Committee for Risk Assessment (RAC)

Opinion

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Chromium (VI) compounds in leather articles

ECHA/RAC/RES-O-0000001412-86-09/F

ECHA/SEAC/RES-O-0000002419-71-02/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 28 November 2012) and SEAC's opinion (adopted 8 March 2013)

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28 November 2012

ECHA/RAC/ RES-O-0000001412-86-09/F

8 March 2013

ECHA/SEAC/ RES-O-0000002419-71-02/F

Opinion of the Committee for Risk Assessment

And

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the Community

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Chromium (VI) compounds**
EC No.:	not applicable
CAS No.:	not applicable

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

Denmark has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at ***http://echa.europa.eu/restrictions-under-consideration*** on ***16 March 2012***. Interested parties were invited to submit comments and contributions by ***16 September 2012***.

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ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by the RAC: Andrew Smith

Co-rapporteur, appointed by the RAC: Urs Schlüter

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***28 November 2012***.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted ***by consensus***.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by the SEAC: *Endre Schuchtár*

Co-rapporteur, appointed by the SEAC: *Janez Furlan*

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***4 December 2012***.

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***14 December 2012***. Interested parties were invited to submit comments on the draft opinion by ***12 February 2013***.

The opinion of SEAC

The opinion of the SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***8 March 2013***.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted **by consensus**.

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OPINION

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the following modified version of the restriction proposed by the Dossier Submitter to address the identified risks posed by chromium (VI) compounds in leather to be the most appropriate Community wide measure in terms of effectiveness and practicability.

The proposed restriction is as follows:

Chromium (VI) compounds

Leather articles, or leather parts of articles, coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) in concentrations equal to or higher than 3 mg/kg (0,0003%) chromium (VI) of the total dry weight of the leather[1].

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on **chromium (VI) compounds** is the most appropriate Community wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope and conditions are modified.

The proposed restriction is as follows:

Chromium (VI) compounds

Leather articles, or leather parts of articles, coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) in concentrations equal to or higher than 3 mg/kg (0,0003%) chromium (VI) of the total dry weight of the leather.

By way of derogation, the restriction shall not apply to leather articles placed on the market for the first time before [12 months after the amendment of the REACH Annex XVII enters into force].

The proposed restriction will apply 12 months after the amendment of the REACH Annex XVII enters into force.

[1] The limit represents the quantitative limit of the analytical method used to determine the content of hexavalent chromium in leather in its current state. The method is the international standard EN ISO 17075:2007.

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JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

Identified hazard and risk

Justification for the opinion of RAC

Information on hazards

The proposed restriction focuses on the risk to consumers (including workers as consumers) of skin sensitisation from direct or indirect skin contact with leather articles that contain chromium (VI). This includes articles for which there is relatively short, repetitive skin contact as well as longer term, repeated contact.

Skin sensitisation potential of chromium (VI) compounds

Chromium (VI) compounds are potent skin sensitisers in animal tests (the guinea pig maximisation test and the local lymph node assay). In humans, they can cause severe allergic contact dermatitis and are able to elicit responses at very low concentrations.

Chromium (VI) is water soluble and has a poor protein binding capacity, which enables it to easily penetrate the epidermis. It is believed to be then reduced to chromium (III), which forms stable conjugates with protein and induces an immune response. Skin sensitisation develops in two distinct phases:

- induction, during which an individual becomes sensitised to a particular allergen (no symptoms); and
- elicitation, which occurs on subsequent exposure (symptoms are apparent).

From local lymph node assay data, the effective concentration (EC_3 value) expressed in dose/unit area of exposed skin can be considered as the LOAEL for induction. An EC_3 value of 10 µg/cm^2 has been reported for chromium (VI).

Both induction and elicitation are considered to be threshold effects. However, because of differences in individual susceptibilities and the effects of the induction regime, thresholds are not absolute values that can be applied to the whole population. Additionally, symptoms can generally be elicited at doses lower than those required for the initial induction of sensitisation; as a result, exposures that are maintained below the elicitation threshold should also be protective against the induction of sensitisation. Consequently, rather than defining a DNEL based on an EC_3 value for induction, the restriction proposal presents the minimum elicitation threshold ($MET_{10\%}$), which is the concentration at which a response is elicted in 10 % of sensitised individuals. A lowest $MET_{10\%}$ (LOAEL) of 0.02 µg Cr(VI)/cm^2 was selected from published human occluded patch-test data as the LOAEL for elicitation.

To derive a DNEL from this starting point, default assessment factors of 3 (extrapolation of LOAEL to NOAEL) and 10 (to compensate for inter-individual variation within the human population) could be applied, while other assessment factors would be set at 1. However, currently, the limit of quantification for chromium (VI) in leather is 3 mg/kg, corresponding to approximately 0.45 µg/cm^2 [2]. This exposure level is already higher than the LOAEL ($MET_{10\%}$ of 0.02 µg/cm^2). Further derivation of a DNEL, a value below the LOAEL, would not lead to any further material changes in the risk characterisation.

[2] See Background Document B.9.3.2.2, Considerations regarding an exposure scenario for leather articles.

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Other effects of chromium (VI) compounds

The other hazards of chromium (VI) compounds were not considered to be relevant to the proposed restriction and therefore were only briefly described in the Background Document.

