) concentrations down to 0.06 mg/m^3 (0.025 mg Cr(VI)/m^3) sodium dichromate (aerosol) produced increased alveolar macrophage and spleen lymphocyte activities following a 90-day exposure in the rat. Much of this enhancement was lost at 0.57 mg/m^3 sodium dichromate (0.2 mg Cr(VI)/m^3); this dose inhibited alveolar macrophage phagocytosis. Repeated chromic acid mist (chromium (VI) trioxide) exposure produced irritant and corrosive effects in the respiratory tract at 3.5 mg/m^3 (1.8 mg Cr(VI)/m^3) and above in an 8-month study. Overall, little useful dose-response information is available (ECB, 2005).

In the rat, testicular degeneration was observed at an oral dose level (40 mg/kg/day (14 mg Cr(VI)/kg/day)) which caused a large decrease in body weight gain following gavage administration of sodium dichromate for 90 days. A NOAEL of 20 mg/kg/day (7 mg Cr(VI)/kg/day) was determined for effects on the testis, the only organ examined. Other studies found no significant toxicity, including no effects on the testis, following administration of potassium dichromate by the dietary route for 9 weeks. The highest dose levels in these studies were 24 mg/kg/day (8 mg Cr(VI)/kg/day) in the rat and 92 mg/kg/day (32 mg Cr(VI)/kg/day) in the mouse. No repeated dermal studies are available, although these substances are recognised as being corrosive on repeated dermal exposure (ECB, 2005).

B 5.7 Mutagenicity

Few studies of genotoxic potential in humans are available. No evidence of genotoxic activity has been found in adequately-conducted studies in circulating lymphocytes from chromium exposed workers. In contrast, there is a vast array of genotoxicity data *in vitro* and less extensive testing in animals available. The evidence clearly indicates that highly water-soluble chromium (VI) compounds[11] can produce significant mutagenic activity *in vitro* and *in vivo*. The chromium (VI) compound under consideration is therefore regarded as *in vivo* somatic cell mutagen. In addition, toxicokinetic and dominant lethal data suggest that water-soluble chromium (VI) has the potential to be an *in vivo* germ cell mutagen (ECB, 2005).

B 5.8 Carcinogenicity

Besides the RAR (ECB, 2005) the following is based on the Annex XV report for potassium dichromate (ECHA, 2011).

Epidemiology data from chromate production, chromium pigment manufacture and other chromium-exposed groups showing clear increases in lung cancers cannot be specifically related to exposure to chromium (VI) compounds. However, it is highly probable that chromium (VI) ions in solution were the ultimate carcinogenic entity in these situations. Hence these epidemiological studies raise concerns for the carcinogenic potential of the chromium (VI) compounds (ECHA, 2011).

In animal carcinogenicity studies, sodium dichromate was carcinogenic in rats, causing lung tumour mice, inhalation or intrabronchial implantation studies using chromium (VI) trioxide produced 1-2 test group animals with lung tumours where such were mainly absent among corresponding controls. Thus, in animal studies there is some evidence of respiratory tract carcinogenic activity for sodium dichromate and chromium (VI) trioxide. Similar studies in rats using other chromium (VI) compounds, able to produce chromium (VI) in solution, produced carcinogenicity in the lung. Hence there is good reason from animal studies to be concerned about the carcinogenic potential of the chromium (VI) compounds, in terms of the inhalation route and the respiratory tract as a site of action. Data for the oral and dermal routes and carcinogenicity studies on the chromium (VI) compounds are not available. Chromium (VI) compounds might be expected to have potential to cause cancer on repeated oral or dermal exposure. In the case of the oral route, any systemic carcinogenic potential could be limited by poor absorption of chromium (VI), and reduction to

[11] Water-soluble hexavalent chromium compounds include: chromic acid, chromic acid anhydrides, monochromates and dichromates of sodium, of potassium, of ammonium, of lithium, of cesium, of rubidium. Water-insoluble hexavalent chromium compounds include: zinc chromate, calcium chromate, lead chromate, barium chromate, strontium chromate and sintered chromium trioxide (ECHA, 2011).

chromium (III) within the gastrointestinal tract although site of contact activity would remain an issue. Similar considerations apply to the skin (ECB, 2005).

Overall, therefore, the chromium (VI) compounds are considered to have proven or suspect carcinogenic potential. From the available information, and taking into account the genotoxic potential of these substances, it is not possible to identify any dose-response relationship or thresholds for this effect (ECB, 2005).

The international Agency for Research on Cancer (IARC) has evaluated that there is *sufficient evidence* in humans for the carcinogenicity of chromium (VI) compounds as encountered in the chromate production, chromate pigment production and chromium plating industries (IARC, 1990).

B 5.9 Toxicity for reproduction

Human data relating to effects on reproduction are limited to poorly reported studies of female workers from which no conclusions can be drawn. There are three animal studies available which focus on fertility (ECB, 2005).

In a fertility study adverse effects were produced in mice receiving potassium dichromate for 12 weeks in drinking water at 333 mg/kg/day (120 mg Cr(VI)/kg/day) and 400 mg/kg/day (140 mg Cr(VI)/kg/day) and above in males and females respectively. A NOAEL of 166 mg/kg/day (60 mg Cr(VI)/kg/day) was identified in males but no NOAEL was found for females as 400 mg/kg/day was the lowest dose level tested. An increase in resorptions following treatment of males and a decrease in implantations in treated females were among the findings in this study (ECB, 2005).

In another study performed to assess the effect of pregestational exposure to chromium on development, pregestational oral administration of potassium dichromate in drinking water to female mice produced adverse effects on fertility (reduced number of corpora lutea and increased pre-implantation loss) at 500 ppm (119 mg/kg/day (40 mg Cr(VI)/kg/day)) and above. NOAEL values of 119 mg/kg/day (40 mg Cr(VI)/kg/day) and 63 mg/kg/day (20 mg Cr(VI)/kg/day) can be identified from this study for maternal toxicity and fertility effects respectively (ECB, 2005).

In a third fertility study, also in the mouse, at 86 mg/kg/day (30 mg Cr(VI)/kg/day), the highest dose level tested, there were no effects of treatment on fertility parameters (ECB, 2005).

In a developmental study, foetotoxicity, including post-implantation losses, has been observed in the mouse following administration of potassium dichromate in drinking water during gestation (days 0-19). Significant developmental effects occurred at the lowest dose level tested, 60 mg/kg/day (20 mg Cr(VI)/kg/day) in the absence of maternal toxicity. Therefore no developmental NOAEL was determined (ECB, 2005).

Qualitatively similar results were obtained in another developmental study in Swiss albino mice in which (350 mg/kg) potassium dichromate (125 mg Cr(VI)/kg) was administered for a shorter period, on days 6-14 of gestation. In a pregestational study in female mice, foetotoxic effects were seen starting from the lowest dose level tested, 250 ppm (63 mg/kg/day (22.1 mg Cr(VI)/kg/day)) potassium dichromate. Significant levels of total chromium were found in treated animals at sacrifice. No NOAEL could be identified for the developmental effects, which included post-implantation losses. These foetal effects may possibly be explained by the presence of chromium in the dams after the end of treatment (ECB, 2005).

Overall, highly water-soluble chromium (VI) compounds should be considered to be developmental toxicants in the mouse. These findings can be regarded as relevant to humans. It is noted that some of the adverse effects on reproduction observed in animal studies may be related to the germ cell mutagenicity of these chromium (VI) compounds (see Mutagenicity section B.5.7) (ECB, 2005).
No reproductive toxicity studies are available using the inhalation or dermal routes of exposure (ECB, 2005).

B 5.10 Other effects

No other effects have been considered.

B 5.11 Derivation of DNEL(s)/DMEL(s)

According to the ECHA Guidance on information requirements and chemical safety assessment - Characterisation of dose [concentration]-response for human health (ECHA, 2010) derivation of an induction specific DNEL[12] for skin sensitisation can be:

- based on LLNA (local lymph node assay) data only,
- based on the weight of evidence (WoE) in combination with historical human predictive test data, or
- based on read-across from structurally related substances.

Using LLNA data the EC_3 value expressed in dose/unit area of exposed skin (e.g. $\mu g/cm^2$) can be considered as the LOAEL (lowest observed adverse effect level) for induction. By application of relevant assessment factors, a DNEL can be derived expressed in $\mu g/cm^2$/day. An EC3 value of 10 $\mu g/cm^2$ is reported (Heeringa, 2004 as cited by Fisher *et al.*, 2011).

As mentioned in section B.5.5.1, skin sensitisation is generally regarded as a threshold effect with dose-response relationships for both the induction and elicitation phase, although these are not absolute values that can be applicable to the whole population. Setting a DNEL in relation to risk assessment may therefore be difficult since individual susceptibility and other factors influence the induction and elicitation thresholds. As a general rule the dose required to induce sensitisation in a non-sensitised individual is greater than the dose required to elicit an allergic response in a previously exposed individual. Keeping exposures below the elicitation threshold should therefore protect against sensitisation.

The elicitation thresholds identified in the literature and presented in section 5.5.1 are as shown in Table 26.

12 DNEL, Derived No-Effect Level. A DNEL is the level of exposure to the substance below which no adverse effects are expected to occur.

TABLE 26 ESTIMATED ELICITATION THRESHOLDS FOR CHROMIUM (VI)

Elicitation threshold	Value	Unit	Number of test subjects	Reference
$MET_{10\%}$	0.09	µg Cr(VI)/cm²/2 days	54	Nethercott *et al.*, 1994
$MET_{10\%}$	0.35	µg Cr(VI)/cm²/2 days	14	Allenby and Goodwin, 1983
$MET_{10\%}$	0.90	µg Cr(VI)/cm²/2 days	17	Kosann *et al.*, 1998
$MET_{10\%}$	0.02	µg Cr(VI)/cm²/2 days	5	Wass and Wahlberg, 1991
$MET_{10\%}$	0.03*	µg Cr(VI)/cm²/2 days	18	Hansen *et al.,* 2003
$MET_{10\%}$	1.04	µg Cr(VI)/cm² (2 days)	17	Fischer *et al.*, 2011

$MET_{10\%}$: Minimum elicitation threshold inducing a response in 10% of the subjects tested

*: Corresponded to 1 ppm in the occlusion solution (15µl of a solution with 1 mg/kg (ppm) = 0, 0001% chromium (VI) applied at 0.5 cm^2 area of skin; see Robinson *et al.*, 2000.

The table shows that the database is fairly consistent. It is not possible however, to define a NOAEL from which to derive a DNEL value or alternatively to define a LOAEL from which a DNEL value can be derived as applying an adequate assessment factor for these types of effects and obtaining a no effect level is very uncertain. Instead a LOAEL of 0.02 µg/cm2 (lowest $MET_{10\%}$) is used as a dose metric or a derived minimum effect level, (DMEL value) for the risk characterization as this exposure is expected to protect the vast majority towards induction as well as elicitation from chromium (VI).

B.6 Human health hazard assessment of physico-chemical properties

Not relevant, see section B.2.4.

B.7 Environmental hazard assessment

Not relevant, see section B.2.4.

B.8 PBT and vPvB assessment

Not relevant, see section B.2.4.

B 8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

Not relevant, see section B.2.4.

B 8.2 Emission Characterisation

Not relevant, see section B.2.4.

B.9 Exposure assessment

B.9.1 General discussion on release and exposure

As the objective of the restriction is to prevent the release of chromium (VI) from articles of leather, which is due to chromium (VI) unintentionally being formed during the manufacturing of the articles of leather, the exposure assessment will focus on the exposure to chromium (VI).

B.9.1.1 Summary of the existing legal requirements

Currently no general EU-wide restriction of chromium (VI) in leather is in force.

Existing restriction of chromium (VI) in articles at EU level
Directive 89/686/EEC on personal protective equipment provides in article 3 that the personal protective equipment must satisfy basic safety and health requirements. According to article 5, the equipment must therefore be in conformity to the relevant harmonised standards. In the case of protective leather gloves the relevant harmonised standard is EN 420:200313, which provides that the chromium (VI) concentration in the gloves should be below the detection limit of 3 mg/kg.

In order to reduce the risk of chromium allergy from chromium (VI) in cement, the EU REACH Regulation (1907/2006/EC) provides in Annex XVII, number 47, Cement that the water-soluble chromium (VI) content of cement shall be below 2 mg/kg.

Chromium (VI) is regulated by the Cosmetics Directive (76/768/EEC). There is a general ban on "Chromium; chromic acid and its salts" in Annex II/97. Annex IV of the same directive provides that the two colorants CI 77288 and CI 77289 should be "free from chromate ion". The Cosmetics Directive will be replaced by the Cosmetic Regulation 1223/2009 by July 11, 2013.

Chromium (VI) is restricted in electrical and electronic equipment by the RoHS Directive (Directive 2002/95/EC). Article 5(1) (a) and the Annex provides that a maximum concentration value of 0.1% (1000 mg/kg) by weight in homogeneous materials shall be tolerated for chromium (VI).

Chromium (VI) is restricted in vehicles by the ELV Directive (2000/53/EC) in article 4(2) (a) and Annex II which provides that a maximum concentration value of 0.1% (1000 mg/kg) by weight in homogeneous materials shall be tolerated for chromium (VI).

This concentration of 0.1% is approximately 10 times higher than the highest chromium (VI) concentrations usually found in chrome tanned leather. However, the general restriction of the chromium (VI) in vehicles has been one of the drivers for the widespread shift to chrome-free leather for car interiors.

Many market actors have responded to the request for information with the statement that chromium (VI) in leather is already restricted at EU level. Some market actors have referred to the standard EN ISO 17075 and consider the detection limit as a restriction. Others refer to general restriction of CMR substances in consumer products and probably mix the discussion up with the restriction of CMR substances in cosmetics (Cosmetics Regulation 1223/2009).

Member States' legislation targeting chromium (VI) in leather
Since August 2010, the content of chromium (VI) in articles of leather has been restricted in Germany. The German Consumer Goods Ordinance (Bedarfsgegenständeverordnung)[14] stipulates that in the production of articles of leather that may come into direct and prolonged contact with the human skin, techniques that may result in a measureable content of chromium (VI) in the articles of leather shall not the be used. The specified test method (§64 LFGB B82:02: 2008-10) is largely

[13] Cf. Commission communication in the framework of the implementation of the Council Directive 89/686/EEC of 21 December 1989 on approximation of the laws of the Member States relating to personal protective equipment (*Publication of titles and references of harmonised standards under the directive)* (2011/C 329/01)
[14] "Bedarfsgegenständeverordnung in der Fassung der Bekanntmachung vom 23. Dezember 1997 (BGBl. 1998 I S. 5), die zuletzt durch Artikel 1 der Verordnung vom 7. Februar 2011 (BGBl. I S. 226) geändert worden ist"

identical to ISO EN 17075 and has a detection limit for chromium (VI) of 3 mg/kg. The ordinance specifically mentions the following articles to be covered by the restriction: clothing, bracelets, bags and backpacks, chair covers, purses and leather toys.

The background for the German restriction is a recommendation from the German Federal Institute for Risk Assessment, (Bundesinstitut für Risikobewertung, BfR) (BfR 2007a, BfR 2007b.). The institute concludes on the basis of a risk assessment that the only way of preventing allergic reactions for allergy sufferers is to avoid contact with leather goods that contain chromium (VI). More than half a million people in Germany react sensitively to this chromium (VI) and the institute concludes that leather consumer goods, in particular leather clothing should not, therefore, in principle contain any chromium (VI) at all (BfR, 2007b). Hence BfR proposes restricting the use of chromium salts in leather production as far as possible or technically reducing their concentrations during processing to such an extent that chromium (VI) can no longer be detected in the end product (BfR, 2007b). No socio-economic assessment of the impact of the German restriction has been undertaken.

It has not been possible to find any data indicating the effect of the regulation in reducing the percentage of articles of leather with chromium (VI) or the exposure of the population.

Ecolabels targeting chromium (VI) in leather

Chromium (VI) content of leather is today targeted by a number of ecolabels (Table 27).

The European Ecolabel (the EU flower), the Nordic ecolabel (the Swan) and the German Blue Angel all refer to the ISO EN 17075 standard which has a detection limit of 3 mg/kg.

The EU Ecolabel previously requires shoes to have a limit value for chromium (VI) of 10 mg/kg as measured in accordance with EN 420. By the revision of July 2009 shoes must not contain chromium (VI) in detectable amount as measured by ISO EN 17075 (detection level of 3 mg/kg).

Whereas the EU flower stipulates that the leather shall not contain chromium (VI) in detectable amounts (the current detection limit of 3 mg/kg of the standard) the Nordic ecolabel and the Blue Angel specifies as limit value of 3 mg/kg.

The OEKO-TEX Standard 100 requirements differ from the other standards, as the standard requires that the chromium (VI) content is below the limit value of the applied method of 0.5 mg/kg.

TABLE 27 LIMIT VALUES FOR CHROMIUM (VI) IN LEATHER RELATED TO DIFFERENT ECOLABEL SCHEMES

Country	Organisation	Name	Articles	Limit value – Cr(VI) mg/kg	Analytical method (Detection limit)
EU	The European Commission	The Ecolabel (The EU Flower)	Shoes	Not detectable (< 3)	ISO EN 17075 (3 mg/kg)
Nordic countries	Nordic ecolabelling	The Nordic ecolabel (Swan)	Skins and leather	3	ISO EN 17075 (3 mg/kg)
Germany	The Federal Ministry for the Environment Nature Conservation and Nuclear Safety	The Blue Angel Die Blaue Engel	Leather	3	ISO EN 17075 (3 mg/kg)
International	International Council of Tanners	Eco-Tox Label	Leather - direct contact with skin	3	ISO EN 17075 (3 mg/kg)
Germany	Prüf- und Forschungsinstitut Pirmasens TÜV Rheinland	SG (Schad-stoffgeprüft)	Leather articles	Not detectable (< 3)	DIN 53314 (3 mg/kg)
International	Oeko-Tex® Association	OEKO-TEX Standard 100		Not detectable (< 0,5)	OEKO-TEX method (0.5 mg/kg)

Voluntary commitments

According to the trade organisation COTANCE, measures to prevent the formation of chromium (VI) are today implemented in most tanneries in the EU. Furthermore, many manufacturers and importers of articles of leather into the EU have already taken action in the form of a voluntary commitment to controlling the content of chromium (VI) in the articles. This seems in particular to apply to leather and leather shoes placed on the market whereas requirements for and control of other articles of leather seems to be less widespread.

There is no official commitment from the industry today to the prevention of the formation of chromium (VI) or to control the concentration of chromium (VI) in articles of leather placed on the market.

The tannery process

Tanneries are covered by the Directive on industrial emissions 2010/75/EU (IED Directive). In accordance with the directive the tanneries are required to apply best available techniques (BAT) as defined in the EU BREF document. The BAT mainly concerns environmental releases from the activities. The options for prevention of the formation of chromium (VI) are described in detail in section C.2.1. In this section only the options included in the BREF document are addressed.

The BREF document only very briefly mentions that “for reasons of product safety, tanners in Europe employ specific precautions to prevent oxidation of chromium (III) to chromium (VI) during manufacture” (BREF, 2011), but in general it does not specify which precautions should be employed. The document more specifically mentions that oxidising bleaching agents have the potential to oxidise chromium (III) to chromium (VI) in leather. The document has specific recommendations regarding BAT for one process only:

- Substitution of ammonia as penetrating agent for dyes in post-tanning processes

Other measures described in section C.2.1 of this report, are not specifically mentioned as BAT. The reason is probably that the formation of chromium (VI) in the leather mainly concerns the product and not the emissions from the industrial processes, which are the concern of the IED Directive. The BREF document describes BAT for prevention of total chromium (measured as chromium (III)) releases from the tanneries. The BAT for waste water from tanning operations are 0.05-2 kg Cr(III) per tonne of raw hide, and 0.1-1 kg Cr(III) per tonne of raw hide for post tanning operations (BREF 2011).

B.9.1.2 Summary of the effectiveness of the implemented operational conditions and risk management measures

According to information from Industry, the measures for prevention of chromium (VI) described in section C.2.1 has today been implemented in most tanneries in Europe. It is also stated that the implemented measures are adequate for the manufacture of leather with chromium (VI) content below the detection limit of 3 mg/kg.

Surveys of chromium (VI) content of marketed articles of leather described in B.2.2.6 in Germany and Denmark, however, demonstrate that approximately 1/3 of the marketed products contain chromium (VI) in levels above 3 mg/kg. The Danish data indicates that half of the articles analysed are imported from countries outside the EU and the country of origin of the other half of the articles is unknown. The German data surveys do not indicate the origin of the articles. An institute providing chromium (VI) analyses for manufacturers, importers and suppliers of articles of leather state that they do not usually know the origin of the products.

It has not been possible to identify any surveys which clearly indicate that the articles with high chromium (VI) content were imported. Consequently, the effectiveness of the operational conditions implemented and risk management measures in the European industry have not been demonstrated by the independent surveys of articles.

B.9.2 Manufacturing

The substance is not intentionally manufactured.

The EU RAR includes data on releases from the production of chromium (VI) compounds and from the manufacturing of chromium salts for tanning. It is estimated that 4.2 tonnes of chromium (VI) are released to water from the chrome tanning salt production (ECB, 2005).

Unintentionally formed chromium (VI) in articles of leather may be considered an additional source of potential releases to the environment. This would be prevented or reduced by the restriction. Releases from the tanning process itself would not be affected by the restriction.

B.9.2.1 Occupational exposure

Not relevant for this dossier as the substance is not intentionally manufactured.

B.9.2.2 Environmental release

Not relevant for this dossier as the substance is not intentionally manufactured.

B.9.3 Formation of chromium (VI) in the production of leather

B.9.3.1 General information

As mentioned in previous sections, chromium (VI) is not used intentionally in the production of leather but may be formed in the process. The following will address the possible effect of the chromium (VI) formed in the production process.

B.9.3.2 Exposure

B.9.3.2.1 Workers exposure

Workers may be exposed to the chromium (VI) in leather at three steps in the product chain:

- The manufacture of the leather;
- The manufacture of articles of leather;
- The occupational use of articles of leather.

Occupational studies with positive findings in relation to specific effects from chromium (VI) indicate that significant exposure may occur.

In the tanning industry, occupational exposure is mostly to soluble chromium (III) (ATSDR, 2000). The occupational exposure to chromium (III) would not be affected by the current restriction proposal. The restriction proposal could reduce possible occupational health effects caused by chromium (VI) formed in the leather during the leather processing.

Several studies report on occupational allergic contact dermatitis (ACD) from exposure to chromium in tanneries or the manufacture of articles of leather.

In Finland, a total of 2,543 cases of occupational allergic contact dermatitis (ACD) were reported during 1991-1997 (Kanerva *et al.*, 2000). Chromium caused 143 (5.6%) cases of occupational ACD. The ranking list of the incidence rates of occupational ACD caused by chromium per 10,000 working years was (incidence rate in parenthesis – i.e. the number of new cases per 10,000 working years) (1) tanners, fellmongers, and pelt dressers (12.20); (2) cast concrete product workers (6.94), and (3) leather goods workers (4.71).

In a Swedish study of 1,752 patients considered to have occupational dermatoses, contact dermatitis was the main diagnosis in 1,496 patients (Fregert, 1975, as cited by ATSDR, 2000). Among 280 chromium-sensitized men, 50% were employed in building and concrete work, 17% in metal work, and 12% in tanneries.

A Finish study from 2000 reports on two men whose duties included the handling of wet hides in the tanning department and who subsequently developed work related dermatitis of the hands, arms and legs (Estlander *et al.*, 2000). The causative exposure is reported to be contact with chromium (III) used in the tanning, but it may in fact have been due to exposure to chromium (VI) unintentionally formed in the leather. The authors do not discuss possible exposure to chromium (VI). Handling of the leather by the post tanning processes may lead to significant exposure of the workers in the tanneries to chromium (VI) if measures for prevention of its formation are not taken.

Investigations of exposures (including both occupational and consumer exposures) of patients with dermatitis and chromate allergy treated in Denmark show that for the period 1995 through 2007, most of the cases were caused by contact with leather shoes and leather gloves. In both female and in male patients, leather footwear was the main cause of the dermatitis (39% and 28% respectively). Cement was estimated to be the cause of 11.6% among male patients (Thyssen *et al.*, 2009).

A German study from 2004 reports on high levels of chromium (VI) in protective gloves of leather with chromium (VI) concentrations of up to 100 mg/kg (Geier *et al.*, 2004). In one of the referenced data surveys from 1998, about 1/3 of the 33 tested gloves contained more than 10 mg/kg of chromium (VI). The authors mention that the information network of dermatological clinics in Germany (IDU) has determined that 20.8% of those tested where glove allergy was suspected, were men with occupational allergic reaction to potassium dichromate. Only half of these workers with an allergic reaction to potassium chromate allergy were currently or formerly employed in the construction sector (and thus potentially exposed to chromium (VI) in cement. The study does not specifically indicate the prevalence of allergy developed as result of occupational use of leather among those tested.

No data on ACD as result of occupational use of leather have been identified.

B.9.3.2.2 Consumer exposure

Consumers may be exposed to Cr (VI)-containing leather from many sources. Leather goods for consumers expected to give rise to the highest exposure are those coming into close contact with the skin for the longest periods of time. Examples include shoes and gloves, clothes, hats, sports equipment, leather covers for seats, steering wheels and gearshift knobs in cars, furniture, watch straps, jewellery, and straps for bags.

As specific exposure values in relation to consumers are not available and the potential for exposure may best be described by data in relation to the chromium (VI) content of various consumer articles.

The Danish EPA carried out an investigation of the content of chromium (VI) and chromium (III) in articles of leather on the Danish market in 2002 (Rydin, 2002). As part of the study forty-three articles of leather were purchased in Denmark and the leather was analysed for the content of chromium (VI) and total chromium. The products represented ten different product groups (watch-straps, shoes, and gloves, baby-shoes, working gloves, leather jackets, trousers, leather-tops, skirts and leather-hats). Fifteen out of the forty-three articles of leather contained chromium (VI) in levels above the detection limit of 3 mg/kg. Hence, thirty-five (35%) of the products contained chromium (VI). In the 15 products where chromium (VI) was detected, the concentration range was from 3.6 to 14.7 mg/kg (analysed according to DIN 53315). In addition, ten baby-shoes were analysed for content of chromium (VI) which was found to be below the detection limit in all samples (Rydin, 2002). Two of the baby-shoes were also analysed for migration of chromium according to the European Standards on safety of Toys, EN 71 Part 3. The upper leather and the sole leather were analysed separately. The migration of total chromium from the samples was between 370-980 mg Cr per kg leather, which is higher than the stated safety requirement of the EN 71 (Rydin, 2002).

Another survey from the Danish EPA (Johansen *et al.*, 2011) on chromium in leather shoes aimed to clarify whether chromium (VI) and chromium (III) compounds are released from leather shoes in Denmark in an amount that constitutes a potential of causing allergic reactions. As part of the study a market survey of volumes of leather shoes available on the Danish market in 2008 was carried out. Sixty pairs of leather shoes (20 ladies' shoes, 20 men's shoes and 20 children's shoes) were purchased in the Copenhagen area and XRF screened. Eighteen pairs were analysed for content of chromium according to ISO EN 17075 (Johansen *et al.*, 2011).

The XRF screening revealed that the typical range of chromium content in leather shoes seems to be between 1 and 3%. The results indicated no correlation between content of chromium and shoe category (ladies', men's or children's shoes) or shoe type (sandals, boots or ordinary shoes). Thus, 18 representative pairs were selected for quantitative analysis using EN ISO 17075. It was found that 8 pairs of shoes out of the 18 pairs of shoes analysed (corresponding to 44%) had chromium (VI) content higher than the determination limit of 3 mg/kg (ppm). The median was 6 ppm and the range from 3 to 62 ppm. A sixth of the shoes contained more than 10 mg/kg chromium (VI). Sandals seemed to be over-represented among the shoes with detectable chromium (VI). This was mentioned as a concern since sandals are more likely to be worn with bare feet and thus the direct exposure to chromium (VI) is likely to be higher. The shoe with one of the highest levels of chromium (VI) content was a child's sandal. No relation was found between chromium (VI) and chromium (III) levels (Johansen *et al.*, 2011).

Results from the investigation of causative exposures among patients with chromium allergy as illustrated in Table 28, showed that among the 136 female patients allergic to chromate, 39% of cases were attributed to leather shoes and among the 61 male patients, this figure was 28% (Thyssen *et al.* 2009).

TABLE 28 CLINICAL CHARACTERISTICS RELATED TO RELEVANT EXPOSURES OF 197 PATIENTS WITH DERMATITIS AND CHROMATE ALLERGY TREATED IN DENMARK BETWEEN 1995 AND 2007

Relevant exposures	**Male patients (n=61) % (n)**	**Female patients (n=136) % (n)**	**Total (n=197) % (n)**
Leather shoes *	27.9 (17)	39.0 (53)	35.5 (70)
Leather gloves	23.0 (14)	5.1 (7)	10.7 (21)
Other leather goods (furniture, watch straps, jacket, bag, belt, cover for car wheel)	11.5 (7)	6.6 (9)	8.1 (16)
Cement	11.5 (7)	0	3.6 (7)
Plywood	3.3 (2)	0	1.0 (2)
Cosmetics	0	1.5 (2)	1.0 (2)
Graphic work and paint	4.9 (3)	0	1.5 (3)
Not reported	16 (10)	48 (65)	38(75)

* The paper uses the term "shoes", but the text indicates that the term "footwear" would have been more appropriate as it includes various types of footwear including sandals.

Source:Thyssen *et al.*, 2009

Changes in chromium exposure among Danish patients with dermatitis tested at a Danish hospital (Gentofte Hospital) in 1989-1994 (79 patients) and 1995-2007 (235 patients) showed that the frequency of clinically relevant cement exposure decreased significantly among patients with chromium allergy from 12.7% during 1989-1994 to 3.0% during 1995-2007 ($p < 0.01$) whereas the frequency of overall leather exposure increased significantly from 24.1% to 45.5% ($p < 0.02$) (Thyssen *et al.*, 2009).

Clinical relevance: Clinical relevance of contact allergy to a substance is defined as contact dermatitis resulting from documented exposure to the allergen in question.

A percentage of leather exposure among all sources of chromium exposure of 45.5% (Thyssen et al., 2009) will be used for the socio-economic analysis.

Hypothetical exposure scenario with leather shoes:

Reliable information is not available to define a realistic exposure scenario, primarily because realistic estimates of chromium released from leather and the release rate under physiological conditions are difficult to establish and are thus not available. The currently available analytical methods are carried out at higher pH than under average physiological conditions and are thus not representative (normal skin falls within the pH 4 to 5.5 range). Furthermore, it has not been possible to establish a relation between reactivity to known chromium solutions and reactivity to leather with known chromium content. A hypothetical exposure scenario based on the following assumptions is presented below:

Exposure to chromium-tanned leather in a shoe. It is assumed that the shoe is worn under wet conditions allowing maximum release of soluble chromium. The chromium (VI) content in the shoe is 3 mg/kg corresponding to the analytical detection limit of the suggested analytical method for compliance control (ISO EN 17075) and all chromium (VI) can be released. The scenario is used to discuss the potential consequences of the release rate.