Skin sensitisation potential of chromium (III) compounds

Chromium (III) has a high protein binding capacity and thus forms stable complexes within the epidermis rather than penetrating the skin. As a result, chromium (III) compounds are less potent skin sensitisers than chromium (VI) compounds. $MET_{10\%}$ values for chromium (III) have been reported in only two, rather contradictory, studies in patients with chromium allergy, but both values were higher than those for chromium (VI). Reports of primary sensitisation to chromium (III) in humans are uncommon.

Information on emissions and exposures

Chromium (VI) can be formed during the chrome tanning process when chromium (III) is oxidised. Chromium (III) compounds are added in some tanning processes to increase dimensional stability, resistance to mechanical action and heat resistance of the leather by cross-linking of the collagen subunits. The mechanisms of and conditions under which chromium (VI) are formed are well understood, and measures have been developed and are widely implemented within EU tanneries (confirmed by industry during public consultation) to minimise its formation.

Several parameters have been described in the technical literature that can facilitate the formation of chromium (VI) in leather even after the tanning process, during storage or the life-cycle of an article. Several strategies have been identified that can enable this "post-formation" of chromium (VI) to be avoided. The following conclusions characterise the current status of knowledge regarding this issue.

- Constituents in the hide structure have no clear influence on the formation of chromium (VI).
- Some modern fatliquoring agents stable to oxidation were unable to inhibit the formation of chromium (VI) on exposure of the leather to UV radiation.
- Reducing agents (e.g. natural antioxidants such as vegetable tannins, ascorbic acid etc.) were effective whether applied in the float as after-treatment or as an after spray; they remained effective after heat treatment.
- Finishing with certain alkaline adhesion binders can promote the formation of chromium (VI) on heat ageing, and particularly with UV exposure.
- There is a linear relationship between total and soluble chrome content but no significant relationship between soluble chrome and chromium (VI) content.
- Higher moisture content during storage of the leather is positive for lowering or preventing the chromium (VI) content.
- Heat aging and UV radiation (artificial ageing under experimental conditions) were found to facilitate chromium (VI) formation in leather that had been chrome tanned.

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In spite of the information received by industry and the availability of techniques that avoid post-formation of chromium (VI), surveys within the last 10 years in Denmark and Germany of chromium (VI) in leather articles have shown that at least 30 % of the articles tested contained detectable levels (> 3 mg/kg) of chromium (VI). For example, the mean value of chromium (VI) levels in gloves was 13.7 mg/kg and in footwear it was 12.7 mg/kg in one German market survey. Taking into account these results, RAC selected a value of 10 mg/kg for the content of chromium (VI) in leather for the purpose of making an illustrative risk assessment. This value is clearly not "worst case".

From the available information, it is not known whether those articles with high levels of chromium (VI) had been produced within the EU or imported.

During the finishing stage of leather production, additionally, chromate pigments (yellow and orange inorganic pigments) may be introduced. The use of such pigments in leather articles would be limited by the proposed restriction.

Leather goods coming into 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 most common cases appear to relate to footwear and it is evident that allergic contact dermatitis can sometimes develop even when the subject is wearing socks or stockings (i.e. by indirect skin contact). Leather goods with which consumers come into shorter term skin contact may also elicit allergic reactions in sensitive individuals; such is the potency of chromium (VI) as a sensitiser. Owing to the wide spread use of leather articles, there is potential for virtually all consumers to be exposed to chromium (VI) via dermal contact.

Several studies report on occupational allergic contact dermatitis from exposure to chromium in tanneries or the manufacture, occupational use or trade of leather articles.

Information on transfer or migration rates of chromium (VI) from leather to human skin or sweat is scarce. In providing an exposure scenario and an illustrative risk assessment, the Dossier Submitter assumed that the total amount of chromium (VI) that can be extracted from an article is representative of the total amount available for migration. However, the underlying supposition here that all of the determined chromium (VI) will leach out from leather during use is a worst case assumption that might well overestimate the capacity for migration. This is because the sample preparation in the test methods used to measure total chromium (VI) in leather (e.g. ISO standard 17075 or DIN 53314) requires the use of a standard analytical solution, not sweat (or even a solution resembling sweat). In a German study on the influence of the pH on the leaching of chromium (VI) from leather into artificial sweat it was found that the migration was at the most 30% of the concentrations determined. Therefore, RAC considers that a migration rate of 30% of the amount of measured chromium (VI) from leather to human skin represents a more realistic but still conservative estimation of the potential exposure. The Committee applied this value in an illustrative risk assessment (see Background Document). RAC does not consider a more detailed exposure assessment necessary using specific exposure models to estimate the potential for contact exposure.

Characterisation of risks

The assessment provided by the Dossier Submitter concluded that extractable chromium (VI) from leather articles represents a risk for the development of contact allergy to chromium for consumers. Given the available evidence from patients attending dermatology clinics with symptoms of allergic contact dermatitis, together with the general data available

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on the skin sensitisation potential of chromium (VI) compounds, RAC agrees with this conclusion.

The available clinical data show that the prevalence rates of chromium allergy amongst patients presenting themselves for investigation appear to be in the range 2.3% (data from Denmark in 2005) to 6.1% (data from Germany in 2007). There do not appear to have been any consistent trends in prevalence rates in recent years. One study comparing rates across different regions of the EU has suggested that the problem may be greater in Southern Europe, but the data are limited. In Denmark, where the available data appear to be the most comprehensive, the average annual prevalence rate for men and women combined for the seven years from 2004 to 2010 was 2.96%. In the absence of more comprehensive data, it seems reasonable to take this value as representative for the EU as a whole.

During the public consultation, the International Society of Contact Dermatitis provided data showing comparable rates of chromium allergy in various clinics located in Belgium, Portugal and Spain. RAC was also provided with supportive information from the UK and Sweden.

For the general population, it is more difficult to obtain information on the total numbers of chromium-sensitive individuals (prevalence) and even the numbers of new cases of the disease (incidence). The most useful information has come from Denmark and this is believed to be broadly representative for the EU as a whole.

The CE-DUR method (clinical epidemiological drug utilisation research) has been employed in recent years to estimate the prevalence of contact allergy. This does not measure prevalence directly, but makes predictions based on expert judgement and knowledge of 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. It has been used particularly effectively in Denmark, giving 10-year prevalence rates for contact allergy overall of between 5.5% ("best case") and 9.7% ("worst case") in the general population. These rates were slightly lower than values determined by more conventional, cross-sectional research in Denmark in the 1990s (the so-called Glostrup allergy studies), and this may have been because of a decrease in nickel allergy. Importantly, however, the comparison served to illustrate the validity of the CE-DUR method as a tool for estimating prevalence rates in general.

Using the same assumptions employed to calculate the scale of contact dermatitis overall in the Danish population, general population prevalence rates were also determined for individual allergens. 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). The Dossier Submitter concluded from this study that the "10-year" prevalence of chromium allergy in the general population (based on data from 2001-2005) in Denmark was in the range 0.2%-0.54%. The average of 0.37%, as a medium case prevalence, corresponded to approx. 20,000 individuals.

However, on further consideration, including a personal communication from one of the Danish study's principal authors and a discussion with another expert, RAC concluded that these estimates of chromium allergy in the general population are unreliable. Whilst it was interesting within the study to compare prevalence values for all the different allergens, this was done crudely by the use of default correction factors for the proportion of previously tested individuals and the proportion of diseased people seeking medical consultation during a 10-year period. Furthermore, the experts advised that it was unlikely people diagnosed with chromium (VI) allergy would be patch re-tested (e.g. after 10 years), given the stress that such testing could cause these sensitised individuals. In order to focus specifically on

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chromium (VI), or indeed any other allergen in the study, more appropriate factors can and should be selected.

The expert advised that the most appropriate factors to be employed for chromium (VI) to account for the proportion of previously tested persons and the proportion of diseased people seeking medical consultation for this severe allergy during a 10-year period should be 25% and 100%, respectively. This was in contrast to the generic factors of 10% and 25% used in the original study. With these new values, which RAC concluded were of greater relevance to chromium (VI), lower prevalence estimates were be derived for the general population.

As described in the Background Document, RAC further assumed that the onset of allergy to chromium (VI) happens on average at 40 years of age (expert estimate, on the basis of the experience in Denmark and published literature). RAC also assumed (worst case) that a sensitised person would remain sensitised for the rest of their life and that an individual aged 40 would have about a remaining 42-year life expectancy. Since the CE DUR method yields a "10-year" prevalence value, RAC concluded that this would not represent the total prevalence of chromium (VI) allergy in the population. In the absence of data to enable a better factor to be derived, recognising the various assumptions and uncertainties described above, RAC decided to multiply the 10-year prevalence derived by the CE DUR method to obtain an estimate of the total population prevalence of the disease.

Using the CE DUR method, RAC estimated the number of people in Denmark with chromium (VI) allergy eligible for patch testing over a 10-year period. From this, estimates were derived for the total prevalence of chromium (VI) across the EU and the number of new cases emerging per annum. RAC derived the following values:

Number of people with chromium allergy eligible for patch testing = 18,280.

Total prevalence (10-year value x 4.2) of chromium allergy in the general population (including data from patients that gave equivocal results due to diagnostic uncertainties of positive patch reactions) = 0.46%.

Total prevalence (10-year value x 4.2) of chromium allergy in the general population (excluding data from patients that gave equivocal results on patch testing) = 0.17%.

The average of these two values gives a medium-case prevalence of 0.32%.

RAC assumed that data from a Danish clinical environment are applicable to the wider EU. This, applying these factors to the EU27 (population 500 million), RAC estimated that this "total" prevalence rate of chromium allergy (contact dermatitis) in the general population equates to 0.84-2.31 million individuals sensitised. Similarly, the number of new cases each year, assuming constant population and constant prevalence, was estimated to be in the range 20,000 - 55,000. The median value is 37,500.

On the basis of the recent experience from Denmark it was estimated by the Dossier Submitter that at least 45% of the new chromium allergy cases are due to exposure from leather or articles of leather. With 20,000 - 55,000 new cases of chromium allergy each year in the EU, 45% of which are due to exposure to leather, RAC estimates the total number of cases caused by leather would be 9,000 – 24,750 per year.