Amount of soluble Cr(VI):	100% (assumption)
Content of Cr(VI) in leather:	3 mg/kg (detection limit)
Density of leather:	1500 kg/m^3
Weight of 1 cm^2 leather of 1 mm:	0.00015 kg
Cr(VI) content per unit area:	0.45 µg/cm^2
LOAEL or DMEL (from $MET_{10\%}$):	0.02 µg/cm^2 over 2 days

It must be expected that the amount of chromium (VI) will be released from the leather over a certain period of time. The LOAEL or DMEL is estimated from the $MET_{10\%}$ which is based on 48 hours occluded exposure. The calculated potential dermal load based on a content of 3 mg/kg in the leather corresponds to 22.5 times the LOAEL or DMEL. Without information on a realistic release rate of chromium VI from the leather, this hypothetic exposure scenario cannot rule out the possibility that the LOAEL or DMEL-value can be exceeded.

B 9.3.2.3 Indirect exposure of humans via the environment

The environmental releases of chromium (VI) from the leather are considered to be very small (see section B.2.4) and the indirect exposure of humans to this chromium (VI) via the environment is considered insignificant. Chromium (VI) formed by the waste disposal of chrome tanned leather is beyond the scope of the current Annex XV report.

B.9.3.2.4 Environmental exposure

Environmental exposure to chromium (VI) formed in the leather is considered to be very small as mentioned in see section B.2.4. Chromium (VI) formed by the waste disposal of chrome tanned leather is beyond the scope of the current Annex XV report.

B.9.4 Other sources (for example natural sources, unintentional releases)

Chromium (VI) is released to the environment from a number of sources. The EU risk assessment report (ECB, 2005) describes the sources of releases of chromium (VI) to the environment as consequence of the use of chromium trioxide, sodium chromate, sodium dichromate, ammonium dichromate and potassium dichromate. The production of chromium (VI) compounds and “metal treatment formulation” represent the major sources of chromium emissions to the air of 12 t/year and 6.2 t/year, respectively, on the continental level. The major source of chromium releases to water is “metal treatment use” which is estimated at 2,342 t/year (worst case). Compared to this other sources are relative small with the major sources being chrome tanning salt production (38 t/year), chromium (III) oxide production (22 t/year) and metal treatment formulation (12 t/year). From the available information is it not possible to estimate how much of the released chromium is in the form of chromium (VI) and the risk assessment for the environmental exposure prepare the calculation assuming as a worst case that all chromium is in the form of chromium (VI) and as a best case that all chromium is in the form of chromium (III).

B.9.5 Overall environmental exposure assessment

Chromium (VI) released from leather is not considered to contribute significantly to the overall environmental exposure to chromium (VI) (see section B.2.4) and an overall environmental exposure assessment has not been undertaken.

B.10 Risk characterisation

B.10.1 Formation of chromium (VI) in the production of leather

B.10.1.1 Human health

B.10.1.1.1 Workers

Workers involved in the manufacturing of articles of leather may be exposed to chromium (VI) in the leather. The exposure situation is quite similar to the exposure of consumers and a specific risk characterisation from workers has not been developed.

B.10.1.1.2 Consumers

Hexavalent chromium is known to cause severe allergic contact dermatitis in humans and to be able to elicit dermatitis at very low concentrations. Previously, cement was a major cause of chromium dermatitis in Europe. However, the introduction of legislation limiting the chromium (VI) content in the cement has had a significant impact of the prevalence of chromium allergy in the population.

Skin sensitisation is generally considered a threshold effect. However, defining the actual threshold for sensitisation can be very difficult, but from experience in the construction industry and among cement workers it is known that levels of 10-20 ppm soluble hexavalent chromium is causing sensitisation with a prevalence around 4 -5 %. As elicitation of chromium allergy can occur at even lower levels, the elicitation threshold is more relevant in a risk assessment context in order to protect the already sensitized individuals. It is reported that persons who have already developed chromium (VI) allergy may be so sensitive that they may even react to levels of chromium (VI) below the determination level (Johansen *et al.*, 2011).

The German Federal Institute for Risk Assessment (BfR) reports that clinical studies have shown that even the lowest levels of chromium (VI) in leather are sufficient to trigger an allergic reaction in hypersensitive individuals. At a level of 5 mg/kg (5 ppm) in leather half of the sensitised individuals already manifested allergic skin reactions such as contact eczema (BfR, 2007b). The BfR therefore concludes that the only effective protection for sensitised individuals against skin disorders is to avoid any contact with products containing chromium (VI). Elicitation caused by low levels of chromium (VI) (below detection limits) in leather was also confirmed in patch testing by Hansen *et al.*, (2003).

Minimum elicitation thresholds which will elicit a reaction in 10% of sensitized individuals ($MET_{10\%}$) are therefore sometimes used directly in relation to risk assessment.

No studies establishing the dose-response relationships in relation to chromium content or migration from leather, and the development of sensitisation are available except for case studies showing that chromium in leather can elicit dermatitis. Therefore it is not possible to establish a risk-based threshold for chromium in leather.

Minimum elicitation thresholds ($MET_{10\%}$) for chromium (VI) which will elicit an allergic response in 10% of already sensitised individuals are found to be in the range of 0.02 to 0.9 µg/cm^2/2 days in different studies from the period 1983 to 2003 (Johansen *et al.*, 2011). As a conservative estimate a LOAEL (or a DMEL-value) of 0.02 µg/cm^2/2 days was established based on the lowest identified $MET_{10\%}$. It must be expected that the content of chromium (VI) will be released from the leather over a certain period of time. The LOAEL or DMEL is estimated from the $MET_{10\%}$ which is based on 48 hours occluded exposure. The worst case exposure scenario was estimated to 0.45 µg/cm^2. The calculated potential dermal load based on a content of 3 mg/kg in the leather corresponds to 22.5 times the DMEL. Without information on a realistic release rate of chromium from leather, the possibility cannot be ruled out, that the LOAEL or DMEL-value can be exceeded.

Germany has successfully introduced legislation with no detectable hexavalent chromium in the finished articles of leather, but for practical reasons based on the content of hexavalent chromium in leather and the analytical detection limit of 3 mg/kg using the DIN 53314 analytical limit. In addition, several eco-labelling schemes for articles of leather also include criteria based on limit values based on the content of chromium (VI) in articles of leather.

The same approach is suggested to benefit from existing experience of using the analytical method in the German legislation in order to regulate the chromium (VI) exposure from leather and from articles of leather in the EU. The restriction proposal would be based on EN ISO 17075:2007 (which has replaced the DIN 53314) and which has a detection limit value of 3 mg/kg in leather.

This value is expected to protect the majority of the already sensitised individuals, but since elicitation has been observed at lower levels, the suggested legislative restriction will be less than 100% effective.

The suggested limit is expected to protect the majority of the population against induction of chromium allergy and approximately 80% of sensitised individuals against manifestation of the disease (expert judgement). With leather exposure accounting for 45% of the chromium sources of exposure (Thyssen *et al.*, 2009), it is thus expected that a restriction will have an effect on approximately 36% of the sensitised individuals.

The actual effect of the restriction can be monitored based on information in the surveillance databases and calculation of 10-year prevalence's of chromium allergy among eczema patients as well as through epidemiological studies of the general population.

B.10.1.1.3 Indirect exposure of humans via the environment

Not relevant, see section B.2.4.

B.10.1.1.4 Combined exposure

Not relevant, see section B.2.4.

B.10.1.2 Environment

Not relevant, see section B.2.4.

B.11 Summary on hazard and risk

The main health impact in relation to dermal contact with leather and articles of leather is skin sensitisation and hexavalent chromium is known to cause severe allergic contact dermatitis in humans and to be able to elicit dermatitis at very low concentrations. Other health effects of different chromium (VI) compounds include mutagenicity, carcinogenicity, reproductive toxicity and respiratory sensitisation. However, in relation to dermal contact with leather and articles of leather, skin sensitisation is considered to be the critical health effect.

Skin sensitisation is generally considered a threshold effect. However, defining the actual threshold for sensitisation can be very difficult, but from experience in the construction industry and among cement workers it is known that levels of 10 -20 ppm soluble hexavalent chromium in the cement causes sensitisation with a prevalence of about 4 -5 %. As elicitation of chromium allergy can occur at even lower levels, the elicitation threshold is more relevant in a risk assessment context in order to protect the already sensitized individuals. It is reported that persons who have already developed chromium (VI) allergy may be so sensitive that they may even react to levels of chromium (VI) below the determination level (Johansen et al., 2011).

Minimum elicitation thresholds ($MET_{10\%}$) for chromium (VI) to elicit an allergic response in 10% of already sensitised individuals are found to be in the range of 0.02 to 0.9 $\mu g/cm^2/2$ days in different studies from the period 1983 to 2003 (Johansen *et al*., 2011). As a conservative estimate a LOAEL (or a DMEL-value) of 0.02 $\mu g/cm^2/2$ days was established based on the lowest identified $MET_{10\%}$. Other studies have shown that elicitation can occur at even lower levels.

The suggested restriction proposal is expected to protect the majority of the population against induction of chromium allergy and approximately 80% of sensitised individuals against manifestation of the disease (expert judgement). With leather exposure accounting for 45% of the chromium sources of exposure (Thyssen *et al.*, 2009), it is thus expected that a restriction will have an effect on approximately 36% of the number of sensitised individuals.

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

The formation of chromium (VI) in leather and articles of leather can basically be prevented by the application of two alternative types of technique:

- Techniques for prevention of the formation of chromium (VI) in chrome tanned leather;
- Non-chrome tanning of the leather.

The formation of chromium (VI) in chrome tanned leather can be effectively prevented by application of the appropriate techniques and these do not have any impact on the leather quality or the further processing of leather. These techniques are considered the main alternatives. The techniques are already widely applied by tanneries in the EU and in case of the introduction of an EU-wide restriction of chromium (VI) in leather, these techniques would be the most likely alternatives applied. It is considered that an EU-wide restriction of chromium (VI) in articles of leather would not be a significant driver for increased use of chromium-free leather, although the possibility that a restriction would result in an increased demand for chromium free leather, cannot be excluded.

C.2 Assessment of techniques for the prevention of formation of chromium (VI) in leather and in articles of leather

C.2.1 Availability of techniques for prevention of formation of chromium (VI) in leather processing

During the 1990's, the possible effects of chromium (VI) in leather and articles of leather in contributing to contact dermatitis were recognised and in particular German research institutions started to study the mechanisms of the formation of chromium (VI) and to develop techniques for the prevention of its formation. A review of the formation, the prevention and the determination of chromium (VI) in leather and articles of leather was undertaken in 2000 by UNIDO as part of the Regional Programme for Pollution Control in the Tanning Industry in South-East Asia (Hauber and Buljan, 2000).

Prevention of formation of chromium (VI) in the tanneries

The Chrom6less project, supported by the European Commission and described in section B.2.2.2, studied the formation of chromium (VI) in leather and articles of leather, and concluded that the formation of chromium (VI) could be efficiently prevented by the application of a number of process specific measures as indicated in Table 29 (Chrom6less, 2005).

The measures basically consist of:

- Finish the wet processes under low (acidic) pH conditions, between 3.5 and 4, by means of formic acid fixation. Carry out a final washing;
- Use between 1 and 3 % of a vegetable tannin extract together with the chrome tanning agents to provide antioxidant protection by the retanning;
- Avoid the use of ammonia prior to the dyeing process;
- Use fatliquoring agents that do not favour the formation of Cr(VI);
- Use of antioxidants in leather where it is not possible to apply vegetable tanning agents due to the colour change in the leather. Examples of antioxidants are ascorbic acid or a 1:1 mixture of a phenolic and an amine antioxidant;
- Avoid the use of chromate pigments (yellow and orange inorganic pigments).

According to both COTANCE and suppliers of chemicals for the tanning sector these prevention techniques are currently implemented all over Europe.

The techniques are integrated in the chemicals systems used for the post-tanning processes and in general not specifically marketed as systems for the prevention of formation of chromium (VI). This entails the addition of vegetable tannin extracts to provide antioxidant protection and not using fatliquoring agents that may result in the formation of chromium (VI). When new agents are introduced, testing is carried out to determine whether chromium (VI) can be formed.

Some major suppliers of agents used in the neutralizing process step specifically state that their agents prevent the formation of chromium (VI). Examples are the agents Neutrigan® and Tamol® NA from BASF (BASF, 2007). As mentioned in Table 29 it is essential that the wet processes are finished under acidic pH conditions, and this is ensured by adjusting the pH to a level between 3.5 and 4 in the neutralisation step.

There seems to be different views on the need for adding antioxidising agents late in the process, as will be discussed further in section C.2.2.

TABLE 29 RECOMMENDED MEASURES FOR THE PREVENTION OF FORMATION OF CHROMIUM (VI) IN LEATHER ACCORDING TO THE RESULTS OF THE CHROM6LESS QUALITY HANDBOOK (CHROM6LESS 2005)

Process	Recommendations
Tanning process Salts and liquors of chromium tanning agents produced by the European chemical industry guarantee the absence of residues of dichromate and other kinds of chromium (VI). Moreover, the acidic pH condition at which tanning is carried out guarantee the reduction of already negligible traces of dichromate. It is difficult to find traces of hexavalent chromium in wet-blue leather for two reasons: acidic pH and the humidity of the skins/hides. The tanning process is not regarded as an especially relevant factor in the formation of chromium (VI). Nevertheless, it is advisable to ask the supplier for a guarantee of absence of dichromate residues especially if the products do not come from the European Union.	Ask the chemical suppliers, mainly from outside the European Union, for a certificate guaranteeing the absence of hexavalent chromium in tanning agents.
Neutralizing process A pH range from 4.3 to 7.2 has been studied in the Chrom6less Project. No significant effect is produced by varying the neutralization pH, using both bicarbonate and formate. This result could be justified because after neutralization by these chemicals, any effect, of the different pH at which neutralization is carried out is eliminated in the following phases of the process (retanning, dyeing, fatliquoring, formic acid fixation, and washings included). As a consequence no effect can be observed in the final leather from varying the pH in the neutralization using sodium bicarbonate or sodium formate. Several synthetic neutralizing agents with buffering and retanning features develop some protective effect against the formation of chromium (VI) according to their properties of binding to the leather.	Finish wet processes at acidic pHs, between 3.5 and 4, by means of formic acid fixation. Carry out a final wash.
Retanning process Retanning plays an important role. It has a greater influence on the formation of chromium (VI) than tanning and neutralization. Some retanning agents do not have any clear effect. Other agents have a slight protective effect, as in the cases of aldehydes or some phenolic syntans, but this Project has confirmed that the best outcome can be attained by natural vegetable tannins of whatever nature. The amount of these vegetable tannins needed to provide a significant protective effect is sufficiently low (1-3%) to not affect the quality or the characteristics of the leather. The skins/leathers produced using 1% of vegetable tannins have the same organoleptic properties as the ones produced by other products and the reference standard. As expected, the colour is the only modified property. In skins/leathers without finishing like nubuck or suede this fact may limit or even prevent its use as protective retanning agents. In these cases, a mixture of antioxidant substances should be applied.	Use between 1 and 3 % of vegetable tannin extract to provide antioxidant protection.

<table>
<tr><th>Process</th><th>Recommendations</th></tr>
<tr><td>Dyeing process
The effect of dyeing is less relevant than for other processes such as retanning and fatliquoring. Nevertheless, the chemical nature of the dyestuff seems to be important in so far as chromium containing metal complex dyes seem to favour the formation of chromium (VI). Avoid the use metal complex dyes containing chromium.
In general, the influence of dyes is not negative. Using higher dyestuff offer (add higher amounts of dyestuff) seems to suppress the formation of chromium (VI).
The fixation of the dyeing should happen at a low pH (between 3 and 4). Better results were obtained with a pH 4 than with pH3. Employing ammonia in the wetting back process should be avoided.
Using special auxiliaries to improve the light fastness seems to suppress the formation of chromium (VI).</td><td>Avoid the use of ammonia prior to the dyeing process</td></tr>
<tr><td>Fatliquoring process
The fatliquoring process exerts a considerable influence on the formation of chromium (VI) when the skins/leathers are subjected to thermal ageing or photo ageing as evidenced by the production of skins with varying contents of hexavalent chromium. The use of lecithin should be monitored because of its potential capacity for the formation of chromium (VI) in skins/leathers without ageing.
Skins with a high content of natural fat should be subjected to a conventional degreasing process in order to diminish the possible formation of Cr (VI). This formation is favoured by the superficial application of large amounts of fatliquoring agents of natural origin (tallow oil). The stabilisation treatment (aeration and sulphitation) of fatliquoring agents reduces the potential formation of hexavalent chromium.
It has been confirmed that vegetable extracts are very effective as antioxidant agents given that they considerably reduce the formation of Cr (VI). The tara extract considerably diminished the content of chromium (VI) in skins which were fatliquored with crude fish oil or lecithin and then subjected to treatments of thermal or photo ageing.</td><td>Assess the influence of fatliquoring agents of natural origin on the formation of chromium (VI) before use.
In leather in which it is not possible to apply a vegetable extract due to the colour change, a 1:1 mixture of a phenolic and an amine antioxidant should be applied because of its protective capacity.
Despite having a smaller protective capacity than tara extract, this mixture adequately diminishes the formation of Cr (VI). Likewise, ascorbic acid also exhibited significant antioxidant properties.</td></tr>
<tr><td>Finishing stage
In general, in the finished leathers lower concentrations of chromium (VI) were observed than in crust leathers.
Nevertheless, the use of certain waxes and pigments can facilitate the detection of Cr (VI).
Most of the common pigments provide an additional protection. However, some pigments contain chromium (VI) in their composition in the form of chromates, as shown in the following table:
<table>
<tr><th>Nature</th><th>Colour</th><th>Reference Colour Index</th></tr>
<tr><td>Lead Chromate ($PbCrO_4$)</td><td>Yellow</td><td>C.I. 77600 Pigment Yellow 34</td></tr>
<tr><td>Lead Sulphochromate ($PbCrO_4$. $xPbSO_4$)</td><td>Green yellow</td><td>C.I. 77603 Pigment Yellow 34</td></tr>
<tr><td>Lead chromo-molybdate</td><td>Orange</td><td>C.I. 77605 Pigment Red 104</td></tr>
</table>
Their solubility constants are very low. Therefore, they are almost insoluble in water. Even then, and due to the strict rule limits (a few parts per million), the low quantities of soluble chromium released are enough to make it difficult to fulfil the regulations.
The limit of 10 mg/kg of chromium (VI) may easily be exceeded using amounts of 8 grams of finishing solution/sqr feet or higher. It has been proved that in vegetable tanned leathers that are free from chromium(III) compounds but finished with Pigment Yellow 34, hexavalent chromium is detected using the methodology CEN/TS 14495</td><td>Avoid the use of yellow and orange inorganic pigments completely</td></tr>
</table>

Prevention of formation of chromium (VI) in the further processing of leather

As described in section B 2.2.2 chromium (VI) may be formed later by the processing of the leather, e.g. in the manufacturing of footwear, and it may be formed within the finished articles of leather.

A recent research project involving 54 shoes without conspicuous initial chromium (VI) values showed that chromium (VI) could be detected in 11 of the shoes after they had been subjected to an ageing process in which the leathers were incubated for 24 hours at 80 °C (PFI, 2011).

A long-term test of the shoes over a period of three months showed a slight increase of chromium (VI) concentration depending upon the amount of chrome tanning agent used. The results indicate that lower total chromium content of the leather in general lead to lower chromium (VI) levels (PFI, 2011).

The effect of antioxidising agents on the chromium (VI) contents of leather and articles of leather was investigated, both in a drum process and an after spray application. The study demonstrated that the antioxidising agents both prevented the formation of chromium (VI) and lowered the concentration of existing chromium (VI) (PFI, 2011).

The increased chromium (VI) levels in the shoes could be greatly lowered by spray application of antioxidising agents. After a four-week treatment of the shoes with antioxidising agents, the individual leathers of the shoes were again examined with regard to their chromium (VI) contents. The antioxidising agent lost some of its potential, but the chromium (VI) levels of the leathers of the shoes still were below the detection limit value of the used detection method for chromium (VI) of 3.0 mg/kg. The findings demonstrate that adoption of specific measures can minimise the risk of the formation of chromium (VI) in articles of leather.

Use of antioxidising agents consistently leads to lower chromium (VI) contents of the leathers treated by thermal ageing and UV irradiation as shown in Table 30. The antioxidising agents are ascorbic acid and a confidential Product X. In leather with no addition of antioxidising agents, the concentrations of chromium (VI) ranged from 6 to 13 mg/kg after thermal ageing and UV irradiation, whereas in the leather treated with the antioxidising agents, the level remained below 3 mg/kg.

TABLE 30 INFLUENCE OF ANTIOXIDANTS ON THE FORMATION OF CHROMIUM (VI) BY THERMAL AGEING AND UV IRRADIATION

	mg/kg dry matter						
	Total Cr	**Original state**		**Thermal ageing**		**UV-irradiation**	
		Soluble Cr	**Cr(VI)**	**Soluble Cr**	**Cr(VI)**	**Soluble Cr**	**Cr(VI)**
Upper leather (crust)							
No treatment	28,391	486	7.05	434	13.05	471	9.39
Ascorbic acid	26,249	1,542	0.92	1,517	1.18	1,517	0.90
Product X	28,316	791	1.49	743	2.21	744	2.12
Leather lining (crust)							
No treatment	32,267	377	2.98	322	12.89	365	5.98
Ascorbic acid	30,239	1,904	< 0.75	1,651	<0.75	1,752	<0.75
Product X	29,814	870	< 0.75	754	0.84	833	<0.75

Source: Meyndt *et al.,* 2011 (same data as described in PFI, 2011)

The three antioxidising agents tested in the study (Meyndt *et al.*, 2011) were ascorbic acid, an unidentified product Product X and an agent traded under the trademark Hexagon®. The ascorbic acid and Hexagon® are further described in section C.2.2.

The effect of three different adhesives on the formation of chromium (VI) was also examined. The leathers were treated with natural latex adhesive, synthetic latex adhesive, and a PU (polyurethane) dispersion adhesive. The leathers were additionally subjected to heating to simulate the footwear production process. Application of an adhesive led to significantly higher chromium (VI) content in some of the tested lining leathers, whereas upper leathers showed hardly any increase in chromium (VI) levels. Adhesive treatment and heat tended to slightly reduce the chromium (VI) levels in leathers with a high initial chromium (VI) concentration. A slight increase in chromium (VI) levels was noted in leathers where the initial chromium (VI) content had been low.

The humidity of the environment during storage of the leather has been demonstrated to have a significant effect on the formation of chromium (VI) in the stored leather. The higher the humidity, the lower the chromium (VI) content and *vice versa* (Congzheng *et al.*, 2005). In addition to the effect of the humidity, a temperature effect was also observed. By increasing the humidity and the temperature simultaneously, the chromium (VI) content of the leather was decreased (Congzheng *et al.*, 2005).

C.2.2 Application of antioxidising agents

As indicated above, addition of 1 to 3 % of vegetable tannin extract is used to provide antioxidant protection. The vegetable tanning extracts are of the same type as used for vegetable tanning which are polyphenolic compounds leached from vegetable material such as tara, quebracho, mimosa and oak.

In leather where it is not possible to apply a vegetable extract due to undesired colour change, application of a 1:1 mixture of a phenolic and an amine antioxidant has been suggested because of its protective properties (Crom6less, 2005). Despite having poorer protective properties than tara extract, this mixture adequately diminishes the formation of chromium (VI) (Crom6less, 2005).

According to TEGEWA (2011), a range of organic and inorganic antioxidants are used to stabilize high quality process chemicals. TEGEWA is the German association of suppliers of auxiliaries for the tanning industry (and other industries) and represents the major manufacturers of tanning agents in the EU. The antioxidants are optimized to the respective requirements. Antioxidants can include components such as ascorbic acid, sulphurous acid derivatives and sterically hindered phenolic radical stoppers. Vegetable tanning agents do act in the same way.

When applying these measures together with the other measures for the prevention of the formation of chromium (VI) mentioned above, it seems that major suppliers of chemicals for the tanning sector did not consider that there would be a need for further addition of antioxidising agent. The suppliers do not specifically indicate that their products include antioxidants. This includes agents from e.g. Lanxess and BASF.

Marketed antioxidising agents
Specific antioxidising agents are marketed by a few of the chemical suppliers for the sector.

Two products specifically marketed for use as antioxidants for prevention of formation of chromium (VI) or reduction of chromium (VI) in leather have been identified.

Sellasol® C6 is marketed by TLF Ledertechnik GmbH to be applied at the end of the wet-end process (TFL, 2009). To ensure the optimum effect the technical data sheet suggests the use of vegetable and/or synthetic retanning agents, use of synthetic fatliquoring agents instead of natural and unsaturated fatliquors, ammonia should be avoided and high amounts of fats should be removed by using appropriate degreasing agents. Sellasol® C6 is added in 2-4% based on shaved wet weight of the hide and should be allowed to exhaust/penetrate over a period of 30-60 min. It is indicated that SELLASOL® C6 can also retard or prevent the formation of chromium (VI) during transport or storage.

Two products, MPH C6.2® and MPH C6.4® from Hexagon Solutions Ltd. (Hong Kong), are marketed for treatment of leather with a chromium (VI) content of less than 30 mg/kg and “low to medium chromium (VI) content”, respectively (Hexagon, 2011). The products are marketed as suitable for application on uncut leather or on finished products such as shoes, bags, belts, leather garments and a wide range of goods. The agents are at least used by one company for reconditioning of articles of leather with a content of chromium (VI) above 3 mg/kg.

Both the Sellasol® C6 and the agents from Hexagon consist of a proprietary mixture of inorganic salts and organic substances (see Table 31). The MSDS for the product from Hexagon indicated the presence of <5% Benzenesulfonic acid, C10-13-alkyl derivatives, sodium salts. The substance is not classified according to the CLP-Regulation (EC) No 1272/2008, but the self classification indicates among others that the substance may be a skin irritant.

Other proposed antioxidising agents

A patent application for the use of D-isoascorbic acid as an antioxidising agent in leather from the chemical suppler TFL provides a review of the different substances which have been used or proposed in the patent literature as antioxidising agents in leather processing (TFL, 2006). Antioxidising agents may either prevent the formation of oxidants (e.g. UV quenchers) or react with the oxidants formed, and the agents are known under the functional terms antioxidants, free radical scavengers, light stabilizers, quenchers and UV absorbers.

A number of antioxidants to be added during different process steps have been proposed: Ascorbic acid, bisphenol derivatives, carotenoids, gallic acid, lecithins, sterically hindered phenols, such as, 2,2'-methylenebis(2,6-di-tert-butylphenol) (TFL, 2006).

Ascorbic acid is demonstrated to be able to prevent formation of chromium (VI), but according to TFL (2006) L-ascorbic acid decomposes and becomes discoloured under the action of light and/or heat. Treatment of leathers tanned with chromium (III) salts with L-ascorbic acid leads to substantial and undesired reddish discolorations during the ageing of the leathers.

It has been found that D-isoascorbic acid (erythorbic acid), an optical isomer of vitamin C or L-ascorbic acid, is suitable as an agent for stabilizing leather tanned with chromium (III) salts, although D-isoascorbic acid is even less stable to ageing than L-ascorbic acid and tends to give brownish, coloured solutions in the ageing test. In order to achieve or to maintain chromium (VI) levels below the limit of detection of 3 mg/kg, an amount of 0.8-1.5% by weight of D-isoascorbic acid or of one of its salts is added to aqueous liquor. In principle, D-isoascorbic acid or one of its salts may be added to the liquor at any desired point in the further processing to give the finished leather, for example during the retanning, fatliquoring and the dyeing, or at the wash stages in between.

No marketed products containing D-isoascorbic acid have been identified for this purpose.

TABLE 31 EXAMPLES OF ANTIOXIDIZING AGENTS WHICH CAN BE APPLIED FOR PREVENTION OF THE FORMATION OF CHROMIUM (VI)

Brand name (manufacturer)	Substances according to Safety Data Sheet (SDS)	Classification according to Safety Data Sheet (SDS)
MPH C6.2® C6.4® from Hexagon Solutions Ltd	Mixture of inorganic salts and organic substances **Hazardous substances:** <5% Benzenesulfonic acid, C10-13-alkyl derivs., sodium salts CAS No 68411-30-3; EC No 270-115-0	Skin classification: No skin classification. Remarks: may cause skin irritation in susceptible persons Not classified according to the CLP-Regulation (EC) No 1272/2008 Self classification (Hexagon Solutions Ltd.): R22: Harmful if swallowed R38: Irritating to skin. R41: Risk of serious damage to eyes
Sellasol® C6 (TFL)	Mixture of inorganic salts and organic substances **Hazardous substances:** No hazardous substances indicated	Skin classification (TFL): No skin classification.
No commercial products for leather tanning identified	D-isoascorbic acid CAS No 89-65-6; EC; No 201-928-0	Not classified according to the CLP-Regulation (EC) No 1272/2008 Self classification (Sigma-Aldrich MSDS): R36/37/38 Irritating to eyes, respiratory system, and skin

C.2.3 Human health risks associated with the prevention of formation of chromium (VI)

The possible human health risks associated with the prevention of chromium (VI) are considered small. Some of the specific agents used late in the process as antioxidising agent may include substances that may be skin irritants, but no data are available to indicate whether any irritation may arise from their presence in leather. The prevention mainly concerns existing processes.

C.2.4 Environment risks related to prevention of formation of chromium (VI)

No environmental risks associated with the prevention of chromium (VI) have been identified as the prevention mainly concerns existing processes.

C.2.5 Technical and economic feasibility of techniques used for prevention of the formation of chromium (VI)

The techniques to prevent the formation of chromium (VI) during processing of the leather in the tanneries can according to COTANCE be applied without any changes in equipment and without any changes in the capacity of the equipment. No investments are needed for the application of the techniques.

According to information obtained from COTANCE and suppliers of chemicals for tanning, the chemicals used in the process account for about 10-15% of the total costs. The EU BREF (2011) indicates that chemicals account for 10% of total costs. Tanning agents accounted for 28% of the value of chemicals for the sector (Reich and Taeger, 2009).

As indicated, the prevention of formation of chromium (VI) depends on slight changes in many of the post-tanning steps and it has not been possible to obtain specific information on the extra costs of applying the techniques. Most probably the techniques have been implemented over time as part of the development of the production processes. According to the industry, the changes in costs have not been a major issue in changing the processes.

According to TEGEWA, since the 1990's the leather auxiliaries producing companies within TEGEWA has been working on specific procedures to prevent the formation of chromium (VI) during the tanning process and during the storage of leather. There had been close cooperation between the German Research Foundation for Leather and the participating research institutes. The TEGEWA companies developed leather chemicals and processes to support the leather industry in establishing the recommendations (from the Chrom6less project mentioned above) in their daily practice. The recipes for leather chemicals and details of the processes are confidential business information and partly protected by patent (TEGEWA, 2011). About 96% of the leather chemicals produced by the TEGEWA companies are exported and knowledge on how to produce chromium (VI) free leather is, according to TEGEWA, globally available.

TEGEWA states that the total costs of manufacturing leather in which chromium (VI) is prevented, is not significantly higher than that of leather with a risk of formation of chromium (VI). However, the costs of individual chemicals that produce leather with comparable aesthetic properties can vary considerably depending on whether they are sourced from a low cost supplier or a reliable producer. In certain cases, the costs can be double or more if sustainable products (not leading to formation of chromium (VI)) are employed.

Several chemical suppliers have indicated that there might be some minor additional costs for avoiding formation of chromium (VI), due to the use of alternative fatliquors, use of antioxidants and more effort required for proper production control. Using an expert estimate the extra costs in general are, roughly thought to be in the order of magnitude of 2-10% for chemicals. As the chemicals account for about 10% of total costs, the costs of these measures are properly less than 1% of the total costs for the production of the leather. This is in accordance with the general view that extra costs of prevention of formation of chromium (VI) have not been a major issue so far.