This estimate of 45% came from a retrospective analysis of patch test data, alongside a review of medical charts from patients with chromium (VI) allergy. The study population included all patients with dermatitis patch tested at a single hospital in Denmark between 1985 and 2007. The 45% value related to the period 1995 to 2007. The study authors

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commented that it was not possible to link the chromium (VI) allergy they saw in many patients to any specific exposure. As exposure via leather seemed to them the most common mode of exposure, they speculated that the true value could well be higher than 45%. During discussion of this study, RAC also noted that the possibility that the study could have over-estimated the scale of chromium (VI) allergy due to exposure via leather. In the absence of firm data to the contrary, RAC assumed that exposures in Denmark are applicable to the wider EU, concluding that 45% was a reasonable value to use.

During the public consultation, the International Society of Contact Dermatitis commented that data from clinics in Belgium, Portugal and Spain indicated exposure to leather, especially footwear, was a key factor in the history of significant numbers of patients with chrome allergy. The most startling figures were from Leuven in Belgium, where 626 (4.7%) of 13,527 patients patch tested between 2000 and 2011 presented with a contact allergy to potassium dichromate, of which 536 (86% of the cases) were considered to have been due to exposure via footwear. This would appear to indicate that the 45% value used by RAC is unlikely to be a gross over-estimate; it may be an under-estimate.

Evidence that the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient

On the basis of a risk assessment performed by the German Federal Institute for Risk Assessment (BfR), the Dossier Submitter concluded that the only way of preventing allergic reactions for allergy sufferers is to avoid contact with leather goods that contain chromium (VI). RAC agreed with this general principle, given the potency of chromium (VI) as a sensitiser.

According to information from industry, the measures for prevention of chromium (VI) are implemented in most tanneries in Europe and are adequate for the manufacture of leather with chromium (VI) content below the quantification limit of 3 mg/kg. This assessment was supported by several stakeholder contributions during the public consultation. However, inspections of the chromium (VI) content of marketed leather articles have demonstrated that at least 30 % of tested products contain chromium (VI) in levels above 3 mg/kg. It has been suggested that imported articles may be more likely to contain such levels of chromium (VI) than those manufactured in the EU, but this does not appear to have been confirmed.

Accordingly, the effectiveness of the already-implemented risk management measures could not be demonstrated by the Dossier Submitter. Therefore, additional risk management measures seem to be necessary.

Some articles may have, as standard, a finish coat to protect the leather surface from damage and to provide resistance to colour fading; examples of such articles include covers for car steering wheels, auto seats, other automotive interior parts and furniture. The finish coat comprises a polyurethane or acrylic layer and prevents direct skin contact with the leather. Notwithstanding, the Dossier Submitter considered that coated articles were within scope of the proposed restriction. RAC was not provided with any analytical data regarding the potential release of chromium (VI) from coated articles. Furthermore, there is no information on how ageing of the article affects the effectiveness of the polyurethane or acrylic layer and, regardless of ageing, the coating might be damaged and thereby exposure would be possible. Overall, these types of articles are included in the scope of the restriction proposal. Although RAC accepts that coatings will limit direct exposure to an extent, it agreed with the Dossier Submitter that they should be included in the scope of the restriction proposal.

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Evidence that the existing regulatory risk management instruments are not sufficient

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

Justification that action is required on a Community-wide basis

Justification for the opinion of RAC

The proposed restriction covers articles of leather that are extensively traded among and used in all Member States. Currently, only in Germany is a national restriction in place to address the risk to consumers of contact dermatitis posed by chromium (VI) in leather articles. In spite of the already implemented measures, a large number of consumers develop each year chromium allergy from exposure to chromium (VI) in leather in different Member States.

It has been suggested that imported leather goods are more likely to contain high levels of chromium (VI) than those manufactured in the EU. Although this has not been proven, concerted action across the EU would be the best way of tackling such a problem.

The Community-wide restriction placed already on chromium (VI) in cement is widely considered to have been effective at reducing the prevalence of contact dermatitis in exposed workers. This restriction is viewed by clinical dermatologists as a model that could be applied successfully to address the risks posed by chromium (VI) in leather articles.

Justification for the opinion of SEAC

The justification to act on a Community-wide basis originates also 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 effects 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 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 leather articles.

Justification that the suggested restriction is the most appropriate Community-wide measure

Justification for the opinion of RAC

RAC acknowledges the justification provided by the Dossier Submitter to restrict those leather articles coming into direct and prolonged contact with the skin (RMO 1). However, the Committee proposes a restriction that would be wider in scope to better reflect the nature of the exposures that pose a risk to consumers (including those exposed to

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consumer articles at work). Specifically, this modified proposal extends the scope to all leather articles that come into contact with the skin when used, either directly or indirectly.

Although the terms *direct and prolonged* contact with the skin do appear in the existing Community-wide restrictions for nickel and azocolourants/azodyes, they have presented difficulties of interpretation for stakeholders. RAC is aware of efforts to clarify these terms, but is of the opinion that definitions for these substances should not automatically be assumed relevant to chromium (VI). Notably, chromium (VI) is a more potent sensitiser than nickel. The need for intimate, close contact between the article and the skin is much diminished in the case of chromium (VI).