C.3 Assessment of chromium-free tanning of leather

C.3.1 Alternatives to the use of chromium in leather tanning (chromium-free tanning)

The chromium (VI) level in the leather can be kept below the detection limit of 3 mg/kg by application of the measures described above and changing to non-chrome tanning would not be necessary in order to comply with the proposed restriction. Consequently, a restriction of chromium (VI) in leather in itself is not considered to be the driver for changing to non-chrome tannage.

The object of the following section is mainly to provide background information for the discussion of the consequences of a general restriction on chromium in leather, which has been considered as an alternative Risk Management Option (see section E.2).

The different methods of tannages used in tanneries are based on the draft EU BREF document (2011) listed in Table 32.

As mentioned, the majority of leather is tanned by chromium tanning. In chromium tanning however, several other tanning agents are used. As indicated in Table 4 a significant quantity of vegetable tannins, aromatic syntans, polymer tanning agents and resin tannins are used in conjunction with the chromium containing tanning agents. They are applied either during the tanning or retanning process.

The major use of non-chrome tanning today is for sole-leather and other heavy leather where vegetable tanning agents are used because they impart the desired properties to the leather for this application area.

The second largest use for non-chrome tanned leather is in the automotive industry where wet white, mainly based in glutaraldehyde, is used.

According to TEGEWA (2011), the chromium-free-tanning process consists of a pretanning step with reactive tanning agents (currently mainly glutaraldehyde) and a retanning step with vegetable tanning agents, synthetic organic tannins or polymeric tannins.

Nearly all chrome-free tannage is based on vegetable tannage or aldehyde tannage. Other tanning agents are typically used in conjunction with those two agents or chromium.

TABLE 32 TYPE OF TANNAGE, MAIN TANNING AGENTS AND AUXILIARIES USED (BREF, 2011)

Type of tannage	Tanning agents used	Auxiliaries used
Chrome tannage	Basic sulphate complex of trivalent chromium	Salt, basifying agents (magnesium oxide, sodium carbonate, or sodium bicarbonate), fungicides, masking agents (e.g. formic acid, sodium diphthalate, oxalic acid, sodium sulphite), fatliquors, syntans, resins
Other mineral tannages	Aluminium, zirconium, and titanium salts	*Masking agents, basifying agents, fatliquors, salts, syntans, resins, etc.
Vegetable tannage	Polyphenolic compounds leached from vegetable material (e.g. quebracho, mimosa, oak, etc.)	Pretanning agents, bleaching and sequestering agents, fatliquors, formic acid, syntans, resins, etc.
Synthetic tannage (Resin-syntans)	Sulphonated products of phenol, cresol, naphthalene, cresylics, poly-acrylates, melamine resins, etc.	Fixing agents, either acid or alkali, fatliquors
Aldehyde tannage	Glutaraldehyde and modified aldehydes and di-aldehydes	Alkali, bleaching agents, tanning agent carrier
Oil tannage	Cod oil and marine oils	Catalysts such as manganese, copper, or chromium. Sodium bicarbonate or other alkali, aldehydes, emulsifiers

Notes: *The auxiliary used vary depending on the mineral used and the type of cross link with the collagen.

C.3.2 Availability of chromium-free tanning techniques

C.3.2.1 Other mineral tannages

Besides chromium, some tanning, retanning or pretanning is done using aluminium, zirconium and titanium. Aluminium, zirconium and titanium cannot be used as substitutes for chromium in the tanning process as the leathers tanned with chromium can have quite different characteristics (e.g. hydrothermal stability) compared to the leathers tanned with other mineral tanning agents (BREF, 2011).

Aluminium as a tanning agent produces a white leather which is, however, not sufficiently water or heat resistant. It is used in pretanning. Occasionally aluminium is used in chrome tanning to increase the uptake of chromium, or for the production of fur (sheep and lamb skins) and of leather for glacé gloves (BREF, 2011). According to TEGEWA (2011), other mineral tanning agents are not used for applications where they compete with chrome tanning agents.

C.3.2.2 Vegetable tannage

The plant extracts applied for vegetable tanning are either polyphenolic compounds (condensed vegetable tannins) or esters of glucose and gallic acid (hydrolysable vegetable tannins), which are leached (with water) from wood, barks, leaves, roots and other plant material (BREF, 2011).

The most commonly used vegetable tannin extracts are (BREF, 2011):

- natural quebracho
- soluble quebracho
- mimosa
- natural chestnut
- sweetened chestnut
- myrobalans
- valonia

Apart from quebracho, all vegetable tanning agents originate from trees or are obtained from renewable sources. An increase in the use of vegetable tanning might cause consumption to exceed this supply (BREF, 2011).

Application
Depending on the type of vegetable tanning employed, vegetable tanned leather can be used for shoe soles, shoe uppers, harnesses, saddles, belts, leather goods, clothing and upholstery (BREF, 2011).

Production of sole leather
Sole leather is a market segment on its own and produced using other methods than those used for other types of leather. Chromium is not used for the production of sole leather as this leather is intended to be relatively stiff. In sole leather about 350-500 kg of tanning extracts per tonne of raw hide are applied. These extracts typically contain 60-70% vegetable tannins, the remainder consisting of non-tannins such as gums, sugars, organic acids, mineral salts and insoluble matter. Sole leathers are typically heavy as they are “stuffed” with tannins. Typically 1 tonne of raw hide can produce approximately 600-650 kg sole leather as against approximately 200-250 kg of chrome tanned leather (BREF, 2011). A significant part of all non-chrome tanned leather produced is used for sole leather.

Other applications and price
Vegetable tannage is to some extent used for other applications where the objective either is to obtain a specific appearance of the leather or to avoid chromium in the leather. For some shoes, clothing and upholstery vegetable tanned leather is used to obtain a “vintage” look, but may also be used to avoid chromium. In general, it seems that vegetable tanned leather is mainly used for high-end aniline leather. In some automotive applications one of the objectives may be to avoid chromium. Prices are in general higher than for chrome tanned leather of a similar quality, and the price is reported to be 1-10% higher than the price of high-end chrome tanned leather of similar quality for use in areas such as furniture. For leather of lower quality the difference would probably be greater.

Emissions
Materials such as splits, shavings and buffing dust can be reused and easily disposed off as they do not contain any minerals (BREF, 2011).

C.3.2.3 Aldehyde tannage

Some aldehydes are used as tanning agents. Glutaraldehyde and modified glutaraldehydes are used for pre-tanning and retanning. They are also used as tanning agents to produce leather with distinct properties (very soft and full, yellowish with high wash and sweat resistance) for special purposes, e.g. golf gloves or woolskin bedspreads for hospitals. Formaldehyde is not used in any European country because of the health risks. It is possible to cross-link aldehydes (oxazolidine) with vegetable tannins and thus substitute any metal salt. Aldehydes are also used in pre-tanning to accelerate vegetable tanning and to fix hair of fur and sheep wool (BREF, 2011).

Applications and price
Aldehyde tanned leather is the leather that most tanners refer to as wet-white leather due to its pale cream or white colour of the tanned pelt before finishing. It is the main type of "chrome-free" leather, often seen in automobiles and shoes for infants (BREF, 2011).

A detailed cost comparison between chrome tanned leather and aldehyde tanned leather from BASF (Wolf and Wittlinger, 2002) showed that the total cost of production of aldehyde tanned leather was about 4% higher, mainly as a result of higher costs of the chemicals (20% higher costs of chemicals).

TEGEWA (2011) reports that chrome free finished leather, based on glutaraldehyde tannage, is on average 2-6% more expensive than chrome tanned finished leather. For automotive purposes it has been indicated by one car manufacturer that the price of the aldehyde tanned leather is of the order of magnitude of 1% higher than the price of comparable chrome tanned leather.

Emissions
Glutaraldehyde is generally fully exhausted in the tanning process. Any residual glutaraldehyde that may reach the waste water treatment plant will react quickly with the proteins from other effluent streams and generally does not pose a problem in effluent treatment (BREF, 2011).

C.3.2.4 Synthetic tannage (resin-syntans)

Synthetic tanning agents (syntans) were developed as substitutes for vegetable tannins. Some syntans are tanning agents in their own right. Others are used in pre-tanning and retanning (e.g. acrylic polymers, sulphonated phenol formaldehyde and naphthalene formaldehyde), some are used as auxiliaries to induce certain leather properties (e.g. urea formaldehyde and melamine resins) (BREF, 2011).

Modern formulations of syntans are available with a low phenol and low formaldehyde content. This also applies to resins with a low formaldehyde content and acrylic acid condensates with low acrylic acid monomer content (BREF, 2011).

Syntans and resins are also used in combination with vegetable tanning to improve the penetration of the vegetable tanning agents (BREF, 2011).

Applications and price
No information on the use of syntans in their own right was found. The main uses seem to be in combination with other tanning agents. TEGEWA (2011) indicating that synthetic tannage is not used for applications where it competes with chrome tannage.

Emissions

The effluents from these processes may carry a high load of COD (chemical oxygen demand) and show a low biodegradability. However, proprietary products are on the market which can significantly lower the COD loading of these effluents (BREF, 2011).

C.3.2.5 Oil tannage

A traditional tanning procedure is chamois tanning or cod oil tanning carried out with unsaturated vegetable or animal oils, particularly for sheepskins and deer hides. They require oxidation with catalysts like Mn, Cr, or Cu-oxides. After wringing of the excess cod oil and washing with sodium carbonate, they may be subject to after-treatments such as dyeing. In an alternative a pretanning step with glutaraldehyde is carried out before the cod oil is applied to the hides and with warm air blowing into the vessel (BREF, 2011).

C.3.3 Human health risks related to chemicals used in chrome-free tanning

A large number of different chemicals are used both in chrome tanning and chrome-free tanning. It is beyond the scope of this dossier to make a comprehensive assessment of the possible effects of all chemicals used for chrome-free tannage.

Tanning with glutaraldehyde is the most common alternative to chrome tanning for a range of leathers, however, it is relevant within this context to mention the possible effects of glutaraldehyde. Glutaraldehyde is included in Part 3 of Annex VI, Table 3.1 of Regulation (EC) No 1272/2008 as indicated in the following table.

TABLE 33 CLASSIFICATION ACCORDING TO PART 3 OF ANNEX VI, TABLE 3.1 (LIST OF HARMONISED CLASSIFICATION AND LABELLING OF HAZARDOUS SUBSTANCES) OF REGULATION (EC) NO 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	203-856-5	111-30-8	Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1	H331 H301 H314 H334 H317 H400	GHS06 GHS08 GHS05 GHS09 Dgr	H331 H301 H314 H334 H317 H400		* Skin Corr. 1B; H314: C ≥ 10 % Skin Irrit. 2; H315: 0,5 % ≤ C < 10 % Eye Dam. ; H318: 2 % ≤ C < 10 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 % STOT SE; H335: C ≥ 0,5 % Skin Sens. 1; H317: C ≥ 0,5 %

According to the OECD SIDS (Screening Information Data Set), the principal health effects of glutaraldehyde are irritation of the skin, eyes and respiratory tract, skin sensitisation and occupational asthma (OECD, 2008). Human evidence has shown that glutaraldehyde is an irritant to the skin, eyes and respiratory system, with the effects consistent with those demonstrated in animal testing. Many cases of dermatitis have been reported for workers exposed to glutaraldehyde solutions, usually 2% or higher. Facial dermatitis has resulted from the use of glutaraldehyde in spray form. Eye irritation was observed in workers exposed to glutaraldehyde vapours above disinfectant solutions. Human evidence indicates that skin and respiratory irritant effects are exacerbated on repeated exposure to glutaraldehyde.

In this context it is relevant to note the extent to which glutaraldehyde in leather can cause contact dermatitis. In leather, glutaraldehyde is bound irreversibly to the collagen molecule and severe acid hydrolysis is required to release it by breaking the peptide bonds within the collagen rather than the actual glutaraldehyde binding site (NICHAS, 1995).

According to Rietschel *et al.*, (2008) there are no reports of shoe dermatitis developing from glutaraldehyde-tanned leather shoes.

A study of the relation between the localisation of foot dermatitis and the causative allergens in shoes included glutaraldehyde in the test series (2 % concentration in petrolatum). The results of patch testing in 1,168 patients with foot dermatitis did not record any patients with a positive reaction to glutaraldehyde (Nardelli *et al.*, 2005).

C.3.4 Environment risks related to chromium-free tanning

It is very difficult to compare the possible environmental effects of chromium tannage with the effects of the non-chrome tanning processes. The tanning processes have different environmental profiles, where different environmental impact categories are of most importance for the different processes, that no process can be preferred for all environmental impacts. Whereas the generation of solid waste and waste water with chromium is a major issue in chromium tanning, high consumption of process water may be an issue for other tanning processes.

The EU BREF document for the tanning sector provides information on best available techniques (BAT) for the different tanning processes, but does not indicate that one type of tanning process is preferable to another.

In order to compare all potential environmental effects of the manufacturing of leather the British Leather Technology Centre (BLC) undertook a comparative LCA (life cycle assessment) of chromium tanning, vegetable tanning and aldehyde tanning (BLC, 2011). The LCA was carried out by the well regarded French consulting company Ecobilan. The overall results of the LCA are shown in Figure 2. Is has not been possible to get permission from BLC to provide more detailed data from the LCA in this Annex XV dossier. The overall conclusion is that post tanning operations have the major influence on the overall environmental impact. Aldehyde and chromium tanning are very similar in terms of environmental impact and vegetable tanning shows strength and weaknesses compared to both (BLC, 2011). Figure 2 shows that vegetable tanning has a higher potential impact on water consumption, photochemical oxidants formation and air acidification than the other processes.

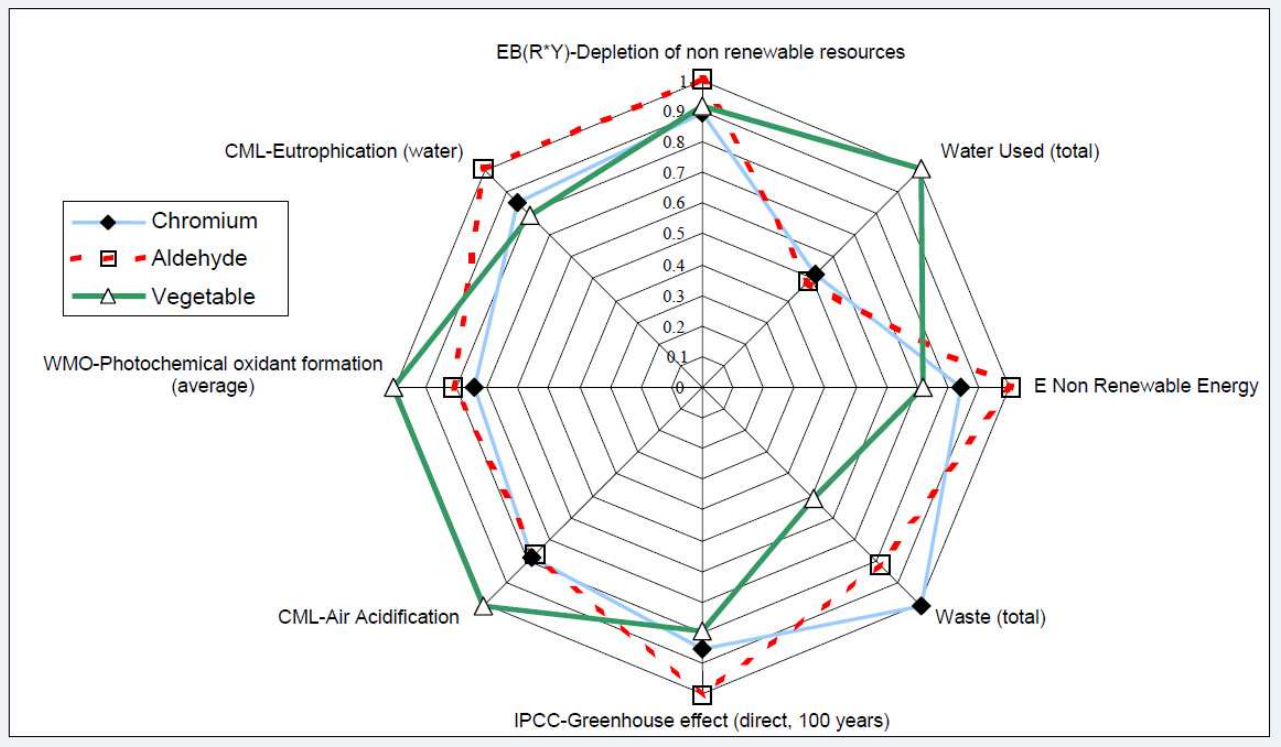

FIGURE 2 RESULTS OF LCA COMPARING CHROMIUM, ALDEHYDE AND VEGETABLE TANNING (BLC, 2011)

In an eco-efficiency analysis carried out in 2002, BASF compared chrome tanned leather for the automotive industry with leather of similar quality tanned with two different glutaraldehyde tanning processes (Wolf and Wittlinger, 2002). From the recipes of the three systems it is clear that the differences in systems are not only in the tanning step, but also those different agents are used for the neutralisation, retanning, and fatliquoring steps.

Comparing the consumption of raw materials, energy consumption, emissions, toxicity potential and the risk of accidents the authors come to the conclusion that the total potential environmental impact is more or less the same for chrome tanned leather and the conventional glutaraldehyde tanning process, but lower for the improved glutaraldehyde process. The results are first of all useful in demonstrating the advantages of the improved glutaraldehyde process compared with the conventional process. The comparison with the chrome tanned leather should be interpreted with care as the study does not include the possible effect of improvement of the chromium tanning process.

From the available data it is not evident that - viewed in a life cycle perspective - the total environmental impacts of non-chrome tanned leather are lower than the impacts of chrome tanned leather.

C.3.5 Technical and economic feasibility of using non-chrome tanned leather compared to chrome tanned leather

Data on the technical and economic feasibility of non-chrome tanning and the use of non-chrome tanned leather as compared to chrome tanned leather were requested from four major German suppliers of chemicals for the tanning sectors. The suppliers of chemicals for the leather sector in Germany are organised in the trade association TEGEWA e.V., and the organisation has provided a common answer regarding the technical and economic feasibility of the non-chrome tanning.

The technical comparison between leather tanned by the different methods, however, is very dependent on the specific application. In the following this is illustrated by a comparison of leather for the automotive industry and shoes, respectively.

Automotive industry
The major part of non-chrome leather (apart from heavy leather) is used in the automotive industry. Many luxury car brands use leather which is either vegetable tanned or tanned with wet-white techniques, primarily glutaraldehyde tannage.

In cars leather may be used for seat covers and head restraints, dashboards, door panels, steering-wheel covers and gear lever knobs.

Several incentives for using non-chrome leather in the car industry have been mentioned:

- Non-chrome leather has less tendency to shrink, which is important for leather dashboards and door panels;

- The ELV Directive (2000/53/EC) stipulates that the chromium (VI) content in any materials in the vehicles shall be below 0.1%. Even the chromium (VI) content of chrome tanned leather is significantly lower, some car manufacturers seem to have intentionally avoided materials containing chromium (VI);

- The ELV Directive (2000/53/EC) has requirements for the disposal of materials from the end of life vehicles, and chromium-free leather is easier to dispose of by composting for example.

- To safeguard people who suffer from chrome allergy (e.g. Volvo, 2011)

BASF (2007) summarises the advantages of using chromium and wet white leather, respectively, for automotive use as follows:

- Wet white leather:
  - Lower shrinkage under hot, dry conditions;
  - Easier to recycle and dispose of, free of heavy metals.

- Chrome tanned leather:
  - Low fogging;
  - Low VOC (volatile organic carbon) content;
  - High migration resistance.

Fogging is the property of the leather when heated, to emit substances that form a haze-like layer on the windscreen of a car.

Non-chrome leather is reported by TEGEWA to be in the range of 2-6% more expensive than chrome tanned leather. One car manufacturer states that the price difference has decreased recently and today non-chrome tanned leather used by this manufacturer is only 1% more expensive than chrome tanned leather.

Shoes
In the manufacture of shoes the leather is typically formed into a complex three dimensional structure by applying rapid heating up to 80ºC and rapid cooling. According to information from a major footwear manufacturer, only chrome leather can remain soft during the process, and a change to non-chrome leather would necessitate thorough changes in the production processes and major changes in shapes and colours of the shoes.

Vegetable tanned leather is reported to be used for nubuck (BASF, 2007) and according to a major footwear manufacturer it is also used for leather shoes with a “vintage” look. When using vegetable tanning the leather becomes brown and it is more difficult to make finished leather shoes in other colours than brown and black.

Wet white tannages are according to BASF increasingly being used for children’s shoes and sports shoes (BASF, 2007). One of the disadvantages of the wet white tanned leather is that the processing creates more stable network structures in the hide and the leather tears more easily than chrome leather.

The chemical manufacturer Clariant has recently introduced a new type of tanning agent "EasyWhite Tan” and according to this manufacturer, leather tanned with this process has approximately the same quality characteristics and range of applications as chrome tanned leather. The agent, Granofin® Easy F-90, is currently undergoing practical trials with customers e.g. shoe manufacturers. It has not been possible to obtain detailed information on the content of this tanning agent.

Overall comparison of costs and reasons for using the different tanning methods
The overall comparison of the tanning methods is summarised in Table 34 on the basis of a summary provided by TEGEWA (2011). The main alternative to chrome tannage is aldehyde tannage and reactive tannins with a price of the final leather 2-6 % higher than the price of chrome tanned leather. According to TEGEWA aldehyde tannage is not appropriate for all application areas.

TABLE 34 COMPARISON OF TANNING METHODS AND PRICE OF FINISHED LEATHER (TEGEWA, 2011]

Type of tannage	**Specific tanning agents used**	**Main area of use today (articles)**	**Main reasons of using the tannage for the specific products**	**Main reasons for not using the tannage for specific products**	**Elements of extra costs as compared to chromium tannage**	**Price of finished leather as compared to chrome tanned (percentage)**
Chromium tannage	Basic sulphate complex of trivalent chrome	Pretanning and retanning to get leather for clothing, upholstery (furniture and cars), upper leather (shoes)	Simplest and most cost-effective tannage	Chrome tanned leather cannot comply with technical specifications for sole leather	-	-
Other mineral tannages	Aluminium, zirconium, and titanium salts	Only in niche markets	Pure white crust leather nearly only available by this technique	Specific reasons in view of: - Technical performance - Ecological aspects - etc.	Articles not in competition	Articles not in competition
Vegetable tannage	Polyphenolic compounds leached from vegetable material (e.g. quebracho, mimosa, oak, etc.)	Pretanning and retanning of sole leather and specific articles Retanning of intermediate leather products (wet blue, wet white)	Sole leather: - Technical performance - Durability	- Limited natural resources to substitute chromium tanning - Limited fastness - Limited range of articles	Articles not in competition	Articles not in competition
Aldehyde tannage other reactive tannins	Aldehydes and reactive tannins	Pretanning step of chromium free tanning process to get specific articles, currently upholstery leather for cars	Thermo dimensional stability better than for chrome tanned leather, important for automotive applications	Currently not usable for all kind of articles	Higher amount of retanning agents necessary	+ 2-6 %
Synthetic tannage (Resin-syntans)	Sulphonated products of phenol, cresol, naphthalene, cresylics, poly-acrylates, melamine resins, etc.	Retanning of intermediate leather products (wet blue, wet white)	Universally used because of retanning and filling properties at the same time	No complete tanning possible because of no pretanning properties	Process not in competition	Process not in competition

C.3.6 Change from chrome tannage to chrome-free tannage

The possible costs involved in changing from chrome tanning to non-chrome tanning have not been investigated in detail. The equipment used in the different tanning methods is more or less the same. When shifting from chrome tannage to chrome-free tannage investment in higher capacity of some of the equipment for the tanning step may be needed as the non-chrome tanning (the tanning step) typically takes longer than chrome tanning. Investments in modified waste water treatment systems may also be needed. The effect of such extra costs of equipment on the price of the finished leather is included in the extra price of the finished leather described above.

D. Justification for action on a Community-wide basis

D.1 Considerations related to human health and environmental risks

Human health impacts of chromium (VI) are described in section B.5.

The severity of the risk

Chromium (VI) is known to cause severe allergic contact dermatitis in humans and to be able to elicit dermatitis at very low concentrations. The typical clinical picture is allergic contact eczema on the areas of the skin which come into contact with chromium (VI) (BfR, 2007b). Chromium contact allergy is a severe allergy. Based on experience from Denmark it is estimated that a person with chromium contact allergy initially has an average of about 200 days per year with symptoms but the number of symptom days decreases gradually to about 100 days over a period of 20 years. On average the person is absent from work for 7 days per year (See section F.1.1.1). When induced to chromium, the sensitised person will normally be sensitive to the substance for the rest of his or her life.

The extent of the risk

Previously cement was a major cause of chromium dermatitis in Europe. However, the introduction of restrictions (Directive 2003/53/EC) in the use of cement containing more than 2 mg/kg soluble chromium (VI) has had a significant impact of the prevalence of chromium allergy in the population.

In a recent study, the development of chromium allergy among patients with eczema was investigated for the period covering 1985 to 2007 in the region of Copenhagen in Denmark. A retrospective analysis of contact allergy to chromium in 16,228 patients was made. The frequency (the prevalence) of chromium allergy among the patients with eczema decreased significantly from 3.6% in 1985 to 1% in 1995, but increased again significantly to 3.3% in 2007.

Leather goods coming into close prolonged contact with the skin are expected to give rise to the highest exposure of consumers. Examples include shoes and gloves, clothes, hats, sports equipment, jewellery, leather upholstery in cars, steering wheel covers and gearshift knobs, furniture, watch straps and straps for bags.

The risk assessment carried out as part of this dossier concludes that extractable chromium (VI) from shoes and other articles of leather represents a risk for the development of contact allergy to chromium for consumers.

The prevalence of chromium allergy in the general population in Denmark (2001-2005) was estimated at 0.2%-0.54% (average: 0.37%) as a medium case prevalence (see section B.5.5.1). By comparison the estimated medium case prevalence in Germany was 0.2%-0.7%. The prevalence here is an indication of the percentage of the total population who has chromium allergy.

On the basis of the available data it is estimated that 0.2-0.7% of the population in the EU is sensitive to chromium (VI) corresponding to approximately 1-3 million people. Chromium (VI) in leather has been demonstrated to be one of the sources of exposure for development of contact dermatitis in patients. Based on survey data from Denmark, it has been estimated that during the last 10 years about 45% of the new chromium allergy cases were due to exposure to leather. This percentage will be applied as the best estimate at EU-level.

Data on the number of new cases of chromium allergy in the general population which could be used to estimate the incidence of chromium allergy have not been available.

The incidence of chromium allergy in the general population in Denmark is estimated at 0.01% per year on the basis of the national surveillance data and applied correction factors. A slightly lower percentage was obtained by estimating the incidence from the prevalence of chromium allergy in the general population (see section B.5.5.1).

On the basis of data on the prevalence of chromium allergy in the general population, the number of new cases of chromium allergy in the EU is estimated at about 44,000 per year. Assuming that 45% of the new chromium allergy cases are due to exposure to chromium (VI) in leather 20,000 new cases per year can be attributed to chromium (VI) in leather.

Evidence of consumer exposure to chromium (VI) in leather
Surveys of chromium (VI) in articles of leather in Germany and Denmark in 2007-2008 have demonstrated that more than 30% of the tested articles of leather contained chromium (VI) in concentrations above 3 mg/kg. The extent to which the articles with high chromium (VI) content were manufactured in the EU or imported from countries outside the EU has not been reported.

Virtually all consumers are to some extent exposed to chromium (VI) in articles of leather such as leather shoes, straps, jewellery, garments made of leather, gloves, bags, car steering wheels and furniture.

Articles of leather, when in direct and prolonged contact with the skin can result in skin sensitisation with symptoms such as contact dermatitis. The main exposure route is dermal contact and in principle all consumers across the EU are at risk of exposure to chromium (VI) in leather.

Chromium (VI) is not used intentionally in the production of leather, but may be formed within the leather by oxidation of chromium (III) used for the tanning of the leather. The mechanisms for the formation of chromium (VI) in the leather are well known today and measures for prevention of the formation of chromium (VI) in measureable concentrations have been developed and implemented in most tanneries in the EU.

Environmental risk
The environmental risk from chromium (VI) in leather is considered insignificant as the quantities of chromium (VI) that may be released from the leather is very small compared to other sources of chromium (VI).

D.2 Considerations related to internal market

The proposed restriction covers articles of leather that are extensively traded among and used in all Member States; most of whom (probably all others than Germany) have not established national restrictions (probably all others than Germany). The articles of leather containing chromium (VI) are both produced in and imported into the EU as reported in section A.2.2. The justification for acting on a Community-wide basis originates from the need to prevent Member States from adopting different legislative requirements with the risk of creating unequal market conditions:

- The proposed restriction would remove the potentially distorting effect that current national restrictions may have on the free circulation of goods;
- Regulating chromium (VI) in leather through Community-wide action ensures that the producers of the articles in different Member States are treated in an equitable manner;
- Acting at Community level would ensure a 'level playing field' among all producers and importers of articles of leather.

D.3 Other considerations

D.4 Summary

The main reasons for acting on a Community-wide basis is the severity of the possible health risk as documented in section B of this dossier, and the extent of the risk (most children and adults are in daily contact with articles of leather that may contain chromium (VI)). The fact that articles of leather - imported as well as produced in EU - needs to be restricted on a common basis within the EU, also stresses the importance of the Community-wide action in order to avoid market distortion. Thus, the content of chromium (VI) in articles of leather needs to be controlled at EU level.

E. Justification for the proposed restriction being the most appropriate Community-wide measure

This section provides justification for the reasoning that the proposed restriction is the most appropriate Community-wide measure. It gives an overview of the effectiveness, practicality and ease of monitoring involved in implementing the proposed restriction. An assessment of other risk management options is also included.

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

As described in Section B.5.5.1 it is estimated that 0.2-0.7% of the population in the EU is sensitive to chromium (VI), and chromium (VI) in leather has been demonstrated to be one of the means by which people can become exposed and develop contact dermatitis.

Articles of leather, when in direct and prolonged contact with the skin can result in skin sensitisation with symptoms such as allergic contact dermatitis. The main exposure route is dermal contact and in principle all consumers across the EU are at risk of exposure to chromium (VI) in leather. The exception is a small group of vegans who do not use leather. It is estimated that exposure to chromium (VI) in leather today is responsible for approximately 45% of the incidences of chromium allergy (see Section B.5.5.1).

Among the articles of leather, shoes have been demonstrated to be the main cause of chromium (VI) induced contact dermatitis, but other articles in prolonged contact with the body have also been demonstrated to induce contact dermatitis. The use of such articles, when in direct and prolonged contact with the skin can result in skin sensitisation with symptoms such as allergic contact dermatitis, following dermal exposure. The main exposure route is dermal contact and the population at risk comprises all potential consumers across the EU.

The total EU wide yearly number of new cases of chromium allergy is in section B.5.5.1 estimated at about 44,000 per year. Assuming that 45% of the new chromium allergy cases are due to leather, the total number of new cases caused by leather would be approximately 20,000 per year.

The chromium (VI) in leather is not expected to constitute a specific risk to the environment due to the relatively small quantities involved (see section B.2.4).

Business as usual
Without any restriction of chromium (VI) in leather, it must be expected that the number of new incidences of chromium (VI) allergy caused by exposure to articles of leather in most EU Member States will remain at the level seen today. The number of new cases is expected to decrease in Germany as a consequence of the German restriction.

E.1.2 Options for restrictions

The risk management options (RMO) should address human exposure caused by releases of chromium (VI) from articles of leather.

Three options for restriction are explored (see section E.2.)

- *RMO 1: (the proposed restriction) – restriction of chromium (VI) content of articles of leather, which may come into direct and prolonged contact with the human skin*

The proposed restriction will ban the placing on the market of specific articles intended for uses where the leather may come into direct and prolonged contact with the skin, if the leather material contains detectable amounts of chromium (VI) as analysed in accordance with EN ISO 17075:2007.

The restriction concerns chromium (VI) unintentionally formed in leather from chromium (III) that is used in the tanning process. The restriction does not target chromium (VI) in waste and wastewater formed by the disposal of chromium containing waste and is not expected to have any impact on chromium in waste and wastewater. Any environmental and health impact from the manufacturing and disposal of chrome tanned leather is covered by legal instruments concerning industrial emissions, waste disposal and occupational health and safety.

The restriction does not target the use of chromium (III) as a tanning agent.

Any authorized use of chromium (VI) will not be affected by this proposal as the proposal targets articles of leather.

- *RMO 2: Wider scope: - restriction of chromium (VI) content of all articles of leather*

In this RMO 2 sale of any articles containing leather would be banned if the leather material contains detectable amounts of chromium (VI) as analysed in accordance with EN ISO 17075:2007 independent whether the article of leather are in contact or not with the human skin.

- *RMO 3: Wider scope – restriction of total chromium content of leather*

In this RMO placing on the market of any article containing leather is banned if the total chromium (both chromium (III) and chromium (VI)) content of the leather is above a certain level (above the natural background chromium concentration in the leather). In practice this means that the placing on the market of chrome tanned leather will be banned.

E.1.3 Other Community-wide risk management options than restriction

Possible Community-wide risk management measures other than a restriction are outlined in Table 35 below. However, it is concluded that none of these constitute realistic, effective or proportionate means of solving the problem. As such, none of these other risk management options have been considered further within this analysis.

TABLE 35 POSSIBLE OTHER COMMUNITY-WIDE OPTIONS DISCARDED AT THIS STAGE

Risk Management Option	Reasons for discarding this option
REACH Authorisation Process	The chromium (VI) is not used intentionally in the tanning process and for tanning agents manufactured in the EU chromium (VI) is not present as impurity in the applied chemicals. The authorization procedures should therefore address the chromium compounds applied in the tanning processes. These substances are not considered SVHC, but may in accordance with article 57 of REACH be considered substances "*(e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e)*" However, the authorisation route only addresses use within the EU. Today, preventive measures have to a large extent been implemented in the tanning sector in the EU and the majority of articles of leather with chromium (VI) are assumed to originate from countries outside the EU. As the Authorisation route does not address the articles placed on the market, the risks to the consumers are not adequately addressed by this route. Placing chromium (VI) compounds on the candidate list for authorisation will not provide further information requirements for articles as chromium (VI) compounds are not intentionally used in articles of leather.
Voluntary industry agreement	Today preventive measures have to a large extent been implemented in the tanning sector in the EU and the majority of articles of leather with chromium (VI) are assumed to originate from countries outside the EU. A voluntary agreement with the tanning sector, which to large extent is organised in COTANCE, would have limited influence on the chromium (VI) in marketed articles of leather as a majority of the articles marketed to consumers originates from countries outside the EU. Likewise a voluntary agreement with the manufacturers of articles of leather such as shoes and garment, would have limited effect as a major part of the articles are imported from countries outside the EU. It does not seem feasible to establish an effective functioning agreement due to the large number of importers and because parts of the sector is not organised. The concerned articles of leather are much diversified. Monitoring compliance within voluntary agreements is difficult as breaches of such agreements can only be found through sampling and chemical analysis done by the competent authorities. The administrative costs of the sector of control of compliance with a voluntary agreement would be more or less the same as for an EU-wide restriction. For the importers it would be more efficient in their communication with the manufacturers abroad to refer to an EU-wide restriction, than a voluntary agreement. With an EU-wide restriction the importers may simply add one substance to the list of substances in leather already restricted in the EU.

Risk Management Option	Reasons for discarding this option
Information to consumers and retailers incl. labelling	The message could be: *To retailers – Avoid selling the articles in question.* This RMO does not seem to be sufficiently effective as it needs to be controlled by the competent authorities, it will be very expensive etc. *To consumers – Avoid buying the articles in question.* For the consumers it is not possible to determine whether the articles of leather contain chromium (VI). The consumers are dependent on voluntary labelling of the articles of leather, either by the use of the official Ecolabels such as the EU flower or the use of the brand's own labels. The EU Ecolabel for leather shoes and a number of other ecolabels requires that the leather contain no detectable chromium (VI) as measured by ISO EN 17075. For other articles of leather than shoes no EU ecolabel requirements exist. A recommendation to consumers could be - *Avoid buying the articles in question without an ecolabel*, but the number of articles of leather with ecolabel is quite limited, and most probably only a smaller part of the consumers would follow such recommendations. Furthermore, it is not considered that the risk is addressed effectively by requiring labelling of articles due to a much diversified market.
General Product Safety Directive 2001/95/EC	In this option a decision in accordance with the General Product Safety Directive (2001/95/EC) would be adopted to address risks to consumers from chromium (VI) in articles of leather coming into direct and prolonged contact with the skin to minimise the risk on a short tem. This option would extend only to products sold in the EU and not those manufactured in the EU for export. Regarding timing, the decision would be valid for one year only and would have to be confirmed after that period.

E.2 Assessment of risk management options

E.2.1 Restriction option 1 (RMO 1) – restriction of the chromium (VI) content of articles of leather which may come into direct and prolonged contact with the human skin

The proposed restriction will ban the placing on the market of specific articles intended for uses where the leather may come into direct and prolonged contact with the skin, if the leather material contains detectable amounts of chromium (VI) as analysed in accordance with EN ISO 17075:2007.

E.2.1.1 Effectiveness

E.2.1.1.1 Risk reduction capacity

The objective of the restriction is to avoid exposure of humans to chromium (VI) in leather and thereby decrease the number of individuals being sensitized to chromium allergy and to alleviate the manifestation of the disease for those who already have chromium allergy.

As described in section B.5.1.1 chromium allergy may both be caused by chromium (III) and chromium (VI), but chromium (VI) is a much more potent allergen. Experience from restrictions of chromium (VI) in cement has demonstrated a significant effect of the restriction of chromium (VI) (CSTEE, 2002).

The proposed restriction will reduce exposure to hexavalent chromium, as articles of leather will not contain more than 3 mg/kg of chromium (VI). It is expected that this limit of 3 mg/kg will significantly reduce the risks of skin sensitisation and dermal contact allergy.

From clinical studies it is known that even the lowest levels of chromium (VI) in leather are sufficient to trigger an allergic reaction in hypersensitive individuals as described in section B.5.5.1. At a level of 5 mg/kg leather, half of the sensitised individuals already manifested allergic skin reactions like for instance contact eczema. The only effective protection for them against skin disorders is to avoid any contact with products containing chromium (VI) (BfR, 2007).

On the basis of the available data it is difficult to estimate the extent to which a restriction to a level of 3 mg/kg would decrease the prevalence of chromium allergy, but as described in section B.5.5.1 it is considered likely that the restriction would lead to a reduction of 80% in new incidences of contact dermatitis caused by chromium (VI) in those articles of leather which are covered by the restriction.

The articles which may be in direct and prolonged contact with the skin include shoes, furniture, outer garments, underwear, gloves, working dress, watch straps, jewellery, bags and sacs, valises and back-packs as listed in Table 17. These products most likely represent more than 90% of all leather goods (in tonnage) and would represent nearly 100% of the exposure of the consumers to leather. The majority of articles of leather which do not fall under the definition of direct and prolonged contact would still be in contact with the hands e.g. when put on, mounted or fitted. Consequently, they may still represent some risk to those already sensitised.

The total number of new cases of allergy to chromium due to chromium (VI) in leather is estimated at approximately 20,000 per year at EU level (section B.5.5.1) and it is estimated that 1-3 million people in the EU are allergic to chromium. It is estimated that about 3,000 new cases per year would be avoided as a consequence of the German restriction but otherwise the number of new cases is expected to remain as it is, as no changes in the chromium (VI) concentrations or in the frequency of using articles of leather are expected.

For those people that already have chromium allergy, it is assumed - based on expert estimates (Menné, 2011) - that a person with chromium allergy is absent from work for an average of 7 days per year. It is based on Danish experience assumed that the number of symptom days will gradually decrease over a period of 20 years after the onset of the allergy from 200 to 100 days per year and then remain at 100 days per year for the rest of the patient’s life (Menné, 2011). For those people, the restriction may result in significantly fewer days per year with symptoms.

E.2.1.1.1.1 Changes in human health risks/impacts

The identified risks deal with exposure to chromium (VI) from articles of leather. The proposed restriction impacts the placing on the market of articles of leather that may come into contact with the skin: consequently, it is clearly targeted to the identified risks.

The presence of chromium (VI) can only be detected by laboratory analysis. In the baseline scenario, where chromium (VI) may still be present in articles of leather, the adverse effect from contact with chromium (VI) may be delayed for some time, and establishing the casual link between exposure to chromium (VI) and these effects is far from obvious, even for trained health personnel. An unidentified or recurrent use in the baseline scenario may therefore cause serious injury to a large number of individuals before the problem is identified and action taken.

Both consumers and workers in the leather sector in prolonged contact with the leather during the production of leather goods are expected to be positively impacted by the proposed restriction.

Given the availability of methods for prevention of chromium (VI) in articles of leather, it is foreseen that the restriction, would significantly reduce the exposure as soon as it is adopted.

E.2.1.1.1.2 Changes in the environmental risks/impacts

No specific environmental hazard is identified for the relatively low quantities of chromium (VI) which could be released from articles of leather to the environment. See section B.2.4.

E.2.1.1.1.3 Other issues

No other issues.

E.2.1.1.2 Proportionality

E.2.1.1.2.1 Technical feasibility

As indicated in section C.2, the mechanisms for formation of chromium (VI) in leather are well known, and techniques for optimization of the tanning process in order to prevent the formation of chromium (VI) in the leather are well established. The tanning step is not the process of importance for the formation of chromium (VI), which may be formed by the post tanning processes such as the neutralizing, retanning and fatliquoring processes. Chemical suppliers today provide leather chemicals and tanning systems where the techniques for prevention of chromium (VI) have been integrated as described in section C.2.

It is generally considered sufficient to follow the guidelines for prevention of formation of chromium (VI) and to use the available chemicals. Specific antioxidising agents for the finishing or the use of the leather in the production of articles of leather can be used by manufacturers of leather who are intent on being “on the safe side” on the issue of the possible formation of chromium (VI). These agents can also be used to reduce the level of chromium (VI) in the leather or articles of leather if chromium (VI) has unintentionally been formed by the leather processing.

By the development of new agents for the leather processing and new leather types, test methods for testing the possible formation of chromium (VI) (e.g. by thermal ageing of the leather) can be applied.

According to COTANCE, the techniques for prevention of formation of chromium (VI) in leather are applied across Europe in both small and large tanneries. The Italian trade organisation for tanners, Unione Nazionale Industria Conciaria (UNIC), which represents more than half of the production volume of leather, states that the EU tanning industry already faced the problem with chromium (VI) and complies with a limit value of 3 mg/mg (UNIC, 2011). Restriction of chromium (VI) in leather consequently will not affect the EU leather production (UNIC, 2011).

It has been noted by market actors that the current German restriction has not had any significant impact on the manufacturing of leather and articles of leather in the EU.

E.2.1.1.2.2 Economic feasibility (including the costs)

Cost benefits

The possible costs and benefits of RMO 1 (the proposed restriction) are estimated in section F, “Socio-economic assessment of the proposed restriction”.

The net benefit of the proposed restriction is significant and growing over time. The health benefits will initially be approximately 1,500 €m and gradually grow as the prevalence of chromium allergy in the EU27 population decreases (see Section F.6). With estimated costs of the restriction proposal in the order of 100 €m the net benefits are substantial. The sensitivity calculations provided in section F.6 indicate that even if the case which could be considered a "worst case" scenario in relation to net benefits of the proposed restriction, the estimated benefits are significantly higher than the costs.

Timing

The implementation of measures for the prevention of formation of chromium (VI) does not require any investment in new equipment, but is rather a question of proper training of personnel in the operation of the processes and the use of the appropriate agents for the different process stages.
For manufacturers of leather and articles of leather outside EU there will be a need for training and for building up procedures for product control and documentation. The results of surveys of chromium (VI) in marketed products, showing that about 1/3 of the products contain chromium (VI) at levels above 3 mg/kg; indicate that changes would be needed by many manufacturers outside EU. As the surveys are more than 2 years old, some manufacturers may already have implemented measures in response to the new German regulation.

The restriction is not expected to have a significant impact on the market for chemicals for the tanning sector in the EU.

The manufacturers of chemicals for the market outside the EU (based within the EU and outside EU) may need some time to adjust the production volume for some of the agents used e.g. the vegetable based antioxidising agents used in the retanning process. Compared to the total supply of chemicals to the sector it is a question of small changes and it is considered that the suppliers will be able to supply the necessary agents within relatively short time. Suppliers of chemicals for the sector in the EU have not indicated that any of the agents could be in short supply as a consequence of the restriction. A very large share of imported leather originates in China and Chinese producers of leather are probably dependent on Chinese produced tanning chemicals. The extent to which any of the applied agents could be in temporary short supply in China (or other countries outside the EU) has not been investigated.

Importers are already supposed to have procedures for compliance control with other EU-wide restrictions of hazardous chemicals in leather. These could rapidly be extended to include chromium (VI).

The actors need some time to adapt after a restriction has come into force. The reasons are technical, economic, practical and regulatory.

The restriction includes a transition period enabling the market to adjust. The transition period should take depletion of stocks into account. As for the length of this transition period, a balance must be struck between the need for protecting human health and the possibility for the market to adjust.

Economic aspects include considerations about restricting manufacturers, importers, wholesalers and retailers from selling their existing stocks. Practical difficulties could be foreseen for importers who need to inform non-EU suppliers about the change in EU regulation.

When considering the length of the transitional period the health benefits should also be taken into consideration. As the articles can have a long service period it is important to avoid having a very long transitional period as this will prolong the exposure time for the general public.

For the above reasons a transitional period of 12 months is considered reasonable for the market operators to adapt to the requirements of the proposed restriction. A shorter period could imply implementation problems on the EU market.

E.2.1.2 Practicality

E.2.1.2.1 Implementability and manageability

As explained in the previous sections, reduction/omission of chromium (VI) or replacement of chromium by alternatives seems to be economically and technically feasible. Consequently, the actors should be capable of complying with the proposed restriction by applying adequate techniques. Furthermore, during the consultation process, the market actors did not mention any potential difficulty in complying with the proposed restriction.

For imported articles of leather it must be expected that there will be a need for an extensive compliance control until all suppliers have implemented the necessary measures for the prevention of formation of chromium (VI) in their products. For articles not in compliance, techniques are available for bringing the articles in compliance by reducing the chromium (VI) in the leather by the use of reducing agents, a practice already available on commercial basis in the EU today (see e.g. Erren, 2011).

Technically and economically feasible measures to prevent the formation of chromium (VI) are available and market actors have procedures for compliance control for other hazardous substances in leather in place. The proposed restriction is easily understandable for affected parties and access to relevant information is easy. Thus, the restriction is considered to be easily manageable for all parties within the entire product chain.

Test of other substances in leather

A number of restricted or undesired substances may be used in leather and are included in laboratory test packages for compliance control of articles of leather. As an example the chemical substances analysed by BLC (the British Leather Technology Centre) include the following substances: Azodyes, chromium (VI), formaldehyde, heavy metals (lead, cadmium, chromium, arsenic, antimony, mercury, barium, and selenium), nonyl phenol ethoxylates (NPEO), and chlorinated phenols (BLC, 2011).

Many test institutes issue certificates for hazardous substances in leather. As an example the SG certificate from Prüf- und Forschungsinstitut Pirmasens and TÜV Rheinland includes those substances listed above, but also a number of other substances including tributyltin compounds, some PAHs, chlorinated paraffins, some pesticides and carcinogenic and allergizing dyes (SG, 2011).

A few of these substances are regulated at EU level for use in leather.

According to Annex XVII of REACH, azocolourants “shall not be used in textile and articles of leather which may come into direct and prolonged contact with human skin or the oral cavity”.

Restrictions in Annex XVII specifically addressing leather processing also include:

- Restriction on short chain chlorinated paraffins in fat liquoring of leather.

- Nonyl and Nonylphenol ethoxylates should not be sold for textiles and leather processing except: processing with no release into waste water, systems with special treatment where the process water is pretreated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin).

Pentachlorophenol (PCP) is restricted in all products according to Annex XVII of REACH. As the substance has been used for preservation of leather and textiles it is often included in tests for compliance control of leather.

TABLE 36 EXAMPLES OF APPLIED METHODS FOR DETERMINATION OF HAZARDOUS SUBSTANCES IN LEATHER

Other hazardous substances:	Analysis method	Legislation at EU level
Azodyes	EN 17234-1	REACH, Annex XVII
Pentachlorophenol / chlorinated phenols (PCP, TriCP, TeCP)	ISO 17070; DIN 53313*	REACH, Annex XVII
Formaldehyde content	EN 17226-1 (HPLC) EN 17226-2 (colorimetry); DIN 53315*	No EU legislation

E.2.1.2.1 Enforceability

For enforcement purposes, it is recommended that the restriction contains a restriction limit so that the enforcement authorities can set up an efficient supervision mechanism.

It is suggested that the restriction specifies that chromium (VI) should not be present in concentration higher or equal to 3 mg/kg.

The limit is chosen as low as possible and for practical reason in accordance with existing standard as measured by EN ISO 17075:2007 “Leather. Chemical tests. Determination of chromium (VI) content”, where the current detection limit of the analytical method is 3 mg/kg.

Determination of chromium (VI) in leather
Chromium (VI) and other chromium forms in leather can be determined in accordance with various analytical standards (Table 37)

EN ISO 17075 – chromium (VI) in leather
Of particular interest is the EN ISO 17075:2007 “Leather – Chemical tests - Determination of chromium (VI) content” published in 2007. The standard is described in some detail here because it is of importance for the discussion of meeting the objectives of the proposed restriction. Using this method, where possible, the leather is sampled in accordance with EN ISO 2418[15] and grounded in accordance with EN ISO 4044[16]. Grinding should take place shortly before the extraction processes. The ground leather is extracted with a phosphate buffer adjusted to pH 7.5-8 which has been degassed to displace oxygen by passing oxygen-free argon (or nitrogen) into the solution. The leather powder suspension is shaken for 3 hours ± 5 min to extract the chromium (VI).

Immediately after completing the 3 hour extraction, the suspension is filtered and the pH of the solution is checked. If the pH of the solution is not between 7.5 and 8 the complete procedure must be started again.

[15] EN ISO 2418: “Leather -- Chemical, physical and mechanical and fastness tests -- Sampling location”
[16] EN ISO 4044: “Leather -- Chemical tests -- Preparation of chemical test samples”

The chromium (VI) oxidises the 1,5-diphenylcarbazide to 1,5-diphenylcarbazone which gives rise to a red/violet complex with chromium which is quantified photometrically at 540 nm.

The content is calculated in mg/kg. The content is based on dry matter. The standard indicates that the method is suitable to quantify the chromium (VI) content in leathers down to 3 mg/kg. The standard indicates that the extraction matrix for leather is complex (for example due to coloration) and results below 3 mg/kg show large variation and has limited reliability.

The standard emphasises that results obtained by other extraction procedures (extraction solution, pH, extraction time, etc.) are not comparable with results produced by the procedure described in the standard.

The methodology can, under certain circumstances, be used for research purposes where quantification limits lower than 3 mg/kg can be applied. The recent study carried out by two German Research institutions described in section B.2.2.2 reports that in-house tests on reproducibility resulted in a lower detection limit of 0.75 mg Cr(VI)/kg leather (Meyndt *et al.*, 2011).

CEN/TS 14495 – chromium (VI) in leather

Using the former DIN 53314, now superseded by the equivalent EN ISO 17075:2007, false positives for chromium (VI) have been detected as a result of the difficulties encountered in strongly coloured extracts and also due to the interference by the 1,5-diphenylcarbazide with some dyes (Chrom6less, 2005). The quality handbook for the production of chromium (VI)-free leather (Chrom6less, 2005) therefore recommends that manufactures of heavily dyed leather samples with positive chromium (VI) result should ask for a verification of this result by an alternative analytical method. In these cases, it is recommended that the technical specification CEN/TS 14495, or its equivalent, is employed. CEN/TS 14495 applies a more complex technique than EN ISO 17075 and requires that equipment for solid phase extraction is available (Chrom6less, 2005). A laboratory performing analysis for the leather sector states that interference can also be a problem using EN ISO 17075, but in this case the laboratory separates the dyes off prior to using the detection method prescribed in EN ISO 17075.

Other standards

Other standards for determination of chromium (VI) in cement and protective gloves are shown in Table 37. The restrictions limit for chromium (VI) in cement is 2 mg/kg and consequently lower than the detection limit of EN ISO 17075. As indicated in EN ISO 17075, the detection limit is determined by the complexity of the leather matrix. The matrix is different for cement samples which may explain the lower detection limit.

The European standard EN 71 specifies safety requirements for toys. EN 71, Part 3 contains one section entitled “Migration of certain elements”. In this section the limits for migration of some elements from toy materials including chromium is defined/set/given. However, the standard has no specific requirements on migration of chromium (VI) from the toys.

TABLE 37 APPLIED ANALYSIS METHODS FOR DETERMINATION OF CHROMIUM (VI) AND OTHER CHROMIUM FORMS

Substance(s)	Analysis method	Detection limit	Legislation at EU level
Chromium (VI):			
Chromium (VI) content of leather	EN ISO 17075	3 mg/kg	No regulation
Chromium (VI) content of leather	CEN/TS 14495	10 mg/kg	No regulation
Methods of testing cement - Part 10: Determination of the water-soluble chromium (VI) content of cement	EN 196-10	2 mg/kg	Directive 2003/53/EC
Protective gloves - General requirements and test methods	EN 420 + A1:2009	3 mg/kg	Directive 89/686/EEC
Other chromium forms:			
Total chromium migration from toys (limit value in mg migrated per kg of material under test conditions)	EN 71-3:1994	60 mg/kg	88/378/EEC [1)]
Leather - Chemical determination of chromic oxide content	EN ISO 5398		No regulation

[1)] The safety of toys Directive 2009/48/EC has requirements as to the migration of chromium (VI) from toys with limits ranging from 0.005 to 0.2 mg/kg toy material dependent on material type. The parts of the Directive relating to chemical content will come into force on 20 July 2013. During this transitional period, part III of annex II of Directive 88/378/EEC will continue to apply.

Consideration has been given to whether the proposed restriction should be migration based, i.e. based on the detection of the migration of the chromium (VI) from the intact material. No standard for the determination of the migration from the intact material exists, and this option has been excluded.

Today, azocolourants, which may release one or more of the aromatic amines in detectable concentrations on cleavage, i.e. above 30 mg/kg in the finished articles or in the dyed parts thereof, shall not be used in textile and articles of leather which may come into direct and prolonged contact with human skin or the oral cavity (REACH Annex XVII). The “definitions” of product groups used for the restriction of azocolourants may also be used for the current proposed restrictions of chromium (VI).

The enforcement of the chromium (VI) restriction in leather and articles of leather can be done concurrently with the enforcement of the restriction of azocolourants and pentachlorophenol (PCP).

As the chromium (VI) is unintentionally formed in leather and articles of leather and not intentionally used by the manufacturing it may be necessary to a larger extent than normally used to base the product control on actual tests. In the case of azocolourants, the control can to a large extent be based on declarations from the manufacturers – unless they deliberately provide misleading information, their products will be in compliance. In the case of chromium (VI) the level can change during the late processing steps, in the manufacturing of articles of leather and even by transport. Consequently, it may be necessary to use more resources on product control.

Chromium (VI) in marketed articles

Although measures for the prevention of the formation of chromium (VI) have been implemented in many European tanneries, surveys of marketed products from 2007 and 2008 in Germany and 2009 in Denmark demonstrate that more than 1/3 of the articles marketed contained chromium (VI) in concentration above 3 mg/kg. The explanation for such a large percentage of articles with high chromium (VI) content might be that the articles with measureable chromium (VI) content are imported from countries outside the EU where measures for the prevention of the formation of chromium (VI) have not been implemented. However, available data indicate that chromium (VI) may form late in the manufacturing process of articles of leather and that there might be a need to improve control of chromium (VI) throughout the entire product chain for articles of leather from both non-European and European sources.

Although the chromium (VI) level in leather and articles of leather manufactured in the EU may be further eliminated by better product control and possible further use of antioxidising agents, this would only have a positive impact on a minor portion of the marketed articles, as the majority of the articles of leather are imported from countries outside the EU. Without a restriction in the content of chromium (VI) in all marketed articles, it must be expected that a significant part of the imported articles will continue to have a high content of chromium (VI). The chromium (VI) content in imported articles is to some extent controlled today as a result of some importers' and major brands' own restriction of chromium (VI) in articles (besides the restriction in Germany), but the market surveys clearly indicate that the implemented measures are not sufficient for preventing the exposure of consumers to high levels of chromium (VI) in articles of leather.

Costs of analysis
Chromium (VI) analysis is carried out by research institutions specialized in leather testing and by the major commercial test laboratories.

Some large tanneries may be able to do the test in their own laboratories, but in general the tests are done by independent laboratories.

According to a large international testing laboratory and a specialised leather testing laboratory the cost of a test of chromium (VI) in leather at an accredited laboratory is currently in the range of 210-280 €. The methodology of chromium analysis is totally different from the methodologies used for testing of other substances in the leather and the price would therefore be the same regardless of which other substances are analysed in the leather samples.

Compliance control for hazardous substances in leather
A restriction of chromium (VI) in leather would not create additional costs to European providers of tanning agents as compliance control (tests, certificates, etc.) in view of chromium (VI) restriction for the chemicals for leather processing was implemented by the suppliers many years ago (TEGEWA, 2011).

Of importance for the assessment of the impact of the current proposal for restriction of chromium (VI) in articles of leather is the fact that some substance restrictions at EU level already specifically address articles of leather that may come into direct and prolonged contact with the human skin. Furthermore, the content of formaldehyde and chromium (VI) in articles of leather is already restricted in some Member States.

Consequently, manufacturers and importers of leather and articles of leather have already established procedures for compliance control of articles of leather sold.

According to market actors who have been contacted, documentation demonstrating that the soluble chromium (VI) content is below detection limit is requested by many actors all over the EU together with compliance documentation for other substances.

European manufacturers of leather in general are able to provide a certificate that the leather does not contain chromium (VI). They carry out regular product control. It has been stated that for product control of leather and articles of leather, chromium (VI) may be tested in the companies' own laboratories or by commercial test laboratories.

German companies do not consider that an EU-wide restriction of chromium (VI) in leather and articles of leather would have any impact because chromium (VI) in articles of leather is already restricted in Germany. Based on information from test laboratories and other sources it is estimated that the market for chromium (VI) tests in Germany is likely to be in the order of magnitude of 1-3 €m per year. This includes compliance control both by market actors and the authorities.

As part of the preparation of this dossier, investigations into the extent to which a restriction would require increased compliance control by importers of articles of leather, wholesalers, footwear chains, supermarkets chains, etc. in Member States without a current restriction (all other than Germany) have been done. The kind of documentation requested and to what extent spot checks of articles are prepared varies.

Examples of current control from countries other than Germany:

- A wholesale dealer of leather and hides has requested a certificate that the leather does not contain chromium (VI) above 3 mg/kg, from all manufacturers of leather (both tanneries within the EU and outside EU) So far, no spot checks have been carried out.

- A supermarket chain requires test reports for leather shoes. So far, no spot checks have been carried out. The company has no specific requirements for other articles of leather.

- Another supermarket chain requires that from 01.01.2012 all articles of leather comply with the German restriction. So far, no spot checks have been carried out.

- A major shoe manufacturer requires test reports from all suppliers of leather and carries out spot checks in his own laboratory. If the leather contains above 3 mg/kg chromium (VI), the sample is analysed further by a commercial test laboratory, in order to provide documentation for claims against the supplier. The total costs of chromium (VI) testing in the whole shoe production supply chain is in the order of 0.5 €m (total for both internal and external laboratories).

E.2.1.3 Monitorability

The efficacy of the restriction can be monitored at two levels:

- Monitoring of chromium (VI) in marketed articles of leather:

  - Monitoring of chromium (VI) in marketed articles of leather at Member State level;

  - Monitoring of notifications of any violation of restriction to the EU Rapid Alert System for Non-Food Products (RAPEX).

- Monitoring of the prevalence of chromium allergy amont patients who are patch tested and monitoring of the symptoms of those already suffering from chromium contact allergy.

Monitoring of chromium (VI) in marketed articles of leather
The costs of the monitoring by compiling information from enforcement activities will be limited. This can be done concurrently with the monitoring of the restriction on azocolourants and pentachlorophenol (PCP) in leather.

The EU Rapid Alert System for Non-Food Products (RAPEX) can be used to monitor compliance with the regulation at EU level. As of 27 October 2011 RAPEX lists 20 notifications for chromium (VI) in articles of leather from 2011. The notifications concern 7 protective gloves notified by Sweden, 11 notifications of footwear notified by Bulgaria and Germany, a leather wristband notified by Germany and a leather shirt notified by Denmark. Eighteen of the notifications concern products imported from countries outside EU (China, Pakistan, Brazil and Turkey) while for 2 products the country of origin is unknown.

Monitoring of the prevalence of chromium allergy
The effect of the restriction on the number of new cases of chromium allergy can be monitored by the prevalence of chromium allergy among patients with dermatitis who are patch tested. At EU-level, changes in prevalence among the tested patients can be monitored by the use of results from the European baseline series from the European Surveillance System on Contact Allergies. Monitored over a period of 10 years it should be possible to evaluate the effect of the proposed restriction and assess whether further measures for reduction of the risk of exposure to low levels of chromium (VI) in the leather would be needed. As discussed in Section B 5.5.1 the incidence (number of new cases divided by the size of the population) is not exactly the same as the prevalence of chromium allergy among patients with dermatitis who are patch tested. The changes in the prevalence among tested patients, however, may be used as an indicator of changes in the incidence.

For those already suffering from chromium contact allergy, monitoring the number of days without symptoms would require specific studies.

The change in prevalence among patients tested is considered a reasonable indicator for an overall evaluation of the effect of the restriction in the general population.

E.2.2 Restriction option 2 (RMO 2) - restriction of chromium (VI) content in all articles of leather

In this RMO, the placing on the market of any articles containing leather is banned if the leather material contains detectable amounts of chromium (VI) as analysed in accordance with EN ISO 17075:2007.

E.2.2.1 Effectiveness

E.2.2.1.1 Risk reduction capacity

Implementing this option would mean that all articles will be covered by the restriction. Compared to RMO 1, it means that a number of products which are only in contact with the human skin for short periods under normal use will be covered by the restriction.

These concern a number of consumer products and technical articles of leather as listed in Table 18 in section B.2.2.8:

- **Consumer articles** such as belts, purses, credit card holders, key rings, spectacle cases, etc., tools and nail holders, pistol holsters, etc., collars for dogs and other pets, dice cups, carpets, book covers, aprons and automotive interior parts apart from upholstery.