In addition to the preferred restriction of the Dossier Submitter, two other options were 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 is very similar in scope to the proposal provided by RAC. Both options would likely provide the same level of consumer protection, but RMO 2 might further protect any workers coming into contact with technical leather used for industrial purposes like leather belts for power transmission and hydraulic packing etc. However, such exposures are considered infrequent and to present very limited skin contact.

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). However, it has not been established that chromium (III) in leather presents a significant risk itself to consumers. Also, as recognised by SEAC, RMO 3 would introduce significantly higher costs than RMO 1 or the proposal made by RAC.

According to the analysis of the Dossier Submitter, RM0 2 and RM0 3 would offer a slightly better protection for the consumers against any risk posed by leather not shaped into a final product; e.g. leather sold to consumers and used by them to make bags, belts, etc. It seems likely that this additional benefit would be small, given that the proposed restriction will already prompt those who produce leather to use methods to minimise chromium (VI) formation.

Justification for the opinion of SEAC

The formation of chromium (VI) in leather and articles of leather can basically be reduced or 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 reduced 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.

In addition to the proposed restriction covering leather articles coming into contact with the skin (RMO 1), two other restriction options have been presented by the Dossier Submitter:

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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).

As recognised by RAC, RMO 2 may provide a slightly better consumer protection, including also technical leather used for industrial purposes like leather belts for power transmission and hydraulic packing etc. However, such exposures are considered infrequent and to present very limited skin contact by RAC. SEAC is aware of the fact that the tanneries in the EU may have changed their production lines for tanning leather, leading to production and placing on the market of leather products and articles that do not lead to chromium sensitization. The result of this transition could be that EU produced articles will already cover the scope of RMO2. Even if the additional cost of restricting technical leather is considered to be small, SEAC agreed with the arguments presented by RAC on the scope of the proposed restriction.

RMO 3 is in practice a ban of chrome tanned leather. As recognised by RAC, this RMO may provide a better consumer protection by omitting all exposure from both chromium (III) and (VI). However, it would introduce significantly higher costs than RMO 1 as especially the shoe production would have to be completely changed. Furthermore, banning chromium (III) would have much larger consequences for the industry, which are not fully assessed in the Background Document. Because of this, the RMO 3 can not be supported.

Besides the restriction of placing on the market, other risk management options were considered e.g. the REACH authorisation process, voluntary industry agreement and information to consumers including labelling. The REACH authorisation process would not be applicable because there is no intentional use of chromium (VI) compounds in the production of leather. A voluntary agreement within the tanning sector already exists, but it should be extended to importers of leather and leather articles. However it is considered that this would prove ineffective owing to a high number of importers and their business partners outside EU. Information to consumers in the form of labelling would have limited effectiveness because it would not prevent new cases of chromium (VI) allergies developing every year. Before symptoms are elicited, the consumers are unaware that they have become sensitive to chromium (VI), but once sensitised, they would suffer from the allergy for the rest of their lifetime. The risk of dermatitis remains even if they avoided chromium (VI) containing leather articles, since there are other sources of exposure. The majority of other sources are reported as "unknown", and it cannot be assumed that consumers would be able to avoid them. Nevertheless, a labelling approach may be helpful in reducing the risk of dermatitis for existing cases, though it has not been possible for SEAC to compare the relative merits of such an approach with the proposed restriction in terms of its proportionality.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

It is proposed that the EN ISO 17075 standard for the determination of chromium (VI) in leather is used for compliance control. As the standard currently has a quantification limit for chromium (VI) of 3 mg/kg, even leather passing the test may contain chromium (VI) in sufficient amounts to elicit dermatitis in some already-sensitised individuals. The quantification limit is determined by the complexity of the leather matrix, and results below 3 mg/kg show large variations and have limited reliability. However, with technical progress it is certainly possible to establish a lower quantification limit.

It was estimated by the Dossier Submitter that their preferred restriction (RMO 1) would cover about 90% of the articles placed on the market (accounting for almost 100% of

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consumer exposure), the remainder being articles with short-time contact with the body. The modification proposed by RAC would cover these additional consumer articles. However, this may not be an issue, since it is apparent that the leather used for the latter articles is to a large extent produced by the same tanneries that produce the leather used for the articles covered by the restriction. It seems most likely that the tanneries would apply the procedures to prevent formation of chromium (VI) whether all of their down-stream users are covered by the restriction or not.

The effectiveness of the proposed restriction has been estimated on the basis of the available information on elicitation threshold and the limit value of the applied standard for compliance control (3 mg/kg). Expert judgement has been applied.

Based on the available data, the total number of new cases of chromium allergy per year in the EU is estimated at 20,000 – 55,000. This figure includes Germany, and is unlikely to account for the impact of the restriction of chromium (VI) in leather that has recently been introduced in that Member State. Of these cases across the EU, it is estimated that at least 9,000 – 24,750 (45%) are caused by exposure to chromium (VI) in leather.

The Dossier Submitter assumed, conservatively, that the restriction would be 80 % effective in reducing the number of new cases, allowing for the possibility that low, undetected levels of chromium (VI) in leather articles might still lead to sensitisation (upper estimate of 20% of cases, based on expert judgement). At this level of effectiveness, the number of new cases that could be avoided can be estimated at 7,200 – 19,800 per year. However, some of these cases would be avoided by the newly introduced (August 2010) German restriction, and this should not be attributed to the proposed restriction. Assuming a prevalence of chromium allergy in the general population of 0.17% to 0.46% and an equivalent effectiveness of the German restriction, the approximate number of cases avoided by the latter would be 1,440 – 3,960. On this basis, it will be assumed that the number of new cases of chromium allergy will be reduced by 5,760 – 15,840 per year as a consequence of the proposed restriction.