- **Technical articles** such leather belts for power transmission and industrial sewing machines, hydraulic leathers for packing, gaskets and seals, frictions leathers for use by certain stamping presses, stropping leathers used for honing / sharpening razor blades and knives.

- **Leather not shaped into a final product.** Covering leather sold to the consumers and used for manufacture of bags, belts, etc.

The list is not exhaustive. For the consumer products it is evident that some consumers may in fact sometimes be in more prolonged direct contact with some of the listed articles, and the difference between prolonged contact and short term contact is not clear-cut.

As mentioned under RMO 1, studies show that even low concentration of chromium (VI) may trigger an allergic reaction in hypersensitive individuals. The only effective protection for hypersensitive individuals against skin disorders is to avoid any contact with products containing chromium (VI). It is likely that repetitive short time contact with higher concentrations of chromium (VI) in leather may also trigger an allergic reaction.

This management option may consequently provide higher protection against exposure to chromium (VI) and this may be of particular importance for those who already have chromium allergy. As RMO 1 is estimated to cover at least 90% of all articles, and exposure to the remaining 10% would in general be shorter, the difference in effectiveness between the two RMOs is expected to be small.

Many technical products are made of leather that is not chrome tanned. Including these products in the restriction would therefore have a limited impact on human health.

E.2.2.1.1.2 Changes in the environmental risks/impacts

Same as for RMO 1.

E.2.2.1.1.3 Other issues

No other issues.

E.2.2.1.2 Proportionality

E.2.2.1.2.1 Technical feasibility

Same as RMO 1.

E.2.2.1.2.2 Economic feasibility (including the costs)

Cost benefits
The possible costs and benefits of RMO 2 would be slightly different from the costs and benefits of RMO 1. RMO 1 already covers about 90% of the articles of leather.

The costs of compliance per tonne of leather for the additional articles would be the same as for RMO 1 but the health benefits would probably be lower due to the shorter time of contact with the body. The costs vs. benefits would consequently be slightly displaced in the direction of a higher cost benefit ratio.

For the consumer products, most probably the market actors would not distinguish and make specific procedures for the products with short time exposure. The costs of implementing the measures for the prevention of formation of chromium (VI) are so small that it probably would be more costly to have different production lines, procedures, etc. The total costs of products control would, due to the higher number of products, are higher if all products are covered.

For the technical products both costs and benefits would be relatively minor as much of the leather is not chrome tanned.

Timing
Same as RMO 1.

E.2.2.2 Practicality

E.2.2.2.1 Implementability and manageability

The consumer products covered by this RMO, which are not covered by RMO 1, basically have the same supply chains as the consumer products covered by RMO 1, and in practice most likely exactly the same types of leather will be used for these products.

For the market actors it would be easiest to implement the compliance control if the articles covered by this restriction are the same as the articles covered by the restriction on azocolourants in leather. The restriction on azocolourants in leather is limited to articles of leather which may come into direct and prolonged contact with the human skin or oral cavity, and it would be easiest for the market actors to implement the restrictions if both restrictions covered the same articles of leather.

Compared to RMO 1, RMO 2 is considered to be slightly less manageable as procedures would need to be developed for articles not covered by the existing restriction on azocolourants in leather.

E.2.2.2.2 Enforceability

For the enforcement of this restriction it would be most efficient if the restriction of chromium (VI) in leather and the restriction of azocolourants in leather covered the same types of articles.

On the other hand, it may be easier to enforce all articles being covered and no articles would be borderline between prolonged and short term contact with the human skin.

Consumers might find it difficult to understand why chromium (VI) is restricted in a bag, but not in a purse or a belt.

E.2.2.3 Monitorability

Same as for RMO 1.

E.2.3 Restriction option 3 (RMO 3) - restriction of total chromium content of leather

In this RMO, placing on the market of any article containing leather is banned if the total chromium (both chromium (III) and chromium (VI)) content of the leather is above a certain level (above the natural background level in the leather – to be defined). In practice it means that placing on the market of chrome tanned leather would be banned.

E.2.3.1 Effectiveness

E.2.3.1.1 Risk reduction capacity

This option entails the banning of all articles containing chrome tanned leather.

A variation of the restriction could be that only articles with prolonged contact with the human skin are covered by the restriction.

As discussed in section B.5.5, some studies show that even low concentrations of chromium (VI) may trigger an allergic reaction in hypersensitive individuals. The only effective protection for them against skin disorders is to avoid any contact with products containing chromium (VI). Furthermore, is has been demonstrated that chromium (III) may also cause allergic reactions though at significantly higher levels than chromium (VI). The results of the analysis of chromium content in articles of leather in section B.2.2.2 show that the concentration of soluble (extractable) chromium (III) in leather is of the order of 10-100 times the concentration of soluble chromium (VI).

This management option may therefore provide higher protection against exposure to chromium (VI) which may be of particular importance for those who already have chromium allergy. Whereas RMO 1 is estimated to provide an 80% reduction in the number of new cases caused by exposure to chromium in leather, this RMO would provide a 100% reduction.

As discussed in section B.5.1.1 the experience with the restriction of chromium (VI) in cement is that the number of incidences decreases significantly when the chromium (VI) in the cement was reduced, even though cement still contains chromium (III). This indicates that the prevention of exposure to chromium (VI) has a significant effect even though workers still are exposed to chromium (III).

E.2.3.1.1.2 Changes in the environmental risks/impacts

A change from chrome tannage to non-chrome tannage would give rise to major changes in the environmental impacts. The use of non-chrome tannage would eliminate releases of chromium from all parts of the life cycle of the leather. This would have a positive impact in particular as concern chromium in waste water from the tanneries and chromium in waste disposed from the manufacturing of leather and articles of leather as well as the disposal of the finished articles. Note that tannery waste containing chromium (III) is not included in the European Hazardous Waste List on the basis that the waste does not possess the characteristics necessary for its classification as hazardous waste (BREF, 2011).

On the other hand, non-chrome tannages have higher environmental impacts on other parameters. Section C.3 presents some data from two life cycle assessments (LCAs) comparing chrome tanned leather with non-chrome tanned leather. The conclusion is that the environmental profiles of the different processes are very different, but that neither of the processes has a significantly better environmental profile than the other overall.

The EU BREF document on the tanning sector presents recommendations for best available techniques for each of the different types of tanning processes, but does not indicate that any of the tanning processes are preferable to others.

E.2.3.1.1.3 Other issues

No other issues.

E.2.3.1.2 Proportionality

E.2.3.1.2.1 Technical feasibility

The technical feasibility of substituting non-chrome leather for chrome leather is very dependent on the application of the leather.

In the automotive sector where non-chrome leather is widely used today, the replacement of the chrome-leather has proven to be technically feasible.

For similar applications such as furniture and some garments it must be expected that the use of non-chrome leather would also be technically feasible and the chrome leather could be replaced without major changes in production equipment.

For shoes, which represent about half of leather use, chrome free leather is only used in very small quantities for special purposes. Chrome-free leather is used for some types of shoes for children.

In the processing of shoes the leather is typically treated by instant shift in temperatures and humidity in order to form the shoes and according to manufacturers chrome leather has the advantage of staying soft after the treatment. The BREF document notes that the substitution of chrome tanning has been limited because no alternative has been found which provides leathers of the same quality (BREF, 2011).

E.2.3.1.2.2 Economic feasibility (including the costs)

Cost benefits
Compared to RMO 1 and RMO 2 the costs of compliance would be significantly higher.

The costs of changes in the production processes will in the end be passed on to the consumer. Whereas for the RMO 1, the increase in price of the leather was estimated at less than 1%, the price of non-chrome leather is typically in the order of 2-6% higher than that of chrome tanned leather, but for some products the price may be even higher.

It is more difficult to prepare shoes from non-chrome tanned leather and major investment in research and development and new equipment would be needed. As a result, the increase in the price of shoes would reflect both the increased cost of the leather and the research investment. At tanneries, some investments would be needed for changing from chrome tannage to non-chrome tannage. The equipment used is broadly the same, but as the non-chrome tannage in general is a lengthier process, there might be a need for increasing the capacity of the equipment.

A major supplier of chemicals for the sector expects that the most significant changes would be changes in waste water treatment systems, modifying the treatment systems that can separate chromium to systems with higher capacity for treatment of the organic tanning substances which are relatively difficult to degrade.

The costs related to chemicals and new investments of implementing RMO 3 are likely to be 5-10 times higher than the costs of RMO 1 and RMO 2. In addition there might be costs for training employees for the new production processes and costs of developments and optimization of production processes, whereas the benefits may only be slightly greater and the marginal costs could exceed the marginal benefits.

The burden of compliance control may be less for importers, as screening analysis would be cheaper and after a run-in period, less frequent spot checks may be justifiable.

If chrome tanning is restricted, chromium (VI) would only be present in leather, if tanneries are in deliberate non-compliance and deliberately provide misleading information to importers.

Chromium (VI) may be formed in chrome tanned leather during storage and transport and non compliance may be due to improper process control and poor practices (but not by deliberate attempts to mislead) and it may be necessary to make more frequent spot checks even from trusted manufacturers of leather or articles of leather.

Timing
Compared with RMO 1, it is expected to take significantly longer to change the whole tanning industry in Europe to non-chrome tannage and before manufacturers of articles of leather (in particular shoe manufacturers) can use exclusively non-chrome tanned leather.

E.2.3.2 Practicality

E.2.3.2.1 Implementability and manageability

Compared to RMO 1 and RMO 2 the implementation would be more difficult. Many market actors would probably find the costs of implementing the RMO 3 restriction to be disproportionate to the benefits achieved by in comparison with RMO 1 and RMO 2.

Whereas RMO 1 and RMO 2 would have little effect on the balance between small and large tanneries, a restriction on chrome tannage may in particular impact the smaller tanneries, and may accelerate the process of closing small tanneries that is already in progress. Many European tanneries and manufacturers of articles of leather are specialised in providing sophisticated high-end products, and by a shift to chrome-free tannage it may be difficult in particular for smaller, specialised companies to be compatible on the market.

E.2.3.2.2 Enforceability

A general ban on chromium in leather would be easier to enforce, as non-destructive screening methods can be applied for screening articles for the presence of chromium. A non-destructive screening test using a portable XRF instrument often used by competent authorities for testing heavy metals in bijouterie and electronic equipment could be used for screening tests, if necessary followed up by laboratory tests on the event of non-compliance. As the total chromium content of chrome tanned leather is typically more than 1 percent, the detection limit of the XRF instrument would be sufficiently high for screening purposes.

E.2.3.3 Monitorability

Same as for RMO 1.

E.3 Comparison of the risk management options

Table 38 provides an indicative qualitative scoring of the three risk management options against each of the criteria and parameters. This is based on a simple appraisal of whether each of the options is likely to be suitable and its degree (high, medium, low) of suitability.

It should be stressed that the scores for different parameters do not have equivalent values. E.g. a "3" in effectiveness cannot be compared with a "3" in practicability. However the table gives an impression of the areas where the different RMOs might differ.

TABLE 38 COMPARISON OF THE THREE DISCUSSED RMOS

Criterion	Parameter	RMO1 (proposed)	RMO2	RM03
		Chromium (VI) in articles of leather with direct and prolonged contact with the human skin	Chromium (VI) in all articles of leather	Chromium in all articles of leather
		Score	Score	Score
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

Note: The score is between 1 and 3, where "3" represents the highest level of suitability.

The following can be concluded:

- The differences between RMO 1 an RMO 2 are small and the overall score of RMO 1 is only slightly higher than the score for RMO 2

- RMO 3 has a higher score for risk reduction capacity, but scores significantly lower on proportionality and implementability.

F. Socio-economic assessment of the proposed restriction

F.1 Human health and environmental impacts

F.1.1 Human health impacts

Human health impacts of chromium (VI) are described in section B.5. The main health impact from leather exposure is dermal contact and development of chromium allergy which is described in detail in section B.5.5.1. An induction threshold for chromium (VI) allergy is difficult to define, but from experience in the construction industry and among cement workers it is well known that levels of 10-20 mg/kg soluble chromium (VI) in the cement has caused sensitisation with a prevalence of about 4-5% of the exposed population (Shelnutt *et al.*, 2007).

Minimum elicitation thresholds ($MET_{10\%}$) which will elicit an allergic response in 10% of already sensitised individuals are found to be in the range of 0.02 to 0.9 μg/cm^2/2 days in different studies from the period 1983 to 2003 (Johansen *et al.*, 2010). As a conservative estimate a LOAEL (or DMEL-value) of 0.02 μg/cm^2/2 days was established based on the lowest identified $MET_{10\%}$. Other studies have shown that elicitation can occur at even lower levels.

On the basis of the available data it is estimated that at 0.2-0.7% of the population of the EU have chromium allergy.

In section B.5.5.1 the total number of new cases of chromium allergy in the EU is estimated at 44,000 each year based on data on the prevalence of chromium allergy in the general population in Denmark. Of the new cases, it is estimated that approximately 45% are due to exposure to leather, and the total number of new cases caused by leather can be estimated at approximately 20,000 per year.

The effect that the restriction would have on the number of new cases is difficult to estimate as the restriction is not considered to be 100% effective because articles of leather in compliance still may contain chromium (III) and low concentrations of chromium (VI) (below 3 mg/kg). As discussed in section B.5.5.1 the best estimate of the effectiveness of the restriction is assumed to be 80%.

With 80% effectiveness, the number of new cases that could be avoided can be estimated at 16,000 per year. It is, however, assumed that some 3000 cases would be avoided by the newly introduced German restriction, and consequently these cannot be attributed to the proposed restriction. On this basis, for the valuation of health impact it will be assumed that the number of new cases of chromium allergy is reduced by 13,000 per year as consequence of the restriction.

F.1.1.1 Valuation of human health impact

The valuation of the quantified number of cases indicated above is based on a valuation study which included contact allergy among several chemical related diseases (COWI, 2004). It should be noted that monetary valuations of health and environmental impacts are subject to significant uncertainty. This study presents a comprehensive assessment and by updating relevant key unit costs to the current price level and to reflect a EU27 average, an order of magnitude monetary value of the health benefits has been estimated.

The COWI (2004) study presents an estimate of the costs of contact allergy. The effects of chromium allergy are more severe and some of the key assumptions have been adjusted. These adjustments are based on expert judgement by Professor Torkil Menné, Gentofte University Hospital, Denmark who is a leading international expert on contact allergy.

The COWI (2004) estimates in DKK have been adjusted to prices of 2010 (16% increase), converted to EUR using a conversion factor 7.4 DKK per EUR and finally adjusted to EU27 price level using the PPP (purchasing power parity) indicator (EU27 price level is 70% the Danish price level). The data have been retrieved from Eurostat (consumer price indexes and comparative price levels).

The valuation of the health impacts includes the following cost elements:

- Health sector costs (GPs (General Practitioners) and hospitals);
- Medication costs (for the affected individuals);
- Production losses (costs of lost working days);
- Welfare costs.

The key assumptions on the health sector costs are presented in table 39. The costs are estimated for establishing a single diagnosis of contact allergy and for one year's treatment of a person with contact allergy.

The assumptions for an average person who is diagnosed with contact allergy are:

- Age: 40 years at time of the diagnosis (based on expert judgement);
- Average expected remaining lifetime: 42 years.

The specific assumptions regarding visits to the GP and specialist doctors and the unit costs of such visits are presented in Table 39.

TABLE 39 ASSUMPTIONS ON COSTS OF ESTABLISHING THE DIAGNOSIS

Service	**Number**	**Costs, €**	**Total costs, €**
Diagnosis at GP			
GP Consultations	2	12	24
Allergy test	1	19	19
Total costs			43
Percentage of patients at GP	70%		
Expected costs of diagnosis at GP			**30**
Diagnosis by Specialist (MS) (Dermatologist)			
1st consultation MS	1	55	55
2nd consultation MS	1	30	30
Subsequent consultations MS	2	15	30
Other services	1	8	8
Total costs			123
Percentage of patients at MS	29%		
Expected costs of diagnosis by Specialist			**36**
Diagnosis at Hospital Out Patients clinic			
Visit to Out Patients clinic	3	147	441
Other services	1	33	33
Total costs			474
Percentage of patients at Hospital ***Out Patients clinic***	12%		
Expected costs associated with Hospital *Out Patients clinic*			**57**
Direct total costs			**123**

GP: General Practitioner

Sources: COWI, 2004. (Cost data are adapted to EU27 level in 2010 prices as explained in the body text).

Based on the assumptions presented in Table 39, the costs of establishing one diagnosis are estimated at around 123 €.

Table 40 indicates the annual costs of visits to the GPs and specialists and the patient's costs for medication (ointments, lotions, creams, etc.).

The annual costs for GPs and hospital costs are about 109 €. With an expected remaining life time of 42 years, the undiscounted value of this cost element is about 4,600 €. Using the recommended EU discount rate of 4%, the discounted value is 2,200 €.

It is assumed that each patient has monthly average expenses for ointments, emollients and topical steroids of a little more than 30 €. This is 363 € per year and with an expected remaining annual life time of 42 years the undiscounted value of this cost element is about 15,250 €. Using the recommended EU discount rate of 4%, the discounted value is 7,300 €.

TABLE 40 ASSUMPTIONS ON ANNUAL COSTS OF TREATMENT OF ONE PATIENT

Service	**Number**	**Costs, €**	**Total costs, €**
GP Services			
GP Consultations	2	12	24
Total costs			24
Percentage of patients at GP	70%		
Expected GP costs			**17**
Services of specialist doctors (Dermatologist)			
1st consultation MS	1	55	55
2nd consultation MS	1	30	30
Subsequent consultations MS	2	15	30
Total costs			115
Percentage of patients at MS	10%		
Expected Specialist costs			**12**
Hospital out patient services			
Out patient visit	2	147	294
Total costs			294
Percentage of patients at Hospital out patients clinic	2.8%		
Expected costs at Hospital Out patient clinic			**8**
In- Patient Hospital Services			
Average costs per discharge	1	2,580	2,580
Percentage of patients	2.8%		2,580
Expected costs of Hospital Services			**72**
Total costs of health care services			**109**
Medication			
Topical steroids	1	27	27
Percentage of patients using topical steroids	69%		
Total costs of topical steroids			19
Specialists (MS) Dermatologist	12	5.5	66
Percentage of patients using emollients	85%		
Total costs of emollients			56
Lotions etc	12	24	288
Total costs of medication etc.			**363**
Direct total costs			**472**

GP: General Practitioner

Sources: COWI, 2004 (Cost data is adapted to EU27 level in 2010 prices as explained above.)

The next cost element to be valued is the possible loss of production value due to restricted activity days. It is based on expert estimates assumed that a person with contact allergy on average is absent from work 7 days per year. The costs associated with this absence from work are estimated based on average EU salaries[17]. It is assumed to be 170 € per day so the total production loss per year is 1,190 €. With an expected remaining number of work years of 25 years, assuming an average retirement age of 65 years, the undiscounted value of this cost element is about 29,750 €. Using the recommended EU discount rate of 4%, the discounted value is 18,590 €.

[17] Eurostat Labour Costs Survey 2008 and Harmonised indices of consumer prices (HICP). EU27 labour costs at 21.84 EUR per hour in 2008 and price index of 3% increase from 2008 to 2010. Assumed 7.5 hours per day.

The last cost element is the individual's loss of welfare due to the discomfort of having contact allergy. There are no specific studies on the individual's willingness to pay (WTP) for avoiding this disease. The reference study of COWI (2004) includes a discussion of using the benefit transfer approach, and on this basis the study suggests applying a WTP to avoid a symptom day as value indicator. The value for WTP applied in the COWI (2004) study was approximately 15 € per day. Later studies on valuation of health impacts indicate that this value could be higher. At EU level, studies in relation to air pollution and air quality suggest that symptom day could be valued at up to 38 € as the WTP for avoiding a symptom day (AEA Technology Environment, 2005). This suggests that the applied WTP is very conservative and hence no need to apply a lower value in the sensitivity assessment.

The number of symptom days will vary from one individual to another. The COWI (2004) study assumed that the number of symptom days for an average person with contact allergy is 73 days (20% of a year). Chromium allergy is a very severe contact allergy so the number of symptom days has been reassessed.

Two factors have been considered. Firstly, the number of symptom days is likely to be higher than the COWI (2004) study estimate given that chromium allergy is a very severe form of contact allergy and secondly, that patients with a chromium allergy may be able to avoid some exposure to leather and over time their symptom days could be reduced. It is on the basis of Danish experience assumed that the number of symptom days will gradually decrease over a 20 year period from an initial level of 200 days per year to 100 days per year and then remain at 100 days per year for the rest of the patient’s life.

In terms of calculation of the welfare loss, an average number of symptom days over a lifetime have been applied. The average number of symptom days is 125 based on the above assumptions of an initial level of 200 days per year which gradually decreases to about 100 days per year.

This means that the total annual welfare loss is 1,875 € and the discounted welfare loss over the remaining lifetime of 42 years can be estimated at 37,850 €. Table 41 provides an overview of the cost elements and the total values for a single case of contact allergy over the patient’s remaining lifetime.

TABLE 41 COSTS PER CASE OF CONTACT ALLERGY - ANNUAL AND DISCOUNTED VALUES OVER REMAINING LIFETIME

Cost elements	**Annual costs in € per case**	**€ per case of contact allergy (discounted over life time)**
Direct costs (health care and medication)	472	9,650
Indirect costs (production loss – lost working time)	1,190	18,590
Welfare loss	1,875	37,850
Total costs	3,537	66,090

Table 41 shows that the costs associated with one case of chromium allergy are significant and that it is the indirect and welfare costs which comprise the main elements. Hence, the key assumptions relate to:

- Loss of production, based on the assumption of 7 days absence from work per year; and
- The welfare loss, based on the assumptions of initially about 200 days per year with "symptoms" and that the number of symptom days will gradually decrease over a 20 year

period from 200 to 100 days per year and then remain at 100 days per year for the rest of the patient's life.

The production loss estimate is a cautious and conservative estimate given that chromium allergy is severe form of contact allergy and no specific sensitivity assessment is made. For the welfare loss, the sensitivity assessment presented in section F.6 includes an alternative calculation using as a lower number of symptom days 50% of the 125 days equal to about 63 days.

If the restriction leads to fewer allergy attacks for those already diagnosed, this would also leads to a reduction in costs. This is assumed to affect only the welfare loss. It is assumed - based on expert judgement[18] - that the number of symptom days per year is reduced by 50% for those already diagnosed with chromium allergy. Instead of having the average of 125 symptom days per year, they might only experience about 63 days with allergic symptoms due to chromium (VI) exposure. It means that for those already diagnosed with chromium allergy, the annual saving due to the proposed restriction will be 940€ per person.

Using the data presented above in section F.1.1, an estimate of the benefits of the restriction proposal can be made. As indicated, the proposed restriction will lead to approximately 13,000 fewer new cases each year. The fact that Germany has already introduced legislation similar to the proposed restriction is being taken into account by assuming that the effect on the number of new cases in Germany will also occur in the baseline and hence not be attributed to the proposed restriction.

The estimation includes the following types of effects:

- The cost savings from avoided cases (constant number per year of avoided cases which leads to increased accumulated cost savings)

- The costs savings from reduced symptom days for existing cases (over time the number of existing cases decrease and therefore this cost saving element is decreasing over time)

Table 42 presents the assumptions and the cost savings for the initial year of the proposed restriction and for year 20.

TABLE 42 ASSUMPTIONS AND ESTIMATED MONETISED ANNUAL HEALTH BENEFITS OF THE RESTRICTION PROPOSAL

	Effects in year 1	**Effects in year 20**
Number of contact allergy cases avoided per year	13,000 [1)]	13,000 [1)]
Number of existing cases	1,537,000	1,279,000
Saved cost of avoided new cases (in million euro)	46	920
Saved cost of avoided symptom days for existing cases (in million euro)	1,437	1,120
Total health benefits (= saved costs) (in million euro)	1,483	2,040

[1)] Estimated that 3,000 cases are due to the German restriction

These annual health costs under the baseline and the proposed restriction are illustrated in Figure 3. It is assumed that the number of new cases of chromium allergy would already be reduced from the first year of the restriction being in force. The fraction of the population with chromium allergy will gradually decrease given that the number of new cases is reduced by about 40%. After

[18] Professor Torkil Menné, Gentofte University Hospital

approximately 42 years the level will stabilise at about 60% of the current level. The baseline costs are expected to decrease as consequence of the current German restriction.

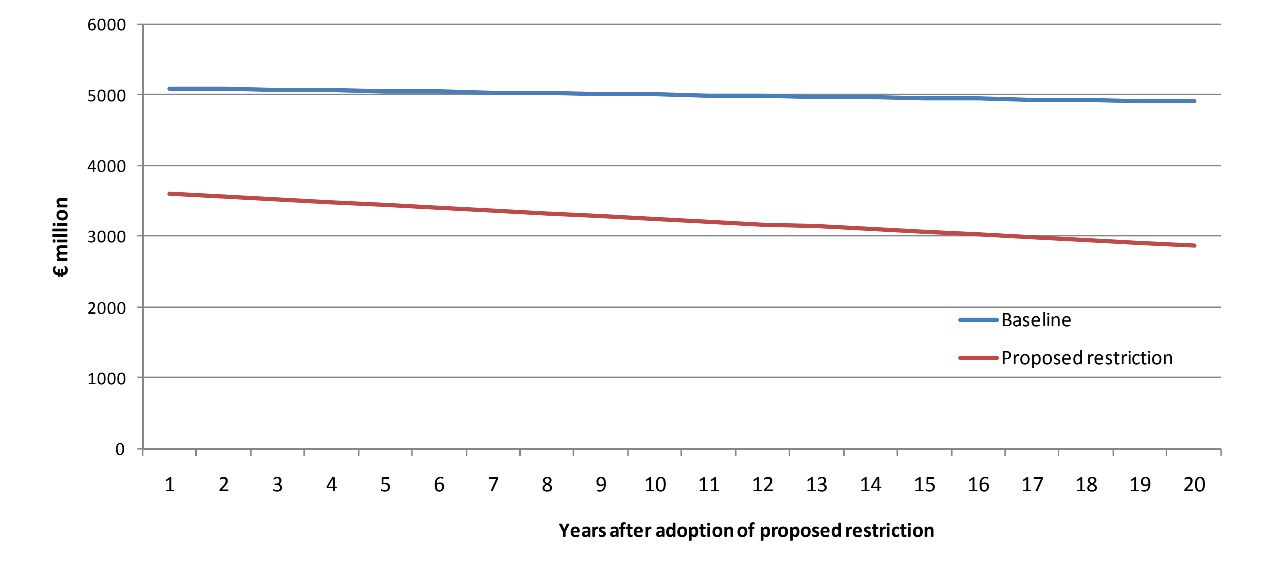

FIGURE 3 DEVELOPMENT IN HEALTH BENEFIT SAVINGS FOR THE BASELINE AND UNDER THE PROPOSED RESTRICTION

The annual saving expected after implementing the proposed restriction will be about 1,500 €m in the first year with savings gradually increasing over time.

F.1.2 Environmental impacts

The risk addressed is focused on the human health effects. The relatively small quantities of chromium (VI) formed in the leather are estimated to contribute insignificantly to the total environmental load of chromium (VI) from human activities.

F.2 Economic impact

F.2.1 Compliance costs

The compliance costs are described for:

- The modified tanning process;
- Reconditioning of articles of leather;
- Testing of articles of leather for chromium (VI) content.

These are the activities that could involve additional costs. Subsequently, it is discussed how these costs are distributed and passed on down the supply chain.

Costs of process changes

The main cost impact is from the additional use of chemicals in the post tanning and finishing processes. From consultations with industry, the overall indication is that many EU tanneries have already implemented measures to eliminate the chromium (VI) content in their leather. The measures have been implemented widely in Europe on a voluntary basis during the last decade. The recent restriction in Germany has been an additional incentive for the implementation of the measures.

There might be some tanneries that have not yet made the change to their production process. In order to illustrate the possible costs, an order-of-magnitude estimate of the cost difference between conventional chrome tannage and chrome tannage optimised for prevention of the formation of chromium (VI) is summarized in Table 43. As many tanneries outside Europe may not have implemented these measures, the estimate may also be used as background for estimating the possible increase in the price of imported leather as a consequence of the proposed restriction.

TABLE 43 KEY ASSUMPTIONS FOR ASSESSING COSTS OF PREVENTION OF CHROMIUM (VI) IN LEATHER

Assumption	Share/change	Costs in € per m^2
Unit turnover		30.0
Cost of chemicals out of total production costs	10%	3.0
Increase in cost of chemicals (in % of total chemicals)	5%	0.2
Cost increase per m^2 of tanned leather	**0.5%**	**0.2**

The turnover estimate per m^2 of tanned leather is based on the data from COTANCE shown in Table 11.

Chemicals account for about 10% of the total production costs. This is based on information from the BREF (2011) and from consultation with Industry. The total sales from chemical suppliers to EU tanneries suggest the same order of magnitude.

The modification of the post tanning and finishing process to avoid formation of chromium (VI) is estimated to increase the total cost of chemicals in the tanning process by no more than 5%, see Section C.2.5[19]. Based on these data the expected increase in the production costs of tanned leather is estimated to be in the order of 0.2 € per m^2 or equivalent to an increase of 0.5%.

The price of the finished leather article will be higher than the cost of the tanned leather used to produce the article. In the case of articles in the high end market, the price of the article will be significantly higher than the costs of the leather used to produce the article. An increase of 0.5% in the price of the leather (accounting for a minor part of total manufacturing costs), consequently will result in an increase in the price of the finished article which is significantly below the 0.5%. Hence, the increase in the price of the finished article as consequence of preventing chromium (VI) in the leather, will be less than 0.2% and may even be much less.

The price of tanned leather accounts for a relatively minor proportion of the cost of a finished leather article (especially a high end article). This means that a 0.5% increase in the price of the leather (to cover the prevention of chromium (VI) will only have a small impact on the price of the finished article (an increase of 0.2% or less may be expected).

Increased price of imported articles of leather

The impact on the price of imported articles of leather is determined by several factors. The most important factors include:

- The costs to the outside EU producers of complying with the reduced chromium (VI) content; and
- The market situation (competition to supply the EU market).

[19] Editorial correction by the dossier submitter after submission of the dossier.

External producers of articles for the EU will face the same additional cost of the chemicals required to prevent the formation of chromium (VI) as producers within the EU. There could be additional start-up costs for improving the production process to achieve better housekeeping that is necessary for compliance. This could include training of their staff, building up compliance procedures, etc.

The market situation might stop producers outside the EU from passing on their additional costs and therefore the EU importers would not have to pay more for articles of leather that comply with the restriction.

The further assessment is based on the assumption, that the cost impact on imported articles can be estimated in a way similar to the estimation of the compliance costs for the EU tanning industry.

As described above, it was estimated that the possible cost increase would be around 0.5% of the total costs of the tanned leather based on the EU data. As the imported articles of leather are cheaper - lower quality/design etc - the relative cost impact on imported articles of leather could be higher. If the absolute cost increase, due to the need for additional chemicals, is the same for the articles of leather produced outside EU as for the EU tanned leather, the relative cost increase could be estimated using the difference between the prices of exported and imported articles of leather. From Table 14, the price per tonne of imported and exported articles of leather can be estimated. The exported articles are more than 3 times as expensive as the imported articles. Therefore, the price of the leather content of the imported articles might increase by 1.7%. As argued above, the cost of the finished article is much higher than the cost of leather used to produce it, so the impact on the price would be less than the 1.7%. The data on the EU leather goods industry suggests that the leather material input comprises around 25% of the production value. This leads to an estimate of the impact on the price of imported articles of leather around 0.4%.

Costs of reconditioning

Any imported articles of leather that are not in compliance with the requirement on the chromium (VI) content, could be reconditioned by the importer to make them compliant. It has not been possible to estimate the costs of reconditioning of imported articles. There is currently a small market for reconditioning of articles of leather. Reduction of chromium (VI) in the articles of leather is only one of many activities carried out during reconditioning. Market actors state that reconditioning is necessary only if the measures for prevention of chromium (VI) are not applied and reconditioning cannot therefore be considered an extra cost.

Costs of compliance control

Testing the finished leather or the leather article would cost in the order of 250 € per test. The impact on the price of finished articles depends on the testing frequency and the price of the finished articles. Some illustrative examples are shown in Table 44.

TABLE 44 RELATIVE PRICE IMPACT ON ARTICLES DUE TO COSTS OF COMPLIANCE CONTROL - ILLUSTRATIVE EXAMPLES

Test frequency	Relative impact on the price of articles in %	
	Average price of articles: 15 €	Average price of articles: 100€
1 per 1000 articles	1.67%	0.25%
1 per 10,000 articles	0.17%	0.03%

The relative impact is very moderate except for low-value imported articles requiring a high test frequency.

The possible total costs of testing during the whole supply chain can be roughly estimated on the basis of information on the current costs of chromium (VI) testing as described in section E.2.1.2.1. Based on information from test laboratories and other sources it is estimated that the market for chromium (VI) tests in Germany is likely in the order of magnitude of 1-3 €m per year. Furthermore, one large manufacturer of shoes stated that the total costs of chromium (VI) testing in the whole supply chain of the shoe production is approximately 0.5 €m. This will not be impacted by an EU wide restriction, but if the German data are extrapolated to the whole EU, it can be estimated that the total costs of testing for chromium (VI) would be in the order of magnitude of 5-15 €m per year.

As specific restrictions at EU level for azocolourants and PCP in leather exist, all actors in the supply chain have procedures for providing and requesting information on compliance to chemical regulation. For many actors, chromium (VI) is already part of the substances restricted in the articles. It is estimated that there will be no extra costs of training, capacity building, development of systems for compliance control, etc. of the proposed restriction.

Total costs impacts

The total cost impacts for the EU industries can be roughly estimated.

Based on the data in Table 11 (Overview of the tanning section in EU), the total turnover in the tanning industry is indicated at 5.25 billion €. Other data suggest turnover in the EU27 tanning industry at 9 billion €. The estimated increase in production costs of 0.5% would mean total costs in the tanning industry at the level of 26 €m to 45 €m per year. The industry has indicated that many tanneries already have adopted the processes to the reduced chromium (VI) content. It is assumed that in the worst case, only one-third of the tanneries still need to modify their production process so the best estimate of the direct cost impacts to the EU tanning industry is 8 to 15 €m.

Using the above estimate for the relative increase in costs of imported leather and articles of leather to ensure compliance with the restriction, the total impact on importers of leather and articles of leather could be in the order of 70 €m per year. The value of imported leather and articles of leather is around 16.4 billion € and the price increase is estimated to 0.42 % which leads to additional costs of 70 €m.

Finally, the additional testing costs have been estimated at 5 to 15 €m per year.

F.2.2 Loss of export revenue

In the part of the EU tannery industry where the production processes are not already modified, the estimated impacts on the tanned leather and on leather goods/articles is very limited - 0.5% of production costs or less. It means that it is unlikely that this will affect the export of leather or leather goods. EU export is mainly of high quality products where the price of the article is not the main parameter and here, the cost increase would be much less than the 0.5%. Furthermore, as the measures for preventing the formation of chromium (VI) are already implemented in most tanneries and by major manufacturers of articles of leather, the proposed restriction would have no impact on the price of exported articles.

In principle, the exporters of leather and leather goods could still export articles with chromium (VI), but it is very unlikely that this would happen as it is currently considered standard for quality articles not to contain chromium (VI).

No loss of export revenue is therefore expected.

The proposed restriction could have a positive impact on the competitiveness of the EU industry as it has already to a large extent adapted to the requirements. It might take some time before the producers of the imported leather or articles of leather have adapted their production which might lead to increased EU production. This effect has not been quantified.

F.2.3 Administrative costs

There should be no additional administrative costs to industry. The administrative costs are those related to reporting requirements, but this restriction does not include any additional reporting requirements. The importers are likely to require documentation that the imported articles comply and this cost will be borne by the foreign producers. As procedures are already implemented for azocolourants in the leather, the extra documentation costs will be minor. It has not been estimated and in many cases it might have no effect on EU importers and hence on EU consumers.

There are also very limited additional costs for the competent authorities.

F.2.4 Overview of economic effects

Table 45 summaries the main economic impacts on different actors in the supply chain for articles of leather.

The first column indicates possible additional production and compliance costs. The second column presents the distribution of the costs based on the expected pass-through of the costs.

The total additional costs could be of the order of 85 to 100 €m per year. This estimate comprises the costs to EU tanneries of 8-15 €m for additional chemical costs, about 70 €m to importers of leather and articles of leather and finally 5-15 €m for additional testing both related to EU production and to imported leather and articles of leather.

The incidence of these additional costs can not easily be estimated. It will depend on the market situation for each type of leather and article of leather. In many cases the additional costs would be passed on to the final consumer, while in other cases the industry would have to accept reduced profits.

TABLE 45 SUMMARY OF ECONOMIC IMPACT ON DIFFERENT ACTORS

Actor	Direct cost impacts	Distribution of costs - impacts on sales etc
Manufacturers and suppliers of chemicals for chrome tannage	No additional costs	Possible increase in demand for auxiliary chemicals for the tanning process Possible small decrease in the demand for chemicals for chrome tannage
Manufacturers and suppliers of chemicals for chrome-free tannage	No additional costs	Possible increase as the demand for auxiliary chemicals for the tanning process Possible small increase in the demand for chemicals for non-chrome tannage
Tanneries involved in beamhouse and tanyard processes	No additional costs	No impact
Tanneries involved in post tanning and finishing	For most tanneries: No additional costs For tanneries which have not yet implemented the measures: Increase in production costs due to additional chemical use - costs of chemicals to increase by around 5% this would increase cost of tanned leather by less than 1% + additional costs of testing products	No impact Given that the EU tanneries supply high quality leather used for high quality products, it is likely that they can pass through the costs
Importers of leather	Additional cost of testing leather	Additional costs of tanned leather - less than 1%
Manufacturers of articles of leather (shoes, garments, etc)	Additional cost of testing leather and articles	Additional costs of tanned leather - less than 1%
Importers of articles of leather	Additional cost of testing of articles of leather Costs of reconditioning of articles of leather if suppliers can not comply, or change supplier	Additional costs due to increased costs of tanned leather
Companies involved in reconditioning of articles of leather	No additional costs	Increased demand from importers of articles of leather if their suppliers can not comply and alternative suppliers will be more expensive
Laboratories	No additional costs	Additional turnover from increased demand for tests
End-users of articles of leather	No additional costs	Potentially higher price - though likely to be less than 1% increase

F.3 Social impacts

F.3.1 Potential for loss of employment

The possible price increase on EU production of tanned leather or articles of leather is very moderate and will not decrease the EU production. It could be that producers outside EU would face difficulties of compliance and hence, the production in EU could increase. If there is going to be an impact on the level of employment, it could be a small increase because the restriction gives EU producers a competitive advantage.

F.3.2 Changes in price for end users

The impacts on consumers of leather goods will be very moderate - below 0.5% of the price of the leather goods.

F.4 Wider economic impacts

No wider economic impacts is expected. The increase in production costs for the tanning sector is not of a magnitude that could generate measurable macro-economic impact.

F.5 Distributional impacts

As illustrated in Table 45, the additional costs associated with reducing the chrome (VI) content is likely to be passed on to the consumers of leather goods.

As the technical measure does not require any investment but is a modification of the production process and changes in the use of chemicals, there should not be a particular issue for SMEs. Indications from industry suggest that most European tanneries have already made the changes to their production process.

F.6 Summary of the socio-economic impacts

The below figure illustrates the costs and benefits of the proposed restriction over a 20-year period.

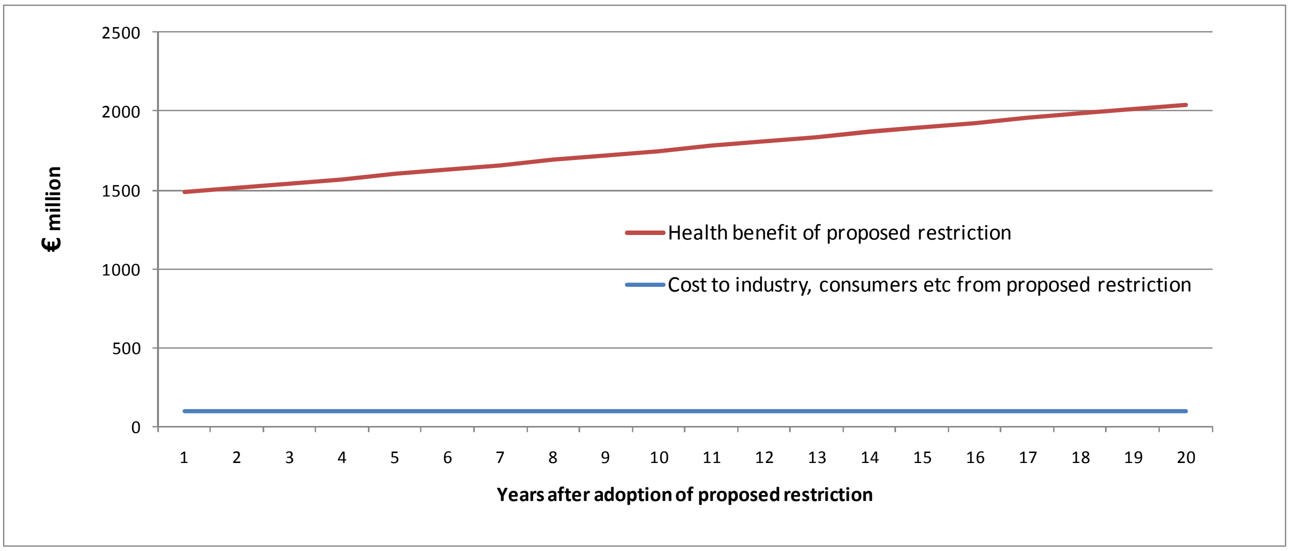

FIGURE 4 DEVELOPMENT IN HEALTH BENEFITS AND COSTS TO INDUSTRY AND CONSUMERS UNDER THE PROPOSED RESTRICTION

The net benefit of the proposed restriction is significant and growing over time. The health benefits will initially be around 1,500 €m and gradually grow as the prevalence of chromium allergy in the EU27 population decreases. With estimated costs of the restriction proposal in the order of 100 €m the net benefit is substantial.

Assessing the sensitivity of the assessment to the key data and key assumptions that have been applied further support this conclusion.

The following sensitivity calculations have been carried out:

- Reducing the prevalence of chromium allergy to 0.20% in the population;
- Reducing the effect of the proposed restriction from 80% to 40%;
- Reducing the welfare costs element by 50% (assuming less symptom days or lower value per day);
- Increasing estimated industry costs by 100%.

The combined effects of these alternative assumptions are estimated below. Even if this case which could be considered a "worst case" scenario in relation to net benefits of the proposed restriction, the estimated benefits are significantly higher than the costs. The assumptions in the "base case" are already conservative so this sensitivity calculation demonstrates the robustness of the assessment.

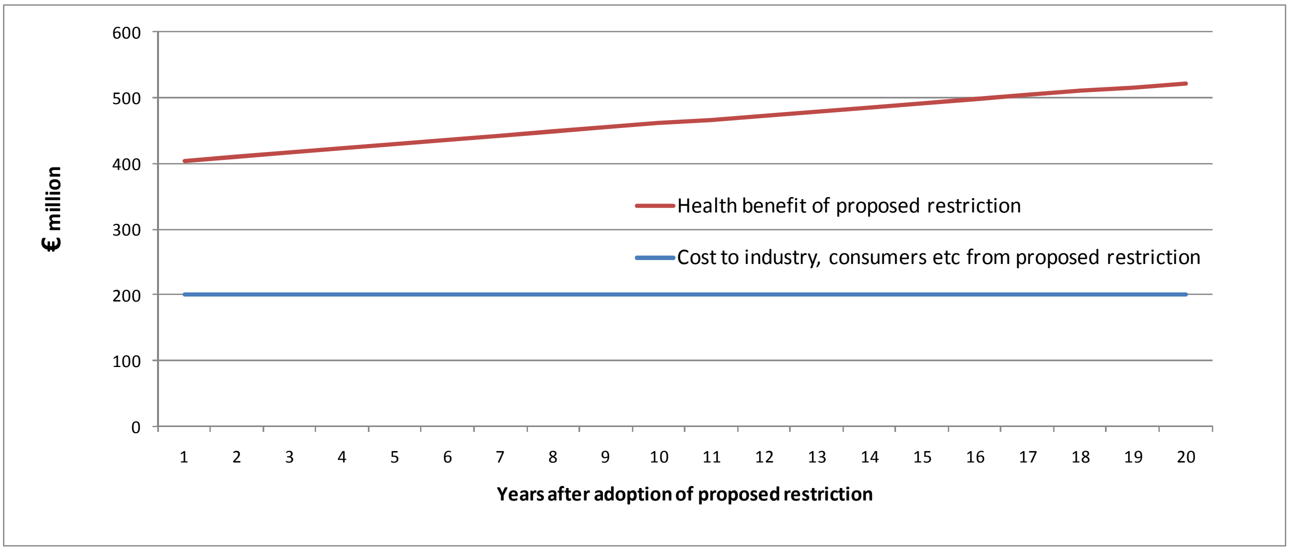

FIGURE 5 DEVELOPMENT IN HEALTH BENEFITS AND COSTS TO INDUSTRY AND CONSUMERS UNDER THE PROPOSED RESTRICTION. SENSITIVITY SCENARIO WITH "WORST CASE" ASSUMPTIONS IN RELATION TO NET BENEFITS

G. Stakeholder consultation

G.1 Industry

In order to obtain information on the manufacture of leather and articles of leather and the possible impact of the restriction of chromium (VI) in leather on the industry, a number of European trade organisations were contacted during the autumn of 2011. The stakeholder consultation was undertaken by a consulting company, COWI A/S (Denmark) which was also responsible for the assessment of the obtained information.

For the stakeholder consultation, a questionnaire was developed for tanneries and for users of leather for production of articles of leather. The questionnaire was sent to the trade organisations mentioned below.

The Confederation of National Associations of Tanners and Dressers of the European Community (COTANCE) is the representative body of the European Leather Industry. COTANCE also acts as the coordinating body for GERIC, the Grouping of European Leather Research Institutes, which gathers all the technological centres of the EU developing R & D for the tanning industry. The members of COTANCE are National associations of tanners in 13 Member States, Norway and Switzerland. COTANCE informed that a restriction would not have any significant impact on the tanning sectors and the companies across Europe had already implemented measures for the prevention of the formation of chromium (VI). In agreement with COTANCE it was decided not to send out extensive questionnaires to the tanneries, but to obtain information on applied and alternative techniques from the sector's technical centres and major suppliers of chemicals and tanning systems for the sector. For this data collection more targeted questions were developed.

Euratex, the European Apparel and Textile Confederation, responded stating that their organisation did not represent the leather sector and made reference to COTANCE. CEC, The European Confederation of the Footwear Industry, did not respond to the request.

Considering the fact that Italian companies represent more than half of the European production of leather and articles of leather, three Italian trade organisations were contacted: UNIC (tanning sector), A.N.C.I. (footwear sector) and Aimpes Servizi s.r.l. (leather goods sector). UNIC (Unione Nazionale Industria Conciaria) answered in accordance with the answer from COTANCE, that measures were implemented all over Europe. Aimpes Servizi s.r.l. made reference to UNIC. A.N.C.I. did not answer.

In order to obtain information on applied techniques and alternatives four large producers of chemicals for the sector were contacted: BASF, Lanxess (BAYER), CLARIANT, and TFL. The companies were asked to assist in providing information relevant for this study by use of a questionnaire. Lanxess kindly organised a visit for the consultant and the Danish EPA to the company's pilot tannery in Leverkusen. The companies jointly responded through the German association TEGEWA e.V. TEGEWA comprises of manufacturers of the following: Textile, paper, leather and fur auxiliaries and colourants, surfactants, complexing agents, antimicrobial agents, polymeric flocculants, cosmetic raw materials, pharmaceutical excipients and allied products. The producers also assisted in the interpretation of the different questions regarding technical aspects of the dossier.

Three research institutions which have been involved in chromium (VI) research and perform tests of chromium (VI) were contacted in order to obtain more information on test methods, formation of chromium (VI) in leather and costs of analysis: Prüf- und Forschungsinstitut Pirmasens e. V (Germany), Lederinstitut Gerberschule Reutlingen (Germany, now closed) and BLC Leather Technology Centre (U.K.). Costs of analysis were further obtaining from a large all-round laboratory.

For information on the possible impact of the restriction on the trade of articles of leather EuroCommerce was contacted. The organisation represents the retail, wholesale and international trade sectors in Europe. The organisation did not respond.

For the understanding of the current practice of companies involved in the manufacturing and trade of leather and articles of leather as to internal requirement regarding chromium (VI) in leather and control of articles, a number of companies, mainly in Denmark, were interviewed. Considering the need for confidentiality, certain specific data from individual companies have not been given with specific reference to the source. Considering that relatively few companies within each sector were contacted, the companies' names are kept confidential.

The stakeholder consultation did not address any NGOs. Apart from the visit to Lanxess no workshops/bilateral meetings were organised by the Danish EPA in the course of the consultation, due to the fact that the Industry did not expect any difficulties in meeting the requirements of the restriction.

The German Federal Environment Agency and the German Federal Institute for Risk Assessment (BfR) provided background information on the current German restriction of chromium (VI) in articles of leather.

G.2 Member States and EEA

In addition to the stakeholder consultation addressing the market actors, the Danish EPA circulated a discussion paper on risk management options and a request for information to Member States and the EEA representatives. The following questions were asked:

1. Are there other uses or exposures to hexavalent chromium compounds that the ones listed in the RMO analysis, which could give rise to mutual concern?

2. Are you aware of whether epidemiological data on chromium allergy is available in your country?

3. Is there any additional information on national measures – planned or already in place - that have been taken in your country regarding hexavalent chromium in various articles, and how effective are these measures in reducing the risk to consumers?

4. Do you have any comments to the proposed approach taken?

Comments and answers were received from Belgium, Germany, Italy, the Netherlands, Norway, Sweden and UK. Comments and answers have to some extent been incorporated in the proposal.

H. Other information

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Appendix 1 Chromium (VI) substances and ions

The following list includes identified chromium (VI) substances and ions.

EC No	CAS No		Substance Name
-	1189-85-1	+6	tert-Butyl chromate(VI)
-	1308-09-4	+6	Cupric chromium oxide
215-159-3	1308-31-2	+2	Chromite
215-607-8	1333-82-0	+6	Chromic trioxide
215-693-7	1344-37-2	?	C.I. 77603; Chromium orange
215-694-2	1344-38-3	?	C.I. Pigment Orange 21
-	1344-74-7	?	Copper zinc chromate oxide (Cu15Zn10(CrO4)6O17), pentacosahydrate
-	1345-08-0	?	Cadmium chromate hydroxide (Cd2(CrO4)(OH)2; C.I. Pigment Yellow 44
216-612-8	1624-02-8	+6	Silanol, triphenyl-, diester with chromic acid (H2CrO4)
-	5188-42-1	+6	Chromic acid (H2CrO4), compd. with guanidine (1:2)
227-022-5	5601-29-6	+3	Chromate(1-), bis[2-[[4,5-dihydro-3-methyl-5-(oxo-.kappa.O)-1-phenyl-1H-pyrazol
228-875-6	6370-08-7	+3	Acid blue 158
231-801-5	7738-94-5	+6	Chromic acid
231-846-0	7758-97-6	+6	Lead chromate
231-889-5	7775-11-3	+6	Sodium chromate
231-906-6	7778-50-9	+6	Potassium dichromate
232-043-8	7784-01-2	+6	Silver chromate(VI)
232-044-3	7784-02-3	+6	Silver dichromate
-	7788-96-7	+6	Chromium difluoride dioxide
232-138-4	7788-98-9	+6	Ammonium chromate
232-140-5	7789-00-6	+6	Potassium chromate
-	7789-01-7	?	Chromic acid (H2CrO4), dilithium salt, dihydrate
232-142-6	7789-06-2	+6	Strontium chromate
-	7789-07-3	-	Chromic acid (H2Cr2O7), copper(2+) salt (1:1), dihydrate
(232-143-1)	7789-09-5	+6	Ammonium dichromate
(232-144-7)	7789-10-8	+6	Mercuric dichromate (VI)
-	7789-12-0	+6	Sodium dichromate dihydrate
-	7789-73-3	?	Calcium dichromate (CaCr2O7) trihydrate
-	10022-48-7	?	Chromic acid (H2Cr2O7), dilithium salt, dihydrate
-	10031-16-0	+6	Barium dichromate dihydrate
-	10034-82-9	+6	Sodium chromate tetrahydrate

EC No	CAS No		Substance Name
-	10039-53-9	+6	Sodium chromate(VI)
-	10060-08-9	+6	Calcium chrome(VI) dihydrate
-	10101-75-4	+6	Tin(IV) chromate
233-660-5	10294-40-3	+6	Barium chromate
233-661-0	10294-52-7	+6	Ferric chromate(VI)
-	10294-53-8	+6	Iron(III) dichromate
234-190-3	10588-01-9	+6	Sodium dichromate
234-329-8	11103-86-9	+6	Zinc potassium chromate
-	11104-59-9	+6	Chromate
-	11114-92-4	?	Cobalt chromium alloy
234-499-3	12007-16-8	0	Chromium boride (CrB2)
-	12010-39-8	+6	Bismuth chromate hydroxide (Bi(CrO4)(OH))
234-613-1	12016-69-2	?	Chromium cobalt oxide (Cr2CoO4)
234-628-3	12017-86-6	+6	Dilead chromate dihydroxide
234-633-0	12018-09-6	+4	Chromium silicide (CrSi2)
234-636-7	12018-18-7	?	Chromium nickel oxide (Cr2NiO4)
235-175-4	12116-44-8	?	Tricarbonyl((1,2,3,4,5,6-eta)-methoxybenzene)chromium
-	12205-18-4	+6	Chromate (CrO4(3-)), calcium (2:3), (T-4)-
-	12206-12-1	+6	Zinc chromate hydroxide
235-499-6	12254-85-2	+3?	Chromium arsenide (Cr2As)
235-662-1	12433-14-6	+6	Tricopper chromate tetrahydroxide
-	12433-30-6	?	(Dioxochromium)di-mu-oxodioxouranium (CrUO6)
235-663-7	12433-50-0	+6	Potassium zinc chromate oxide (K2Zn4(CrO4)4O)
235-759-9	12656-85-8	?	Molybdenum orange [Chromium and chromium compounds]
235-852-4	13007-92-6	+6	Chromium carbonyl
236-540-0	13423-61-5	+6	Magnesium chromate
-	13444-75-2	+6	Mercury(II) chromate
236-601-1	13446-72-5	+6	Rubidium chromate
236-602-7	13446-73-6	+6	Dirubidium dichromate
236-626-8	13453-35-5	+6	Dithallium dichromate
236-640-4	13454-78-9	+6	Cesium chromate (Cs2CrO4)
236-651-4	13455-25-9	+6	Cobaltous chromate(III)
	13465-34-4	+6	Mercury(I) chromate
236-760-2	13473-75-1	+6	Dithallium chromate

EC No	CAS No		Substance Name
236-761-2	13477-01-5	+6	Barium dichromate
-	13517-17-4	+6	Chromic acid, disodium salt, decahydrate
236-878-9	13530-65-9	+6	Zinc chromate
236-879-4	13530-67-1	+6	Caesium dichromate
236-881-5	13530-68-2	+6	Chromic acid
236-922-7	13548-42-0	+6	Cupric chromate(VI)
237-161-3	13675-47-3	+6	Copper dichromate
237-366-8	13765-19-0	+6	Calcium chromate
237-567-0	13843-81-7	+6	Lithium dichromate(VI)
-	13845-31-3	?	Chromic acid (H2CrO4), lead(2+) potassium salt (2:1:2)
-	13907-45-4	+6	Chromate (CrO42-)
-	13907-47-6	+6	Bichromate
237-843-0	14018-95-2	+6	Zinc dichromate
237-959-1	14104-85-9	+6	Magnesium dichromate
238-243-1	14307-33-6	+6	Calcium dichromate(VI)
238-244-7	14307-35-8	+6	Lithium chromate
238-252-0	14312-00-6	+6	Cadmium chromate
-	14333-16-5	?	Chromate (CrO4(sup 3-))
238-422-4	14445-91-1	+6	Chromic acid, ammonium salt
-	14507-18-7	?	Ferrous chromate
-	14682-96-3	+6	Strontium dichromate
238-766-5	14721-18-7	+6	Chromic acid, nickel(2+) salt (1:1)
239-056-8	14977-61-8	+6	Chromyl oxychloride
-	14986-48-2	+6	Chromium chloride, (OC-6-11)-
239-646-5	15586-38-6	+6	Nickel dichromate
-	15710-39-1	+6	Chromium, pentacarbonyl(piperidine)-
-	15804-54-3	+6	Chromic acid (H2CrO4), lead(2) salt
-	15930-94-6	+6	Zinc chromate oxide
240-174-7	16037-50-6	?	Chlorotrioxochromic acid
-	16565-94-9	?	Chromic acid (H2CrO4), lanthanum(3+) salt (3:2)
-	16569-85-0	?	Magnesium chromate
-	16569-86-1	?	Chromic acid (H2CrO4), lanthanum(III) salt (3:2), heptahydrate
-	16569-87-2	?	Chromic acid (H2CrO4), neodymium(3+) salt (3:2), heptahydrate
242-339-9	18454-12-1	+6	Lead chromate oxide

EC No	CAS No		Substance Name
-	18540-29-9	+6	Chromium hexavalent ion
242-656-2	18906-50-8	+6	Copper chromate oxide (Cu2(CrO4)O)
243-478-8	20039-37-6	+6	Pyridinium dichromate
243-592-8	20203-47-8	+6	Cyclohexylammonium chromate
243-853-6	20492-50-6	+6	Chromium, trioxobis(pyridine)-, (TB-5-22)-
-	20736-64-5	+6	Chromic acid, compd. with cyclohexanamine
-	22323-45-1	+6	Chromic acid (H2CrO4), mercury zinc salt
-	22614-53-5	+6	Chromium, bis(trimethoxyphosphine)tetracarbonyl-
-	22708-05-0	+3	Chromate(1-), diamminetetrakis(thiocyanato-N)-, barium, (OC-6-11)-
-	24613-38-5	?	Cobaltous chromate
246-356-2	24613-89-6	+6,+3	Chromic acid (H2CrO4), chromium(3+) salt (3:2)
247-595-5	26299-14-9	+6	Pyridinium chlorochromate
248-243-3	27133-42-2	+6	Chromium oxide (Cr8O21)
248-244-9	27133-66-0	+6	Chromic acid, barium potassium salt
-	34448-20-9	?	Magnesium dichromate (MgCr2O7) hexahydrate
252-062-5	34493-01-1	+6	Dichromic acid, sodium salt
-	36563-89-0	?	Chromic acid (H2CrO4), lanthanum (3+) salt (3:2), octahydrate
-	37224-57-0	+3	Zinc chromate
253-420-3	37235-82-8	?	Dibismuth dichromium nonaoxide
-	37324-38-2	+6	Chromated zinc chloride
253-490-5	37382-24-4	?	Chromium cobalt oxide
-	38006-68-7	+6	Chromium, isotope of mass 51 (51Cr6+)
253-946-3	38455-77-5	+6	Tin chromate
-	38719-42-5	+6	Cupric chromium oxide
-	39400-35-6	?	Sodium uranium chromate oxide (Na2U2(CrO4)3O4) hexahydrate
255-252-6	41189-36-0	+6	Chromic acid, potassium zinc salt
-	41261-95-4	+6;+2	Chromium chromate (H2CrO4)
256-418-0	49663-84-5	+6	Pentazinc chromate octahydroxide
-	50316-88-6	?	Chromic acid (H2CrO4), neodymium(3+) salt (3:2), dihydrate
256-848-9	50922-29-7	?	Chromium zinc oxide
-	51899-02-6	?	Lead chromate sulfate (Pb9(CrO4)5(SO4)4)
-	53206-40-9	?	Chromic acid (H2CrO4), praceodymium(3+) salt (3:2)
-	53206-41-0	?	Chromic acid (H2CrO4), praceodymium(3+) salt (3:2), heptahydrate
-	53795-87-2	?	C.I. 77600 ; Chromium yellow

EC No	CAS No		Substance Name
259-621-2	55392-76-2	+6	Chromic acid, manganese salt
-	56320-90-2	?	Cesium chromate
260-315-6	56660-19-6	+6	Tetrabutylammonium, salt with chromic acid (2:1)
-	58319-32-7	+6 (124 33-50-0)	potassium zinc salt (1:2:4) [K2Zn4(CrO4)4O]
-	60586-86-9	?	Chromic acid (H2CrO4), cesium lithium salt
-	61204-26-0	+6	Chromic acid (H4-Cr-O5), bismuth(3+) salt (1:1)
262-936-8	61725-86-8	?	Chromium naphthalenesulfonate rhodamine violet complex
-	63020-43-9	?	Dipotassium zinc bis(chromate)
-	63950-89-0	+6	Chromium, bis(benzoato)dioxo-, trihydrate
266-501-3	66860-79-5	+6	Tricopper chromate dioxide
269-108-5	68187-56-4	+6	Coal, brown, reaction products with sodium dichromate, neutralized
270-647-3	68475-49-0	+0	Chromium hydroxide oxide silicate
272-261-0	68784-60-1	+6	Chromic acid (H2Cr2O7), sodium salt (1:2), reaction products with (alphaR,1R,2R,4 alpha,2,5,5,8a-pentamethyl-1-naphthalenepropanol, hydrogenated
273-689-0	69011-07-0	+6	Lead chromate silicate (Pb3(CrO4)(SiO4))
-	74278-22-1	+6	Methaminium, N-[4-[[4-(dimethylamino)phenyl]phenylmethylene]-2,5-cyclohexad decanedioate (1:1), chromic acid (H2CrO4) dipotassium salt and tetramethylthiop
-	75578-75-5	+6	Phenazinium, 3-((8-((4-aminophenyl)amino)-10- phenylphenazinium-2-yl)amino)-5 yl)amino)-, salt with chromic acid (H2Cr2O7) (2:3)
-	76055-69-1	+6	Chromate (CrO42-)
280-502-6	83588-58-3	+3?	Phosphoric acid, triethyl ester, reaction products with aluminum sec-butoxide, chr
280-503-1	83588-59-4	+3?	Phosphoric acid, triethyl ester, reaction products with chromium oxide (CrO3) and
290-947-8	90294-61-4	+6	Chromic acid (H2Cr2O7), disodium salt, reaction products with diazotized 2-aminc naphthalenesulfonic acid monosodium salt reaction products
296-042-4	92202-10-3	+6	Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, salts with chror
-	92203-02-6	+3?	Phosphoric acid, reaction products with aluminum hydroxide and chromium oxide
-	92203-03-7	+3?	Phosphoric acid, reaction products with aluminum hydroxide, chromium oxide (Cr
-	92414-43-2	?	Chromium oxide (CrO4), (T-4)-
-	93215-61-3	?	Chromic acid (H2CrO4), lead(2+) sodium salt (2:1:2)
-	94007-86-0	+6 **(120 10-39-89)**	Bismuth chromate hydroxide
303-973-2	94232-45-8	+6	Dichromic acid, potassium sodium salt
305-229-2	94350-11-5	?	Saccharomyces cerevisiae, chromium-rich
305-832-0	95046-44-9	?	Sphene, chromium tin pink violet

EC No	CAS No		Substance Name
306-249-4	96690-54-9	+6	Sulfuric acid, reaction products with d-glucose and chromic acid (H2Cr2O7) disodi
307-577-0	97660-63-4	+6	Phenothiazin-5-ium, 3,7-bis(dimethylamino)-, chloride, reaction products with chr
308-967-3	99328-50-4	+6	Nitric acid, barium salt, reaction products with ammonia, chromic acid (H2CrO4) d
309-501-1	100402-65-1	+6	Nitric acid, copper(2+) salt, reaction products with ammonia, chromic acid (H2CrO
-	100468-44-8	6?	Magnesium, dibutyl-, reaction products with chromium oxide (CrO3), iso-Pr alc. ti
-	102262-19-1	+3	Chromium cobalt manganese oxide
-	102262-21-5	?	Chromium cobalt copper iron manganese oxide
-	102262-22-6	?	Chromium cobalt iron manganese oxide
-	143080-18-6	?	Iron molybdenum chromate oxide
-	199194-95-1	+	Chromic acid (H2CrO4), bis(triphenylsilyl) ester, reaction products with ethoxydiet

Appendix 2 Production and trade statistics

TABLE 46 EU27 IMPORT DATA 2006-2010 (RAW HIDES AND SKINS AND ARTICLES OF LEATHER)

IMPORT			IMPORT [€m]				
Product type	**CN codes***	**Description/period**	**2006**	**2007**	**2008**	**2009**	**2010**
Raw hides and skins	4101-4106	Hides and skins (all animals included)	1,973	1,957	1,484	954	1,518
Leather articles:							
Pure leather	4107-4115	Processed leather (all animals included)	1,047	1,254	1,158	762	1,050
Containers	4202	Travelling bags, cases, wallets etc.	5,385	5,977	6,189	5,574	6,633
Accessories	4203+91139010	Gloves, belts, watch straps etc.	1,690	1,697	1,804	1,504	1,605
Footwear 1)	6403-6406	Boots, shoes, soles etc.	7,022	6,981	7,109	5,921	6,638
Technical use	4204+42050011+42050019	Conveyor, transmission belts, others	5	5	5	4	6
Others	4201+42050000+42050090 +59111+95066210	Saddlery, textile fabrics laminated with leather, inflatable leather balls	440	488	484	410	481
Total leather articles			**15,589**	**16,403**	**16,750**	**14,175**	**16,414**

1) Also includes footwear where leather only is a smaller part of the product.