RAC acknowledges that these estimates rely to an extent on expert judgement and various assumptions, some of which are more intuitive than empirical. However, overall, the estimates summarised above represent the best the Committee could provide in the circumstances. Further, they are considered to be an improvement on those provided originally by the Dossier Submitter.

The proposed restriction would protect both consumers and workers who come into direct or indirect contact with leather or leather articles.

Proportionality to the risks

Justification for the opinion of SEAC

As presented in the opinion of RAC, it is estimated that the proposed restriction would reduce 5,760 – 15,840 (mean being 10,800) chromium allergy cases per year in the EU. RAC also estimates that currently between 0.84 million and 2.31 million people have chromium allergy in the EU (mean being 1.58 million). Since Germany already has a national ban, this figure was reduced to 1.32 million. These mean figures were used as a basis for the benefit estimates of SEAC. SEAC acknowledge that there are uncertainties (see later section on uncertainties) associated with these figures, but that they are the best that RAC could provide in the circumstances. As such, SEAC's assessment of proportionality is in part conditional on the uncertainties and validity of the estimates of prevalence and incidence provided.

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It is difficult and impractical to enforce a restriction on the placing on the market for second hand articles as well as articles that are in the supply chain (i.e. stocks) at the date of entry into force. Furthermore, based on the Background Document it is not possible to evaluate the economic and other impacts if a batch of leather articles in stocks did not comply with the limit value. Therefore, the restriction should not apply to articles placed on the market for the first time before the restriction becomes effective.

Costs

The Dossier Submitter estimated the costs of the proposed restriction to be of the order of €83 to €100 million per year. The costs comprise of higher prices of leather products placed on the market in the EU including Germany and costs related to additional testing of chromium (VI) content of these products. According to the Dossier Submitter, the prices of imported leather articles are expected to increase with around 0.4% and the prices of articles produced in the EU with less than 0.2% due to an increase of about 5% in the costs for chemical of the tanneries. The difference in price increase reflects the lower share of the price of the leather of the total price of article produced in the EU compared to imported product. About €70 million of the cost is allocated to increased prices of imported leather articles and €8-15 million to cost increase of the EU production. Finally, the additional testing of both EU production and imports is estimated to cost €5-15 million. The cost estimates are based on information from the tanning industry and suppliers of chemicals for tanning, as well as information from testing laboratories in Germany. SEAC recognises that these figures on costs are mainly based on industry estimates of aggregated cost increases, such that they could not be fully scrutinized by SEAC in terms of the underlying methodology used for their derivation or indeed their validity more generally. The figures presented are thereby uncertain and could either be under- or overestimated. However, these are the only data available to SEAC on costs and therefore used in the cost-benefit analysis. According to the Dossier Submitter administrative costs of the competent authorities would be very limited.

The allocation of the costs is difficult to estimate, such that SEAC could not reach a definite conclusion on this issue. It depends 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. The voluntary shift in the EU production toward tanning process where chromium (VI) formation is minimised can be considered as an indication of the moderate costs faced by industry. It is not known who would carry out the additional testing (industry or authorities).

The costs related to the increased price of imported articles of leather may be over estimated to some extent, as some of the importers already require chromium (VI) free products, and consequently some non-EU tanneries have already implemented the changes in their processes. The price increase of leather articles produced in the EU may also be overestimated, though this depends on the validity of the assumption in the cost calculations that 1/3 of the European tanneries would still need to change their process. According to the European industry, the necessary measures to minimise the formation of chromium (VI) are already in place across the EU. Although uncertainties clearly remain as to the exact amount of costs, in the absence of more robust evidence, SEAC accepts the order of magnitude of the costs estimated by the Dossier Submitter.

Although it has not been possible to assess the magnitude in detail, restricting some additional articles used in the industry, as proposed under RMO 2 would result in slightly higher costs compared to the proposed restriction. However, the proposed restriction covers almost all articles of leather and the tanneries (especially in the EU) are not expected to have different production lines for tanning leather to be used for articles that are either in or

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outside the scope of the restriction. This is because the additional costs are small compared to the price of the end product and the process changes to reduce the formation of chromium (VI) in leather have already been made. In addition, this additional cost is partly covered in the estimated increase in the price of imported articles which is based on the total value of the imported products (including leather articles not covered by the proposed restriction). There is insufficient information in the Background Document to conduct a robust assessment of the costs of RMO 3.

Benefits

The Dossier Submitter estimated that the total health benefits of existing and new cases will initially be around €1,250 million per year and gradually grow as the prevalence of chromium allergy in the EU27 population decreases as a result of the restriction. The benefits comprise of reduced health sector and medication costs, reduced production losses due to days off from work and reduced welfare loss of the individuals suffering symptoms. The saved health and medication costs were estimated to be €470 per year per case, reduced production losses €1,200 per year per case (from 7 days less off the work per year) and the welfare savings from avoiding the chromium allergy (new cases) and related symptom days €1,900 per year per case. These values were used in the calculations by SEAC for the new cases, alongside an alternative valuation method for existing cases of individuals suffering symptoms, which was considered to be more appropriate by SEAC than the one proposed by the Dossier Submitter.