Source: Eurostat (EU27 Trade since 1995 by CN8 (DS_016890))

TABLE 47 EU27 EXPORT DATA 2006-2010 (RAW HIDES AND SKINS AND LEATHER ARTICLES)

EXPORT			EXPORT [€m]				
Product type	**CN codes***	**Description/period**	**2006**	**2007**	**2008**	**2009**	**2010**
Raw hides and skins	4101-4106	Hides and skins (all animals included)	898	825	772	688	1,003
Leather articles:							
Pure leather	4107-4115	Processed leather (all animals included)	2,152	2,292	2,084	1,708	2,184
Containers	4202	Travelling bags, cases, wallets etc.	3,775	4,036	4,283	3,758	4,600
Accessories	4203+91139010	Gloves, belts, watch straps etc.	741	789	817	613	771
Footwear 1)	6403-6406	Boots, shoes, soles etc.	4,082	4,399	4,484	3,605	4,046
Technical use	4204+42050011+42050019	Conveyor, transmission belts, others	8	11	12	7	9
Others	4201+42050000+42050090+ 59111+95066210	Saddlery, textile fabrics laminated with leather, inflatable leather balls	470	430	437	453	539
Total leather articles			**11,228**	**11,957**	**12,116**	**10,143**	**12,149**

1) Also includes footwear where leather only is a smaller part of the product.

Source: Eurostat (EU27 Trade since 1995 by CN8 (DS_016890))

TABLE 48 EU27 IMPORT DATA 2006-2010 (RAW HIDES AND SKINS AND LEATHER ARTICLES)

IMPORT			IMPORT [1,000 tonnes]				
Product type	**CN codes***	**Description/period**	**2006**	**2007**	**2008**	**2009**	**2010**
Raw hides and skins	4101-4106	Hides and skins (all animals included)	708	625	483	453	548
Leather articles:							
Pure leather	4107-4115	Processed leather (all animals included)	84	95	85	65	79
Containers	4202	Travelling bags, cases, wallets etc.	853	940	947	790	858
Accessories	4203+91139010	Gloves, belts, watch straps etc.	109	111	107	80	83
Footwear [1)]	6403-6406	Boots, shoes, soles etc.	526	515	507	418	449
Technical use	4204+42050011+42050 019	Conveyor, transmission belts, others	0.40	0.49	0.40	0.40	0.35
Others	4201+42050000+42050 090+59111+95066210	Saddlery, textile fabrics laminated with leather, inflatable leather balls	51.4	55.8	55.2	46.8	49.8
Total leather articles			**1,624**	**1,717**	**1,701**	**1,401**	**1,518**

1) Also includes footwear where leather only is a smaller part of the product.

Source: Eurostat (EU27 Trade since 1995 by CN8 (DS_016890))

TABLE 49 EU27 EXPORT DATA 2006-2010 (RAW HIDES AND SKINS AND LEATHER ARTICLES)

EXPORT			EXPORT [1,000 tonnes]				
Product type	**CN codes***	**Description/period**	**2006**	**2007**	**2008**	**2009**	**2010**
Raw hides and skins	4101-4106	Hides and skins (all animals included)	529	477	512	591	589
Leather articles:							
Pure leather	4107-4115	Processed leather (all animals included)	160	163	143	124	140
Containers	4202	Travelling bags, cases, wallets etc.	50	53	56	49	57
Accessories	4203+91139010	Gloves, belts, watch straps etc.	7	8	8	7	7
Footwear [1)]	6403-6406	Boots, shoes, soles etc.	99	99	94	72	80
Technical use	4204+42050011+42050 019	Conveyor, transmission belts, others	0.40	0.49	0.40	0.40	0.35
Others	4201+42050000+42050 090+59111+95066210	Saddlery, textile fabrics laminated with leather, inflatable leather balls	51.4	55.8	55.2	46.8	49.8
Total leather articles			**368**	**379**	**358**	**299**	**334**

1) Also includes footwear where leather only is a smaller part of the product.

Source: Eurostat (EU27 Trade since 1995 by CN8 (DS_016890))

TABLE 50 EU27 PRODUCTION SOLD DATA 2006-2010 (RAW HIDES AND SKINS AND LEATHER ARTICLES)

		PRODUCTION SOLD (€m)				
Product type	**Description/period**	**2006**	**2007**	**2008**	**2009**	**2010**
Raw hides and skins	Hides and skins (all animals included)	1,155	1,095	779	632	1,067
Leather articles:						
Pure leather	Processed leather (all animals included)	8,443	8,814	6,582	5,604	6,287
Containers	Travelling bags, cases, wallets etc.	2,983	3,516	3,185	3,086	3,493
Accessories	Gloves, belts, watch straps etc.	929	922	877	710	792
Footwear [1)]	Boots, shoes, soles etc.	12,743	13,117	12,108	10,385	11,429
Technical use	Conveyor, transmission belts, others	197	281	209	160	240
Others	Saddlery, textile fabrics laminated with leather, inflatable leather balls	2,774	2,531	1,875	2,019	1,917
Total leather articles		**28,069**	**29,181**	**24,835**	**21,964**	**24,158**

1) Also includes footwear where leather only is a smaller part of the product.

Source: Eurostat (Prodcom annual sold 1.1)

TABLE 51 EU27 PRODUCTION, IMPORT AND EXPORT DATA 2010 (RAW HIDES AND SKINS AND LEATHER ARTICLES)

		2010 (€m)		
Product type	**Description**	**PRODUCTION**	**IMPORT**	**EXPORT**
Raw hides and skins	Hides and skins (all animals included)	1,067	358	591
Leather articles:				
Pure leather	Processed leather (all animals included)	6,287	2,019	2,437
Containers	Travelling bags, cases, wallets etc.	3,493	3,464	3,114
Accessories	Gloves, belts, watch straps etc.	792	674	434
Footwear [1)]	Boots, shoes, soles etc.	11,429	8,344	4,065
Technical use	Conveyor, transmission belts, others	240	6	9
Others	Saddlery, textile fabrics laminated with leather, inflatable leather balls	1,917	1,124	714
Total leather articles		**24,158**	**15,631**	**10,773**

1) Also includes footwear where leather only is a smaller part of the product

Source: Eurostat (Prodcom annual sold 1.1)

Appendix 3 CN8 and PRODCOM codes included in the import/export assessment

	CN8 code	Description
Raw skins and hides - semimanufacturers	41012010	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN <= 16 KG, FRESH
	41012030	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN <= 16 KG, WET-SALTED
	41012050	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN <= 8 KG WHEN SIMPLY DRIED OR <= 10 KG WHEN DRY-SALTED
	41012090	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN <= 16 KG, LIMED, PICKLED OR OTHERWISE PRESERVED (EXCL. FRESH OR WET-SALTED, SIMPLY DRIED OR DRY-SALTED, TANNED OR PARCHMENT-DRESSED)
	41015010	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN > 16 KG, FRESH
	41015030	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN > 16 KG, WET-SALTED
	41015050	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN > 16 KG, DRIED OR DRY-SALTED
	41015090	WHOLE RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED OR SPLIT, OF A WEIGHT PER SKIN > 16 KG, LIMED, PICKLED OR OTHERWISE PRESERVED (EXCL. FRESH OR WET-SALTED, SIMPLY DRIED OR DRY-SALTED, TANNED OR PARCHMENT-DRESSED)
	41019000	BUTTS, BENDS, BELLIES AND SPLIT RAW HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, WHETHER OR NOT DEHAIRED, FRESH, OR SALTED, DRIED, LIMED, PICKLED OR OTHERWISE PRESERVED, AND WHOLE RAW HIDES AND SKINS OF A WEIGHT PER SKIN > 8 KG BUT < 16 KG WHEN SIMPLY DRIED AND > 10 KG BUT < 16 KG WHEN DRY-SALTED (EXCL. TANNED, PARCHMENT-DRESSED OR FURTHER PREPARED)
	41021010	RAW SKINS OF LAMBS, WITH WOOL ON, FRESH OR SALTED, DRIED, LIMED, PICKLED OR OTHERWISE PRESERVED (EXCL. THOSE OF ASTRAKHAN, CARACUL, PERSIAN, BROADTAIL OR SIMILAR LAMBS, OR OF INDIAN, CHINESE, MONGOLIAN OR TIBETAN LAMBS)
	41021090	RAW SKINS OF SHEEP, WITH WOOL ON, FRESH OR SALTED, DRIED, LIMED, PICKLED OR OTHERWISE PRESERVED (EXCL. THOSE OF LAMBS)
	41022100	RAW SKINS OF SHEEP OR LAMBS, WITHOUT WOOL ON, PICKLED, WHETHER OR NOT SPLIT
	41022900	RAW SKINS OF SHEEP OR LAMBS, WITHOUT WOOL ON, FRESH OR SALTED, DRIED, LIMED OR OTHERWISE PRESERVED, WHETHER OR NOT SPLIT (EXCL. PICKLED OR PARCHMENT-DRESSED)
	41031020	RAW HIDES AND SKINS OF GOATS OR KIDS, FRESH, WHETHER OR NOT DEHAIRED OR SPLIT (EXCL. HIDES AND SKINS OF GOATS OR KIDS FROM YEMEN, MONGOLIA OR TIBET WITH HAIR ON)
	41031050	RAW HIDES AND SKINS OF GOATS OR KIDS, SALTED OR DRIED, WHETHER OR NOT DEHAIRED OR SPLIT (EXCL. HIDES AND SKINS OF GOATS OR KIDS FROM YEMEN, MONGOLIA OR TIBET WITH HAIR ON)

	CN8 code	Description
	41031090	RAW HIDES AND SKINS OF GOATS OR KIDS, LIMED, PICKLED OR OTHERWISE PRESERVED, WHETHER OR NOT DEHAIRED OR SPLIT (EXCL. FRESH, SALTED, DRIED, PARCHMENT-DRESSED, AND HIDES AND SKINS OF GOATS OR KIDS FROM YEMEN, MONGOLIA OR TIBET WITH HAIR ON)
	41032000	RAW HIDES AND SKINS OF REPTILES, FRESH OR SALTED, DRIED, LIMED, PICKLED OR OTHERWISE PRESERVED (EXCL. PARCHMENT-DRESSED)
	41033000	RAW HIDES AND SKINS OF SWINE, FRESH, OR SALTED, DRIED, LIMED, PICKLED OR OTHERWISE PRESERVED, WHETHER OR NOT DEHAIRED OR SPLIT (EXCL. PARCHMENT-DRESSED)
Raw skins and hides - semimanufacturers	41039000	OTHER RAW HIDES AND SKINS, FRESH OR SALTED, DRIED, LIMED, PICKLED OR OTHERWISE PRESERVED, WHETHER OR NOT DEHAIRED, INCL. BIRDSKINS WITHOUT FEATHERS OR DOWN (EXCL. PARCHMENT-DRESSED, HIDES AND SKINS OF BOVINE ANIMALS, EQUINE ANIMALS, SHEEP, LAMBS, GOATS, KIDS AND REPTILES)
	41039010	RAW HIDES AND SKINS OF GOATS OR KIDS, LIMED, PICKLED OR OTHERWISE PRESERVED, WHETHER OR NOT DEHAIRED OR SPLIT (EXCL. PARCHMENT-DRESSED, AND HIDES AND SKINS OF GOATS OR KIDS FROM YEMEN, MONGOLIA OR TIBET WITH HAIR ON)
	41039090	RAW HIDES AND SKINS, FRESH, OR SALTED, DRIED, LIMED, PICKLED OR OTHERWISE PRESERVED, WHETHER OR NOT DEHAIRED, INCL. BIRDSKINS WITHOUT FEATHERS OR DOWN (EXCL. PARCHMENT-DRESSED, HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, EQUINE ANIMALS, SHEEP, LAMBS, GOATS, KIDS, REPTILES AND SWINE)
	41041110	FULL GRAINS, UNSPLIT AND GRAIN SPLITS, IN THE WET STATE "INCL. WET-BLUE", OF THE WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF <= 2,6 M^2, TANNED, WITHOUT HAIR ON (EXCL. FURTHER PREPARED)
	41041151	FULL GRAINS, UNSPLIT AND GRAIN SPLITS, IN THE WET STATE "INCL. WET-BLUE", OF THE WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF > 2,6 M^2, TANNED, WITHOUT HAIR ON (EXCL. FURTHER PREPARED)
	41041159	FULL GRAINS, UNSPLIT AND GRAIN SPLITS, IN THE WET STATE "INCL. WET-BLUE", OF HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, TANNED, WITHOUT HAIR ON (EXCL. FURTHER PREPARED AND OF THE WHOLE HIDES AND SKINS)
	41041190	FULL GRAINS, UNSPLIT AND GRAIN SPLITS, IN THE WET STATE "INCL. WET-BLUE", OF HIDES AND SKINS OF EQUINE ANIMALS, TANNED, WITHOUT HAIR ON (EXCL. FURTHER PREPARED)
	41041910	WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF <= 2,6 M^2, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND FULL GRAINS, UNSPLIT AND GRAIN SPLITS)
	41041951	WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF > 2,6 M^2, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND FULL GRAINS, UNSPLIT AND GRAIN SPLITS)
	41041959	HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND WHOLE HIDES AND SKINS AND FULL GRAINS, UNSPLIT AND GRAIN SPLITS)
	41041990	HIDES AND SKINS OF EQUINE ANIMALS, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND FULL GRAINS, UNSPLIT AND GRAIN SPLITS)
	41044119	FULL GRAINS LEATHER, UNSPLIT AND GRAIN SPLITS LEATHER, IN THE DRY STATE "CRUST", OF WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO", WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET", WITHOUT HAIR ON (EXCL. FURTHER PREPARED AND EAST INDIA KIP OF SUBHEADING 4104.41.11)
	41044151	FULL GRAINS LEATHER, UNSPLIT AND GRAIN SPLITS LEATHER, IN THE DRY STATE "CRUST", OF WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF > 2,6 M^2 "28 SQUARE FEET", WITHOUT HAIR ON (EXCL. FURTHER PREPARED AND EAST INDIA KIP OF SUBHEADING 4104.41.11)

	CN8 code	Description
	41044159	FULL GRAINS LEATHER, UNSPLIT AND GRAIN SPLITS LEATHER, IN THE DRY STATE "CRUST", OF HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF > 2,6 M^2 "28 SQUARE FEET", WITHOUT HAIR ON (EXCL. FURTHER PREPARED AND WHOLE HIDES AND SKINS AND EAST INDIA KIP OF SUBHEADING 4104.41.11)
	41044190	FULL GRAINS LEATHER, UNSPLIT AND GRAIN SPLITS LEATHER, IN THE DRY STATE "CRUST", OF HIDES AND SKINS OF EQUINE ANIMALS, WITHOUT HAIR ON (EXCL. FURTHER PREPARED)
	41044919	WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET", IN THE DRY STATE "CRUST", WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND FULL GRAINS, UNSPLIT, GRAIN SPLITS AND HIDES AND SKINS OF EAST INDIA KIP OF SUBHEADING 4104.49.11)
	41044951	WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF > 2,6 M^2 "28 SQUARE FEET", IN THE DRY STATE "CRUST", WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND FULL GRAINS, UNSPLIT AND GRAIN SPLITS)
Raw skins and hides - semimanufacturers	41044959	HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF > 2,6 M^2 "28 SQUARE FEET", IN THE DRY STATE "CRUST", WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND WHOLE HIDES AND SKINS AND FULL GRAINS, UNSPLIT AND GRAIN SPLITS)
	41044990	HIDES AND SKINS OF EQUINE ANIMALS, IN THE DRY STATE "CRUST", WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND FULL GRAINS, UNSPLIT AND GRAIN SPLITS)
	41051010	SKINS OF SHEEP OR LAMBS, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT WOOL ON, UNSPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41051090	SKINS OF SHEEP OR LAMBS, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT WOOL ON, SPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41062110	SKINS OF GOATS OR KIDS, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT WOOL ON, UNSPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41062190	SKINS OF GOATS OR KIDS, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT WOOL ON, SPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41062290	HIDES AND SKINS OF GOATS OR KIDS, IN THE DRY STATE "CRUST", WITHOUT WOOL ON, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY AND VEGETABLE PRE-TANNED INDIAN GOAT OR KID HIDES AND SKINS OF SUBHEADING 4106.22.10)
	41063110	HIDES AND SKINS OF SWINE, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT HAIR ON, UNSPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41063190	HIDES AND SKINS OF SWINE, IN THE WET STATE "INCL. WET-BLUE", TANNED, WITHOUT HAIR ON, SPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41063210	HIDES AND SKINS OF SWINE, IN THE DRY STATE "CRUST", WITHOUT WOOL ON, UNSPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41063290	HIDES AND SKINS OF SWINE, IN THE DRY STATE "CRUST", WITHOUT WOOL ON, SPLIT (EXCL. FURTHER PREPARED AND PRE-TANNED ONLY)
	41064010	HIDES AND SKINS OF REPTILES, VEGETABLE PRE-TANNED ONLY
	41064090	TANNED OR CRUST HIDES AND SKINS OF REPTILES, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND VEGETABLE PRE-TANNED ONLY)

	CN8 code	Description
	41069100	HIDES AND SKINS OF ANTELOPES, DEER, ELKS, ELEPHANTS AND OTHER ANIMALS, INCL. SEA ANIMALS, WITHOUT WOOL OR HAIR ON, AND LEATHER OF HAIRLESS ANIMALS, IN THE WET STATE "INCL. WET-BLUE", TANNED, WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND OF BOVINE AND EQUINE ANIMALS, SHEEP AND LAMBS, GOATS AND KIDS, SWINE AND REPTILES, AND PRE-TANNED ONLY)
	41069200	HIDES AND SKINS OF ANTELOPES, DEER, ELKS, ELEPHANTS AND OTHER ANIMALS, INCL. SEA ANIMALS, WITHOUT WOOL OR HAIR ON, AND LEATHER OF HAIRLESS ANIMALS, IN THE DRY STATE "CRUST", WHETHER OR NOT SPLIT (EXCL. FURTHER PREPARED AND OF BOVINE AND EQUINE ANIMALS, SHEEP AND LAMBS, GOATS AND KIDS, SWINE AND REPTILES, AND PRE-TANNED ONLY)
Finished leather	41071190	FULL GRAINS LEATHER "INCL. PARCHMENT-DRESSED LEATHER", UNSPLIT, OF THE WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. OF BOVINE "INCL. BUFFALO" ANIMALS WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET", CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41071211	BOXCALF GRAIN SPLITS LEATHER, OF WHOLE CALFHIDES AND CALFSKINS, WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET"
	41071219	GRAIN SPLITS LEATHER "INCL. PARCHMENT-DRESSED LEATHER", OF THE WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET", WITHOUT HAIR ON (EXCL. BOXCALF, CHAMOIS LEATHER, PATENT LEATHER, PATENT LAMINATED LEATHER AND METALLISED LEATHER)
Finished leather	41071291	GRAIN SPLITS LEATHER "INCL. PARCHMENT-DRESSED LEATHER", OF THE WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. OF BOVINE "INCL. BUFFALO" ANIMALS WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET", CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41071299	GRAIN SPLITS LEATHER "INCL. PARCHMENT-DRESSED LEATHER", OF THE WHOLE HIDES AND SKINS OF EQUINE ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41071910	LEATHER "INCL. PARCHMENT-DRESSED LEATHER" OF THE WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET", WITHOUT HAIR ON (EXCL. UNSPLIT FULL GRAINS LEATHER, GRAIN SPLITS LEATHER, CHAMOIS LEATHER, PATENT LEATHER, PATENT LAMINATED LEATHER AND METALLISED LEATHER)
	41071990	LEATHER "INCL. PARCHMENT-DRESSED LEATHER" OF THE WHOLE HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. OF BOVINE "INCL. BUFFALO" ANIMALS WITH A SURFACE AREA OF <= 2,6 M^2 "28 SQUARE FEET", UNSPLIT FULL GRAINS LEATHER, GRAIN SPLITS LEATHER, CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41072100	LEATHER OF REPTILES, VEGETABLE PRE-TANNED ONLY
	41072910	LEATHER OF REPTILES, TANNED ONLY (EXCL. VEGETABLE PRE-TANNED ONLY)
	41072990	LEATHER OF REPTILES PREPARED AFTER TANNING (EXCL. PATENT LEATHER, PATENT LAMINATED LEATHER AND METALLIZED LEATHER)
	41079010	LEATHER OF ANTILOPES, DEER, ELKS, ELEPHANTS AND OTHER ANIMALS, INCL. SEA CREATURES, DEHAIRED, AND LEATHER OF HAIRLESS ANIMALS, TANNED ONLY (EXCL. LEATHER OF BOVINE AND EQUINE ANIMALS, SHEEP AND LAMBS, GOATS AND KIDS, SWINE AND REPTILES)
	41079090	LEATHER OF ANTILOPES, DEER, ELKS, ELEPHANTS AND OTHER ANIMALS, INCL. SEA CREATURES, DEHAIRED, AND LEATHER OF HAIRLESS ANIMALS, PREPARED AFTER TANNING OR PARCHMENT-DRESSED (EXCL. LEATHER OF BOVINE AND EQUINE ANIMALS, SHEEP AND LAMBS, GOATS AND KIDS, SWINE AND REPTILES, PLUS CHAMOIS LEATHER, PATENT LEATHER, PATENT LAMINATED LEATHER AND METALLIZED LEATHER)

	CN8 code	Description
	41079110	FULL GRAINS SOLE LEATHER "INCL. PARCHMENT-DRESSED LEATHER", UNSPLIT, OF THE PORTIONS, STRIPS OR SHEETS OF HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41079190	FULL GRAINS LEATHER "INCL. PARCHMENT-DRESSED LEATHER", UNSPLIT, OF THE PORTIONS, STRIPS OR SHEETS OF HIDES AND SKINS OF BOVINE "INCL. BUFFALO" OR EQUINE ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. SOLE LEATHER, CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41079210	GRAIN SPLITS LEATHER "INCL. PARCHMENT-DRESSED LEATHER", OF THE PORTIONS, STRIPS OR SHEETS OF HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41079290	GRAIN SPLITS LEATHER "INCL. PARCHMENT-DRESSED LEATHER", OF THE PORTIONS, STRIPS OR SHEETS OF HIDES AND SKINS OF EQUINE ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41079910	LEATHER "INCL. PARCHMENT-DRESSED LEATHER" OF THE PORTIONS, STRIPS OR SHEETS OF HIDES AND SKINS OF BOVINE "INCL. BUFFALO" ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. UNSPLIT FULL GRAINS LEATHER, GRAIN SPLITS LEATHER, CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41079990	LEATHER "INCL. PARCHMENT-DRESSED LEATHER" OF THE PORTIONS, STRIPS OR SHEETS OF HIDES AND SKINS OF EQUINE ANIMALS, FURTHER PREPARED AFTER TANNING OR CRUSTING, WITHOUT HAIR ON (EXCL. UNSPLIT FULL GRAINS LEATHER, GRAIN SPLITS LEATHER, CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
Finished leather	41080010	CHAMOIS LEATHER, INCL. COMBINATION CHAMOIS LEATHER, OF SHEEP AND LAMBS (EXCL. GLACE-TANNED LEATHER SUBSEQUENTLY TREATED WITH FORMALDEHYDE AND LEATHER STUFFED WITH OIL ONLY AFTER TANNING)
	41080090	CHAMOIS LEATHER, INCL. COMBINATION CHAMOIS LEATHER (EXCL. THAT OF SHEEP AND LAMB, GLACE-TANNED LEATHER SUBSEQUENTLY TREATED WITH FORMALDEHYDE AND LEATHER STUFFED WITH OIL ONLY AFTER TANNING)
	41090000	PATENT LEATHER AND PATENT LAMINATED LEATHER; METALLIZED LEATHER (EXCL. LACQUERED OR METALLIZED RECONSTITUTED LEATHER)
	41100000	PARINGS AND OTHER WASTE OF LEATHER, PARCHMENT-DRESSED LEATHER OR COMPOSITION LEATHER, NOT SUITABLE FOR THE MANUFACTURE OF LEATHER ARTICLES; LEATHER DUST, POWDER AND FLOUR
	41110000	COMPOSITION LEATHER BASED ON LEATHER OR LEATHER FIBRE, IN SLABS, SHEETS OR STRIP, WHETHER OR NOT IN ROLLS
	41120000	LEATHER FURTHER PREPARED AFTER TANNING OR CRUSTING "INCL. PARCHMENT-DRESSED LEATHER", OF SHEEP OR LAMBS, WITHOUT WOOL ON, WHETHER OR NOT SPLIT (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41131000	LEATHER FURTHER PREPARED AFTER TANNING OR CRUSTING "INCL. PARCHMENT-DRESSED LEATHER", OF GOATS OR KIDS, WITHOUT WOOL OR HAIR ON, WHETHER OR NOT SPLIT (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41132000	LEATHER FURTHER PREPARED AFTER TANNING OR CRUSTING "INCL. PARCHMENT-DRESSED LEATHER", OF PIGS, WITHOUT HAIR ON, WHETHER OR NOT SPLIT (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)
	41133000	LEATHER FURTHER PREPARED AFTER TANNING OR CRUSTING "INCL. PARCHMENT-DRESSED LEATHER", OF REPTILES,, WHETHER OR NOT SPLIT (EXCL. CHAMOIS LEATHER, PATENT LEATHER AND PATENT LAMINATED LEATHER, AND METALLISED LEATHER)

	CN8 code	Description
	41139000	LEATHER FURTHER PREPARED AFTER TANNING OR CRUSTING "INCL. PARCHMENT-DRESSED LEATHER", OF ANTELOPES, DEER, ELKS, ELEPHANTS AND OTHER ANIMALS, INCL. SEA ANIMALS, WITHOUT WOOL OR HAIR ON, AND LEATHER OF HAIRLESS ANIMALS, WHETHER OR NOT SPLIT (EXCL. LEATHER OF BOVINE AND EQUINE ANIMALS, SHEEP AND LAMBS, GOATS OR KIDS, SWINE AND REPTILES, AND CHAMOIS LEATHER, PATENT LEATHER, PATENT LAMINATED LEATHER AND METALLISED LEATHER)
	41141010	CHAMOIS LEATHER, INCL. COMBINATION CHAMOIS LEATHER, OF SHEEP OR LAMBS (EXCL. GLACÉ-TANNED LEATHER SUBSEQUENTLY TREATED WITH FORMALDEHYDE AND LEATHER STUFFED WITH OIL ONLY AFTER TANNING)
	41141090	CHAMOIS LEATHER, INCL. COMBINATION CHAMOIS LEATHER (EXCL. THAT OF SHEEP OR LAMBS, GLACÉ-TANNED LEATHER SUBSEQUENTLY TREATED WITH FORMALDEHYDE AND LEATHER STUFFED WITH OIL ONLY AFTER TANNING)
	41142000	PATENT LEATHER AND PATENT LAMINATED LEATHER; METALLISED LEATHER (EXCL. LACQUERED OR METALLISED RECONSTITUTED LEATHER)
	41151000	COMPOSITION LEATHER BASED ON LEATHER OR LEATHER FIBRE, IN SLABS, SHEETS OR STRIP, WHETHER OR NOT IN ROLLS
	41152000	PARINGS AND OTHER WASTE OF LEATHER OR OF COMPOSITION LEATHER, NOT SUITABLE FOR THE MANUFACTURE OF LEATHER ARTICLES; LEATHER DUST, POWDER AND FLOUR
Containers	42021110	EXECUTIVE-CASES, BRIEFCASES, PORTFOLIOS, SCHOOL SATCHELS AND SIMILAR CONTAINERS WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR PATENT LEATHER
	42021190	TRUNKS, SUITCASES, VANITY CASES AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR PATENT LEATHER (EXCL. EXECUTIVE-CASES)
	42021211	EXECUTIVE-CASES, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF PLASTIC SHEETING
	42021219	TRUNKS, SUITCASES, VANITY CASES AND SIMILAR CONTAINERS OF LEATHER, WITH OUTER SURFACE OF PLASTIC SHEETING (EXCL. EXECUTIVE-CASES)
	42021250	TRUNKS, SUITCASES, VANITY CASES, EXECUTIVE-CASES, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF MOULDED PLASTIC MATERIAL
	42021291	EXECUTIVE-CASES, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF PLASTIC, INCL. VULCANISED FIBRE, OR OF TEXTILE MATERIALS (EXCL. THOSE WITH AN OUTER SURFACE OF PLASTIC SHEETING OR MOULDED PLASTIC MATERIAL)
Containers	42021299	TRUNKS, SUITCASES, VANITY CASES AND SIMILAR CASES, WITH OUTER SURFACE OF PLASTICS OR TEXTILE MATERIALS (EXCL. THOSE WITH AN OUTER SURFACE OF PLASTIC SHEETING OR MOULDED PLASTIC MATERIAL, AND EXECUTIVE-CASES)
	42021910	TRUNKS, SUITCASES, VANITY CASES, EXECUTIVE-CASES, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF ALUMINIUM
	42021990	TRUNKS, SUITCASES, VANITY CASES, EXECUTIVE-CASES, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS (EXCL. WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER, PATENT LEATHER, PLASTICS, TEXTILE MATERIALS OR ALUMINIUM)
	42021991	ATTACHE CASES, BRIEFCASES, PORTFOLIOS, SCHOOL SATCHELS AND SIMILAR CONTAINERS (EXCL. THOSE WITH AN OUTER SURFACE OF LEATHER, COMPOSITION LEATHER, PATENT LEATHER, PLASTIC, TEXTILE MATERIALS OR ALUMINIUM)
	42021999	TRUNKS, SUITCASES, VANITY CASES AND SIMILAR CASES (EXCL. THOSE WITH AN OUTER SURFACE OF LEATHER, COMPOSITION LEATHER, PATENT LEATHER, PLASTIC, TEXTILE MATERIALS OR ALUMINIUM, AND ATTACHE CASES)
	42022100	HANDBAGS, WHETHER OR NOT WITH SHOULDER STRAPS, INCL. THOSE WITHOUT HANDLES, WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR PATENT LEATHER