Estimation of benefits for existing cases of chrome allergy sufferers

The estimation prepared by the Dossier Submitter has been re-estimated by SEAC using different assumptions regarding the possibilities for consumers with chromium allergy to avoid symptoms caused by chromium (VI) in leather products. Due to the fact that exposures and hence health damages can be avoided, SEAC considers an approach based on the loss of consumer choice opportunities to be more suitable for estimating the welfare loss associated with chromium (VI) exposure after the diagnosis, than the approach used by the Dossier Submitter based on damage costs using the unit value of a symptom day. Patients with chromium allergy are expected to receive information via clinics about the common sources of chromium (VI) exposure, including leather. Considering the severity and longevity of symptoms, patients would therefore be expected to take reasonable actions to avoid leather articles potentially containing chromium (VI) if they wish to avoid the health impacts associated with exposure to such articles. Because of this, SEAC estimated the benefits of the restriction for existing allergy cases based on the lost consumer choice opportunities associated with individuals having to avoid chrome tanned leather articles. The benefits, in terms of the avoided lost consumer choice opportuntities, are given by the "consumer surplus" economic welfare measure associated with these products[3]. Although some existing sufferers may choose to continue to purchase chrome tanned leather articles and hence accept the risk of suffering symptoms, their choice in doing so implicitly values the health consequences as being less than the loss of consumer choice opportunties given by the consumer surplus measure. SEAC also acknowledges that some existing chrome allergy sufferers will unknowingly be exposed to chrome tanned leather articles and hence suffer health impacts.

[3] For those who can make informed decisions to avoid exposure, welfare losses are given by the consumer surplus change associated with the restricted consumer choice over leather articles.

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Estimates of the consumer surplus from chrome tanned leather shoes are not readily available and hence it was necessary for SEAC to make some simplified assumptions from which an estimate could be derived. In SEAC's calculations €50 was used as the average consumer surplus of leather goods per year for an individual person. This can be considered as equivalent to half the average price of a pair of leather shoes (€100/2 = €50), based on the conventional assumptions of a linear demand curve with a price elasticity of -1. SEAC acknowledge the lack of evidence regarding the assumptions of a linear demand curve and price elasticity of unity. Indeed, some of the technologies to avoid formation of chromium (VI) should not affect the quality of the products suggesting that they might be close substitutes, implying that the elasticity could be relatively high. Nevertheless, accepting the uncertainties associated with making such a calculation based on unsubstantiated, but conventionally adopted assumptions, SEAC estimated that on the basis of the consumer surplus approach, the benefits for existing patients (around 1.32 million people) are around €66 million per year.

Estimation of benefits for new cases of chrome allergy sufferers

In contrast to the estimation of benefits for existing cases of chrome allergy sufferers, SEAC does not consider the consumer surplus approach to be appropriate for estimating the benefits associated with reductions in the induction of new chromium allergies. In such cases, individuals are unaware of their potential to develop the allergy and hence of the need to take avertive behavioural action to avoid the possible symptoms.

Such instances of newly induced cases will therefore be involuntary, such that individuals will suffer welfare losses associated with unavoidable exposures and corresponding symptoms. The appropriate approach to valuation the benefits for individuals is thus based on their ex-ante Willingness to Pay to reduce the risk of suffering the chrome allergy symptoms. SEAC were unable to establish any such directly related willingness to pay estimates for such reductions in risk of suffering chrome allergy. As a consequence, SEAC agrees with the approach employed by the dossier submitter, based on estimation of the health damage costs associated with the estimated number of newly induced chrome allergy cases. In this case the costs include welfare losses based on valuing the number of symptom days experienced by allergy sufferers and any consequential reduction in quality of life they cause. Considering the reduced health sector and medication costs, reduced production losses due to days off from work and reduced welfare loss of the individuals suffering symptoms, SEAC estimated the benefits for new cases (around 10,800 per year) to be approximately €38 million in year 1 and to increase over time to €764 million in year 20.

Uncertainties

SEAC notes that there are a number of inherent uncertainties with the assumptions and analysis underpinning both the cost and benefit estimates associated with the restriction proposal. It has not been possible for SEAC to fully assess the implications of these uncertainties on the estimates of costs and benefits. Nevertheless, SEAC summarises below the main areas of uncertainty and the nature of the uncertainties therein.

- Assessment of Costs - As discussed earlier, there are a number of uncertainties associated with the information on costs. Given the limited ability to confirm the methodological approach and sources of the information used to determine costs, SEAC could not fully confirm the accuracy of the cost estimates, but accept to compare them to the benefits of the proposed restriction to assess the proportionality of the proposal.

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- Assessment of Prevalence of Chrome Allergy used in the Benefit Estimation - With respect to the prevalence and incidence of chrome allergy estimates provided by RAC for the purposes of the benefits estimation, SEAC acknowledge the inherent uncertainties and caveats discussed in the RAC opinion. SEAC also note that in order to derive EU wide estimates of prevalence, the prevalence evidence, which is based on Danish data has to be aggregated to the EU level. As such any biases and uncertainties arising from the above issues may be magnified at the EU level.