	CN8 code	Description
	42022210	HANDBAGS, WHETHER OR NOT WITH SHOULDER STRAPS, INCL. THOSE WITHOUT HANDLES, WITH OUTER SURFACE OF PLASTIC SHEETING
	42022290	HANDBAGS, WHETHER OR NOT WITH SHOULDER STRAPS, INCL. THOSE WITHOUT HANDLES, WITH OUTER SURFACE OF TEXTILE MATERIALS
	42022900	HANDBAGS, WHETHER OR NOT WITH SHOULDER STRAP, INCL. THOSE WITHOUT HANDLE, WITH OUTER SURFACE OF VULCANISED FIBRE OR PAPERBOARD, OR WHOLLY OR MAINLY COVERED WITH SUCH MATERIALS OR WITH PAPER
	42023100	WALLETS, PURSES, KEY-POUCHES, CIGARETTE-CASES, TOBACCO-POUCHES AND SIMILAR ARTICLES CARRIED IN THE POCKET OR HANDBAG, WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR PATENT LEATHER
	42023210	WALLETS, PURSES, KEY-POUCHES, CIGARETTE-CASES, TOBACCO-POUCHES AND SIMILAR ARTICLES CARRIED IN THE POCKET OR HANDBAG, WITH OUTER SURFACE OF PLASTIC SHEETING
	42023290	WALLETS, PURSES, KEY-POUCHES, CIGARETTE-CASES, TOBACCO-POUCHES AND SIMILAR ARTICLES CARRIED IN THE POCKET OR HANDBAG, WITH OUTER SURFACE OF TEXTILE MATERIALS
	42023900	WALLETS, PURSES, KEY-CASES, CIGARETTE-CASES, TOBACCO-POUCHES AND SIMILAR ARTICLES OF A KIND NORMALLY CARRIED IN THE POCKET OR HANDBAG, WITH OUTER SURFACE OF VULCANISED FIBRE OR PAPERBOARD, OR WHOLLY OR MAINLY COVERED WITH SUCH MATERIALS OR WITH PAPER, INCL. SPECTACLE CASES OF MOULDED PLASTIC MATERIAL
	42029110	TRAVELLING-BAGS, TOILET BAGS, RUCKSACKS AND SPORTS BAGS WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR PATENT LEATHER
	42029150	MUSICAL INSTRUMENT CASES WITH AN OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR PATENT LEATHER
	42029180	INSULATED FOOD OR BEVERAGE BAGS, SHOPPING BAGS, MAP-CASES, TOOL BAGS, JEWELLERY BOXES, CUTLERY CASES, BINOCULAR CASES, CAMERA CASES, MUSICAL INSTRUMENT CASES, GUN CASES, HOLSTERS AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR OF PATENT LEATHER (EXCL. TRUNKS, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR; ARTICLES NORMALLY CARRIED IN THE POCKET OR IN THE HANDBAG; TRAVELLING, TOILET OR SPORTS BAGS; RUCKSACKS)
Containers	42029190	SHOPPING OR TOOL BAGS, MAP-CASES, JEWELLERY BOXES, CASES FOR CUTLERY, BINOCULARS, CAMERAS OR GUNS, HOLSTERS AND SIMILAR, WITH OUTER SURFACE OF LEATHER, COMPOSITION LEATHER OR PATENT LEATHER (EXCL. TRUNKS, SUIT- VANITY- EXECUTIVE- OR BRIEF-CASES, SCHOOL SATCHELS AND SIMILAR; HANDBAGS; LEATHER ARTICLES NORMALLY CARRIED IN THE POCKET OR HANDBAG; TRAVEL, TOILET OR SPORTS BAGS; RUCKSACKS; CONTAINERS FOR MUSICAL INSTRUMENTS)
	42029211	TRAVELLING-BAGS, TOILET BAGS, RUCKSACKS AND SPORTS BAGS, WITH OUTER SURFACE OF PLASTIC SHEETING
	42029215	MUSICAL INSTRUMENT CASES, WITH AN OUTER SURFACE OF PLASTIC SHEETING
	42029218	SHOPPING BAGS, MAP-CASES, TOOL BAGS, JEWELLERY BOXES, CUTLERY CASES, BINOCULAR CASES, CAMERA CASES, MUSICAL INSTRUMENT CASES, GUN CASES, HOLSTERS AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF PLASTIC SHEETING (EXCL. TRUNKS, BRIEF-CASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, ARTICLES OF A KIND NORMALLY CARRIED IN THE POCKET OR IN THE HANDBAG, TRAVELLING-BAGS, TOILET BAGS, SPORTS BAGS AND RUCKSACKS)
	42029219	SHOPPING BAGS, MAP CASES, TOOL BAGS, MAKE-UP BOXES, CUTLERY BOXES, CASES FOR BINOCULARS, CAMERAS, VIDEO CAMERAS OR ARMS AND SIMILAR CONTAINERS, WITH AN OUTER SURFACE OF PLASTIC SHEETING (EXCL. TRUNKS, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, HANDBAGS, ARTICLES CARRIED IN THE POCKET OR HANDBAG, TRAVEL BAGS, TOILET AND SPORTS BAGS, RUCKSACKS AND MUSICAL INSTRUMENT CASES)

	CN8 code	Description
	42029291	TRAVELLING-BAGS, TOILET BAGS, RUCKSACKS AND SPORTS BAGS, WITH OUTER SURFACE OF TEXTILE MATERIALS
	42029295	MUSICAL INSTRUMENT CASES, WITH AN OUTER SURFACE OF TEXTILE MATERIALS
	42029298	INSULATED FOOD OR BEVERAGE BAGS, SHOPPING BAGS, MAP-CASES, TOOL BAGS, JEWELLERY BOXES, CUTLERY CASES, BINOCULAR CASES, CAMERA CASES, MUSICAL INSTRUMENT CASES, GUN CASES, HOLSTERS AND SIMILAR CONTAINERS, WITH OUTER SURFACE OF TEXTILE MATERIALS (EXCL. TRUNKS, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, ARTICLES OF A KIND NORMALLY CARRIED IN THE POCKET OR IN THE HANDBAG, TRAVELLING-BAGS, TOILET BAGS, SPORTS BAGS AND RUCKSACKS)
	42029299	SHOPPING BAGS, MAP CASES, TOOL BAGS, MAKE-UP BOXES, CUTLERY BOXES, CASES FOR BINOCULARS, CAMERAS, VIDEO CAMERAS OR ARMS AND SIMILAR CONTAINERS, WITH AN OUTER SURFACE OF FABRIC (EXCL. TRUNKS, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR CONTAINERS, HANDBAGS, ARTICLES CARRIED IN THE POCKET OR HANDBAG, TRAVEL BAGS, TOILET AND SPORTS BAGS, RUCKSACKS AND MUSICAL INSTRUMENT CASES)
	42029900	TRAVELLING-BAGS, SHOPPING OR TOOL BAGS, JEWELLERY BOXES, CUTLERY CASES AND SIMILAR, WITH OUTER SURFACE OF VULCANISED FIBRE OR PAPERBOARD; CASES FOR BINOCULARS, CAMERAS, MUSICAL INSTRUMENTS, GUNS, HOLSTERS AND SIMILAR CONTAINERS WITH OUTER SURFACE OF MATERIALS (NOT LEATHER, PLASTIC SHEETING OR TEXTILE MATERIALS) (EXCL. TRUNKS, BRIEFCASES, SCHOOL SATCHELS AND SIMILAR; HANDBAGS; ARTICLES NORMALLY CARRIED IN POCKET OR HANDBAG)
	42029910	MUSICAL INSTRUMENT CASES (EXCL. THOSE WITH AN OUTER SURFACE OF LEATHER, COMPOSITION LEATHER, PATENT LEATHER, PLASTIC SHEETING OR TEXTILE MATERIALS)
	42029990	TRAVEL, SHOPPING & TOOL BAGS, JEWELLERY & CUTLERY BOXES AND SIMILAR, WITH OUTER SURFACE OF VULCANIZED FIBRE OR PAPERBOARD, OR WHOLLY OR MAINLY COVERED WITH SUCH MATERIALS OR PAPER; CASES FOR BINOCULARS, CAMERAS, GUNS OR SIMILAR (EXCL. WITH OUTER SURFACE OF LEATHER, PLASTIC SHEETING OR TEXTILE MATERIAL; EXCL. MUSICAL INSTRUMENT CASES, TRUNKS, BRIEF-CASES, SCHOOL SATCHELS OR SIMILAR, HANDBAGS & ARTICLES CARRIED IN POCKET)
Accessories	42031000	ARTICLES OF APPAREL, OF LEATHER OR COMPOSITION LEATHER (EXCL. CLOTHING ACCESSORIES, FOOTWARE AND HEADGEAR AND PARTS THEREOF, AND GOODS OF CHAPTER 95, E.G. SHIN GUARDS, FENCING MASKS)
	42032100	SPECIALLY DESIGNED GLOVES FOR USE IN SPORT, OF LEATHER OR COMPOSITION LEATHER
	42032910	PROTECTIVE GLOVES OF LEATHER OR COMPOSITION LEATHER, FOR ALL TRADES
	42032991	MEN''S AND BOYS'' GLOVES, MITTENS AND MITTS, OF LEATHER OR COMPOSITION LEATHER (EXCL. SPECIAL SPORTS GLOVES AND PROTECTIVE GLOVES FOR ALL TRADES)
	42032999	GLOVES, MITTENS AND MITTS, OF LEATHER OR COMPOSITION LEATHER (EXCL. MEN''S AND BOYS'', SPECIAL SPORTS GLOVES AND PROTECTIVE GLOVES FOR ALL TRADES)
	42033000	BELTS AND BANDOLIERS, OF LEATHER OR COMPOSITION LEATHER
	42034000	CLOTHING ACCESSORIES OF LEATHER OR COMPOSITION LEATHER (EXCL. GLOVES, MITTENS AND MITTS, BELTS, BANDOLIERS, FOOTWARE AND HEADGEAR AND PARTS THEREOF, AND GOODS OF CHAPTER 95 [E.G. SHIN GUARDS, FENCING MASKS])
	91139010	WATCH STRAPS, WATCH BANDS AND WATCH BRACELETS, AND PARTS THEREOF, OF LEATHER OR OF COMPOSITION LEATHER

	CN8 code	Description
Technical use	42040010	CONVEYOR OR TRANSMISSION BELTS OR BELTING, OF LEATHER OR COMPOSITION LEATHER
	42040090	ARTICLES FOR TECHNICAL USE, OF LEATHER OR COMPOSITION LEATHER (EXCL. CONVEYOR OR TRANSMISSION BELTS OR BELTING)
	42050011	CONVEYOR OR TRANSMISSION BELTS OR BELTING, OF LEATHER OR COMPOSITION LEATHER
	42050019	ARTICLES FOR TECHNICAL USE, OF LEATHER OR COMPOSITION LEATHER (EXCL. CONVEYOR OR TRANSMISSION BELTS OR BELTING)
Footwear	64031100	SKI-BOOTS AND CROSS-COUNTRY SKI FOOTWEAR, WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER AND UPPERS OF LEATHER
	64031200	SKI-BOOTS, CROSS-COUNTRY SKI FOOTWEAR AND SNOWBOARD BOOTS, WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER AND UPPERS OF LEATHER
	64031900	SPORTS FOOTWEAR, WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER AND UPPERS OF LEATHER (EXCL. SKI-BOOTS, CROSS-COUNTRY SKI FOOTWEAR, SNOWBOARD BOOTS AND SKATING BOOTS WITH ICE OR ROLLER SKATES ATTACHED)
	64032000	FOOTWEAR WITH OUTER SOLES OF LEATHER, AND UPPERS WHICH CONSIST OF LEATHER STRAPS ACROSS THE INSTEP AND AROUND THE BIG TOE
Footwear	64033000	FOOTWEAR WITH LEATHER UPPERS, MADE ON A BASE OR PLATFORM OF WOOD, WITH NEITHER AN INNER SOLE NOR A PROTECTIVE METAL TOECAP
	64034000	FOOTWEAR, INCORPORATING A PROTECTIVE METAL TOECAP, WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER AND UPPERS OF LEATHER (EXCL. SPORTS FOOTWEAR AND ORTHOPAEDIC FOOTWEAR)
	64035105	FOOTWEAR WITH LEATHER UPPERS, MADE ON A BASE OR PLATFORM OF WOOD, COVERING THE ANKLE, WITH NEITHER AN INNER SOLE NOR A PROTECTIVE METAL TOECAP
	64035111	FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, COVERING THE ANKLE BUT NOT THE CALF, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOECAP, SPORTS FOOTWEAR, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64035115	MEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, COVERING THE ANKLE BUT NOT THE CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOECAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64035119	WOMEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, COVERING THE ANKLE BUT NOT THE CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOECAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64035191	FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, COVERING THE ANKLE AND CALF, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOECAP, SPORTS FOOTWEAR, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64035195	MEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, COVERING THE ANKLE AND CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOECAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64035199	WOMEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, COVERING THE ANKLE AND CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOECAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64035905	FOOTWEAR WITH LEATHER UPPERS, MADE ON A BASE OR PLATFORM OF WOOD, WITH NEITHER AN INNER SOLE NOR A PROTECTIVE METAL TOECAP (EXCL. COVERING THE ANKLE)

	CN8 code	Description
	64035911	FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF > 3 CM (EXCL. WITH UPPERS WHICH CONSIST OF LEATHER STRAPS ACROSS THE INSTEP AND AROUND THE BIG TOE)
	64035931	FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF <= 3 CM, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. WITH UPPERS WHICH CONSIST OF LEATHER STRAPS ACROSS THE INSTEP AND AROUND THE BIG TOE, AND TOY FOOTWEAR)
	64035935	MEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF <= 3 CM, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. WITH UPPERS WHICH CONSIST OF LEATHER STRAPS ACROSS THE INSTEP AND AROUND THE BIG TOE)
	64035939	WOMEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF <= 3 CM, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. WITH UPPERS WHICH CONSIST OF LEATHER STRAPS ACROSS THE INSTEP AND AROUND THE BIG TOE)
	64035950	SLIPPERS AND OTHER INDOOR FOOTWEAR, WITH OUTER SOLES AND UPPERS OF LEATHER (EXCL. COVERING THE ANKLE, WITH A VAMP OR UPPER MADE OF STRAPS, AND TOY FOOTWEAR)
	64035991	FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. COVERING THE ANKLE, INCORPORATING A PROTECTIVE METAL TOECAP, MADE ON A BASE OR PLATFORM OF WOOD, WITHOUT IN-SOLES, WITH A VAMP OR UPPER MADE OF STRAPS, INDOOR FOOTWEAR, SPORTS FOOTWEAR, ORTHOPAEDIC FOOTWEAR, AND TOY FOOTWEAR)
	64035995	MEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. COVERING THE ANKLE, INCORPORATING A PROTECTIVE METAL TOECAP, MADE ON A BASE OR PLATFORM OF WOOD, WITHOUT IN-SOLES, WITH A VAMP OR UPPER MADE OF STRAPS, INDOOR FOOTWEAR, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
Footwear	64035999	WOMEN"S FOOTWEAR WITH OUTER SOLES AND UPPERS OF LEATHER, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. COVERING THE ANKLE, INCORPORATING A PROTECTIVE METAL TOECAP, MADE ON A BASE OR PLATFORM OF WOOD, WITHOUT IN-SOLES, WITH A VAMP OR UPPER MADE OF STRAPS, INDOOR FOOTWEAR, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64039105	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, MADE ON A BASE OR PLATFORM OF WOOD, COVERING THE ANKLE WITH NEITHER AN INNER SOLE NOR A PROTECTIVE METAL TOECAP
	64039111	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE BUT NOT THE CALF, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOE-CAP, SPORTS FOOTWEAR, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64039113	FOOTWEAR (NOT IDENTIFIABLE AS MEN'S OR WOMEN'S FOOTWEAR), WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE (BUT NOT THE CALF), WITH IN-SOLES OF A LENGTH >= 24 CM, (EXCL. 6403.11-00 TO 6403.40-00)
	64039115	MEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE BUT NOT THE CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOE-CAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64039116	MEN"S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE (BUT NOT THE CALF), WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00)
	64039118	WOMEN"S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE (BUT NOT THE CALF), WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00)

	CN8 code	Description
	64039119	WOMEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE BUT NOT THE CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOE-CAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64039191	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE AND CALF, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOECAP, SPORTS FOOTWEAR, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64039193	FOOTWEAR NON-IDENTIFIABLE AS MEN"S OR WOMEN"S FOOTWEAR, WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE, WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.1-00 TO 6403.40.00)
	64039195	MEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE AND CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOE-CAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64039196	MEN"S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE, WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00 NOR 6403.90-16)
	64039198	WOMEN"S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE, WITH IN-SOLES OF LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00 NOR 6403.91.18)
	64039199	WOMEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, COVERING THE ANKLE AND CALF, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. INCORPORATING A PROTECTIVE METAL TOE-CAP, SPORTS FOOTWEAR, AND ORTHOPAEDIC FOOTWEAR)
	64039905	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, MADE ON A BASE OR PLATFORM OF WOOD, WITH NEITHER AN INNER SOLE NOR A PROTECTIVE METAL TOECAP (EXCL. COVERING THE ANKLE)
	64039911	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF > 3 CM
Footwear	64039931	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF <= 3 CM, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. TOY FOOTWEAR)
	64039933	FOOTWEAR NON-IDENTIFIABLE AS MEN"S OR WOMEN"S FOOTWEAR, WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER (NOT COVERING THE ANKLE), WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH SOLE AND HEEL HEIGHT <= 3 CM, WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00)
	64039935	MEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF =< 3 CM, WITH IN-SOLES OF >= 24 CM IN LENGTH
	64039936	MEN"S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER (NOT COVERING THE ANKLE), WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH SOLE AND HEEL HEIGHT <= 3 CM, WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00)
	64039938	WOMEN"S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER (NOT COVERING THE ANKLE), WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH SOLE AND HEEL HEIGHT <= 3 CM, WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00)
	64039939	WOMEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, WITH A MAXIMUM SOLE AND HEEL HEIGHT OF =< 3 CM, WITH IN-SOLES OF >= 24 CM IN LENGTH

	CN8 code	Description
	64039950	SLIPPERS AND OTHER INDOOR FOOTWEAR, WITH OUTER SOLES OF RUBBER, PLASTICS, OR COMPOSITION LEATHER AND UPPERS OF LEATHER (EXCL. COVERING THE ANKLE, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, AND TOY FOOTWEAR)
	64039991	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, WITH IN-SOLES OF < 24 CM IN LENGTH (EXCL. COVERING THE ANKLE, INCORPORATING A PROTECTIVE METAL TOECAP, MADE ON A BASE OR PLATFORM OF WOOD, WITHOUT IN-SOLES, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, INDOOR FOOTWEAR, SPORTS FOOTWEAR, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64039993	FOOTWEAR NON-IDENTIFIABLE AS MEN''S OR WOMEN''S FOOTWEAR, WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER AND UPPERS OF LEATHER, WITH IN-SOLES OF A LENGTH OF >= 24 CM (EXCL. FOOTWEAR COVERING THE ANKLE; WITH A PROTECTIVE METAL TOECAP; WITH A MAIN SOLE OF WOOD, WITHOUT IN-SOLE; FOOTWEAR WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR MORE PIECES CUT OUT; INDOOR, SPORTS OR ORTHOPAEDIC FOOTWEAR)
	64039995	MEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. COVERING THE ANKLE, INCORPORATING A PROTECTIVE METAL TOE-CAP, MADE ON A BASE OR PLATFORM OF WOOD, WITHOUT IN-SOLES, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, INDOOR FOOTWEAR, SPORTS FOOTWEAR AND ORTHOPAEDIC FOOTWEAR)
	64039996	MEN''S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER (NOT COVERING THE ANKLE), WITH IN-SOLES OF A LENGTH >= 24 CM (EXCL. 6403.11-00 TO 6403.40.00, 6403.99.11, 6403.99.36, 6403.99.50)
	64039998	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER AND UPPERS OF LEATHER, WITH IN-SOLES OF A LENGTH OF >= 24 CM, FOR WOMEN (EXCL. FOOTWEAR COVERING THE ANKLE; WITH A PROTECTIVE METAL TOECAP; WITH A MAIN SOLE OF WOOD, WITHOUT IN-SOLE; FOOTWEAR WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR MORE PIECES CUT OUT; INDOOR, SPORTS OR ORTHOPAEDIC FOOTWEAR; FOOTWEAR WHICH CANNOT BE IDENTIFIED AS MEN''S OR WOMEN''S)
	64039999	WOMEN'S FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS OR COMPOSITION LEATHER, WITH UPPERS OF LEATHER, WITH IN-SOLES OF >= 24 CM IN LENGTH (EXCL. COVERING THE ANKLE, INCORPORATING A PROTECTIVE METAL TOE-CAP, MADE ON A BASE OR PLATFORM OF WOOD, WITHOUT IN-SOLES, WITH A VAMP MADE OF STRAPS OR WHICH HAS ONE OR SEVERAL PIECES CUT OUT, INDOOR FOOTWEAR, SPORTS FOOTWEAR AND ORTHOPAEDIC FOOTWEAR)
Footwear	64042010	SLIPPERS AND OTHER INDOOR FOOTWEAR WITH OUTER SOLES OF LEATHER OR COMPOSITION LEATHER AND UPPERS OF TEXTILE MATERIALS (EXCL. TOY FOOTWEAR)
	64042090	FOOTWEAR WITH OUTER SOLES OF LEATHER OR COMPOSITION LEATHER AND UPPERS OF TEXTILE MATERIALS (EXCL. INDOOR FOOTWEAR AND TOY FOOTWEAR)
	64051000	FOOTWEAR WITH UPPERS OF LEATHER OR COMPOSITION LEATHER (EXCL. WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER AND UPPERS OF LEATHER, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64051010	FOOTWEAR WITH UPPERS OF LEATHER OR COMPOSITION LEATHER AND OUTER SOLES OF WOOD OR CORK (EXCL. ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64051090	FOOTWEAR WITH UPPERS OF LEATHER OR COMPOSITION LEATHER (EXCL. WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER AND UPPERS OF LEATHER, OR WITH OUTER SOLES OF WOOD OR CORK, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64052099	FOOTWEAR WITH UPPERS OF TEXTILE MATERIALS (EXCL. WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER, WOOD OR CORK, INDOOR FOOTWEAR, ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)
	64059010	FOOTWEAR WITH OUTER SOLES OF RUBBER, PLASTICS, LEATHER OR COMPOSITION LEATHER AND UPPERS OF MATERIALS OTHER THAN LEATHER, COMPOSITION LEATHER OR TEXTILE MATERIALS (EXCL. ORTHOPAEDIC FOOTWEAR AND TOY FOOTWEAR)

	CN8 code	Description
	64061010	UPPERS AND PARTS THEREOF, OF LEATHER (EXCL. STIFFENERS)
	64061011	LEATHER UPPERS, WHETHER OR NOT ATTACHED TO SOLES OTHER THAN OUTER SOLES
	64061019	PARTS OF LEATHER UPPERS (EXCL. STIFFENERS)
	64069960	OUTER SOLES OF SHOES, OF LEATHER OR COMPOSITION LEATHER,
Other	42010000	SADDLERY AND HARNESS FOR ANY ANIMAL, INCL. TRACES, LEADS, KNEE PADS, MUZZLES, SADDLE CLOTHS, SADDLEBAGS, DOG COATS AND THE LIKE, OF ANY MATERIAL (EXCL. HARNESSES FOR CHILDREN AND ADULTS, RIDING WHIPS AND OTHER GOODS OF HEADING 6602)
	59111000	TEXTILE FABRICS, FELT AND FELT-LINED WOVEN FABRICS, COATED, COVERED OR LAMINATED WITH RUBBER, LEATHER OR OTHER MATERIAL, OF A KIND USED FOR CARD CLOTHING, AND SIMILAR FABRICS OF A KIND USED FOR OTHER TECHNICAL PURPOSES, INCL. NARROW FABRICS MADE OF VELVET IMPREGNATED WITH RUBBER, FOR COVERING WEAVING SPINDLES "WEAVING BEAMS"
	95066210	INFLATABLE LEATHER BALLS
	42050000	ARTICLES OF LEATHER OR COMPOSITION LEATHER (EXCL. SADDLERY AND HARNESS BAGS; CASES AND SIMILAR CONTAINERS; APPAREL AND CLOTHING ACCESSORIES; ARTICLES FOR TECHNICAL USES; WHIPS, RIDING-CROPS AND SIMILAR OF HEADING 6602; FURNITURE; LIGHTING APPLIANCES; TOYS; GAMES; SPORTS ARTICLES; BUTTONS AND PARTS THEREOF; CUFF LINKS, BRACELETS OR OTHER IMITATION JEWELLERY; MADE-UP ARTICLES OF NETTING OF HEADING 5608; AND ARTICLES OF PLAITING MATERIALS)
	42050090	ARTICLES OF LEATHER OR COMPOSITION LEATHER (EXCL. SADDLERY AND HARNESS BAGS; CASES AND SIMILAR CONTAINERS; APPAREL AND CLOTHING ACCESSORIES; ARTICLES FOR TECHNICAL USES; WHIPS, RIDING-CROPS AND SIMILAR OF HEADING 6602; FURNITURE; LIGHTING APPLIANCES; TOYS; GAMES; SPORTS ARTICLES; BUTTONS AND PARTS THEREOF; CUFF LINKS, BRACELETS OR OTHER IMITATION JEWELLERY; MADE-UP ARTICLES OF NETTING OF HEADING 5608; AND ARTICLES OF PLAITING MATERIALS)

	PRODCOM CODE	Description
Raw skins and hides	15112400	Raw hides and skins of bovine or equine animals, whole
	15112500	Raw hides and skins of bovine or equine animals (excluding whole)
	15112600	Skins of sheep or lambs
	15112700	Raw hides and skins of goats or kids but not tanned, fresh or preserved
Pure leather	19101100	Chamois leather and combination chamois leather
	19101200	Patent leather; patent laminated leather and metallised leather
	19102100	Leather, of bovine animals, without hair, whole
	19102200	Leather, of bovine animals, without hair, not whole
	19102300	Leather, of equine animals, without hair
	19103130	Sheep or lamb skin leather without wool on; tanned but not further prepared (excluding chamois leather)
	19103150	Sheep or lamb skin leather without wool on; parchment-dressed or prepared after tanning (excluding chamois, patent, patent laminated leather and metallised leather)
	19103230	Goat or kid skin leather without hair on; tanned or re-tanned but not further prepared (excluding chamois leather)
	19103250	Goat or kid skin leather without hair on; parchment-dressed or prepared after tanning (excluding chamois leather, patent leather; patent laminated leather and metallised leather)
	19103330	Leather of swine without hair on, tanned but not further prepared
	19103350	Leather of swine without hair on; parchment-dressed or prepared after tanning (excluding patent leather; patent laminated leather and metallised leather)
	19104130	Animal leather without hair on, tanned but not further prep. (excluding chamois, patent and patent laminated, metallized, bovine, equine, sheep or lamb skin, goat or kid skin, swine)

	19104150	Animal leather without hair on, parchment dressed/prepared after tanning excluding chamois - patent and patent laminated, metallized bovine, equine, sheep, lamb skin, goat, kid skin,swine
	19104200	Composition leather with a basis of leather or leather fibre; in slabs; sheets or strips
Containers	19201210	Trunks, suitcases, vanity-cases, briefcases, school satchels and similar containers of leather, composition leather, patent leather, plastics, textile materials, aluminium or other materials
	19201220	Handbags of leather, composition leather, patent leather, plastic sheeting, textile materials or other materials (including those without a handle)
Accessories	18243173	Protective gloves, mittens and mitts for all trades, of leather or composition leather
	18243175	Gloves, mittens and mitts, of leather or composition leather (excluding for sport, protective for all trades)
	18243180	Belts and bandoliers, of leather or composition leather
	18243190	Clothing accessories of leather or composition leather (excluding gloves, mittens and mitts, belts and bandoliers)
	19201300	Watch straps, bands, bracelets and parts thereof (including of leather, composition leather or plastic; excluding of precious metal, metal or base metal clad/plated with precious metal)
Footwear	19301351	Men's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)
	19301352	Women's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)
	19301353	Children's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)
	19301361	Men's sandals with leather uppers (including thong type sandals, flip flops)
	19301362	Women's sandals with leather uppers (including thong type sandals, flip flops)
	19301363	Children's sandals with leather uppers (including thong type sandals, flip flops)
	19301370	Slippers and other indoor footwear with rubber; plastic or leather outer soles and leather uppers (including dancing and bedroom slippers, mules)
	19301380	Footwear with wood; cork or other outer soles and leather uppers (excluding outer soles of rubber; plastics or leather)
	19301445	Footwear with rubber; plastic or leather outer soles and textile uppers (excluding slippers and other indoor footwear, sports footwear)
	19302150	Ski-boots; cross-country ski footwear and snowboard boots with leather uppers

	19302350	Sports footwear with rubber; plastic or leather outer soles and leather uppers (excluding ski-boots; cross-country ski footwear and snowboard boots)
	19303150	Footwear with rubber; plastic or leather outer soles and leather uppers; and with a protective metal toe-cap
Footwear	19303255	Sandals with leather outer soles and uppers; consisting of leather straps across the instep and around the big toe (including Indian sandals)
	19303257	Footwear with a wooden base and leather uppers (including clogs) (excluding with an inner sole or a protective metal toe-cap)
	19304065	Leather uppers and parts thereof of footwear (excluding stiffeners)
Technical use	19201430	Articles of leather or composition leather of a kind used in machinery or mechanical appliances or for other technical uses
Others	19201450	Articles of leather or of composition leather, n.e.c.
	18101000	Articles of apparel of leather or of composition leather (including coats and overcoats) (excluding clothing accessories, headgear, footwear)