- Assessment of Benefit Estimates – As discussed earlier the benefit estimates are based on different general methodological approaches depending on whether existing or new cases of chromate allergy are being considered. For the existing cases the main uncertainties concern the empirical estimation of consumer surplus and in particular the uncertainties related to the assumptions required to be made in this respect. For the approach used to consider new cases, this included damage costs and required a number of assumptions to be made regarding the average number of symptom days associated with new cases of chrome allergy, as well as the economic welfare value per symptom day. The assumption on the average number of symptom days (reduced by the proposed restriction), was not derived from empirical data but based on an expert judgment. Furthermore, the economic welfare value per symptom day reduced by the proposed restriction is based on a willingness to pay values from studies that were not specifically concerned with chromium allergy[4]. It is not clear therefore to what extent the values are applicable to chromium allergy symptoms. SEAC also notes that such WTP values may already include a persons implicit valuation of the medical and other indirect costs associated with the illness. As such it is unclear to what extent the overall estimate of benefits to new cases of chrome allergy sufferers may be double counting some of the benefits. In addition to number of symptom days, also the estimated production loss due to days off from work is based on an expert judgement on the average number of sick leave days (7 per year). Based on the opinion of RAC, the patients with chromium allergy are assumed to suffer symptoms in average for 42 years, that is for the rest of their life after induction. The unit values for each benefit element (welfare loss, produciton loss, and health care and medication costs) are estimated for an average year during the 42 years period.

SEAC has considered the extent to which some of the uncertainties associated with benefits affect the comparison of costs and benefits. In this respect, several sensitivity calculations were performed in section F.6 of the Background Document e.g. with reduced numbers of avoided new allergy cases per year (7237), as well as reduced number of symptom days to 25 days, compared to the original estimate of 125 days, and simultaneously reduced value per symptom day of €9 (instead of €15). Even with these assumptions the benefits break even with the costs after approximately 9 years and exceed the costs by over €800 million after 20 years.

SEAC concludes that the impact of the uncertainties could be appreciable, and that whilst the value of net benefits associated with the restriction proposal is expected to be positive it is not possible to fully rule out the possibility that the uncertainties might invalidate this conclusion.

[4] In fact, the WTP value presented in the Annex XV restriction report was derived from studies that were not concerned with skin disease. However, this value was compared against WTP values relevant for dermatitis in the literature by SEAC, and found reasonable to be used in the assessment.

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Conclusions

The cost-benefit analysis conducted by SEAC demonstrates that the monetised health benefits are significantly higher than the costs of the restriction and growing over time. With the estimated implementation costs of the restriction proposal in the order of €100 million per year, the discounted accumulated net benefit over 20 years exceeds €4,400 million and hence the benefits of the restriction are clearly proportional to the costs.

Despite all the uncertainties surrounding the estimations, there is sufficient socio-economic information available for SEAC to support the restriction. The mere fact that European industry has already shifted to chromium (VI) reducing technologies on a voluntary basis indicates that costs of these alternative technologies are reasonable and economically feasible to industry.

The changes introduced to the original restriction proposal by Denmark are not considered to significantly impact the cost benefit ratio of the restriction.

Practicality, including enforceability

Justification for the opinion of RAC

RAC agrees with the opinion of SEAC on practicality. Given comments received from the Forum[5] about problems that can be created when a restriction is worded ambigiously, the simplified description of the scope of the restriction is expected to aid its enforcement.

Justification for the opinion of SEAC

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 azo-colorants in leather and the same reporting procedures applied for the azo-colorants, can be used for the chromium (VI). A standard for the determination of chromium (VI) in leather has been developed (EN ISO 17075) and procedures for compliance with the companies' own restrictions 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. 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.

SEAC has not identified issues of concern related to the practicality of the proposed restriction.

[5] Forum for Exchange of Information on Enforcement - a network of Member State authorities responsible for enforcement.

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Monitorability

Justification for the opinion of RAC
There is uncertainty about the potential for chromium (VI) formation in leather articles after they have been produced. Technology appears to be available to minimise this threat, but it cannot be excluded. Additionally, it is at least plausible that high concentrations of chromium (III) could also be a contributing factor in the allergic contact dermatitis problem posed by leather articles. RAC therefore emphasises the importance of monitoring to be able to evaluate the effectiveness of the restriction.

The effect of the restriction on the presence of chromium (VI) in leather can be monitored by tests of chromium (VI) in articles (e.g. EN ISO 17075).

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 that 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 similar approach has been taken by the clinical dermatology community to monitor the impact of the Community-wide restriction placed on chromium (VI) in cement.

Justification for the opinion of SEAC

SEAC agrees with the opinion of RAC on monitorability. The Committee has not identified any issues of concern related to the monitorability of the proposed restriction.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

The main changes introduced in the restriction suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by Denmark are as follows:

(i) A modest increase in scope, such that the restriction covers all articles of leather coming into contact with the skin, and not just those with direct and prolonged skin contact. This is viewed to better cover the exposure conditions by which chromium (VI) in leather articles can produce allergic contact dermatitis. The original motivation for introducing this alternative came from the Forum, who indicated that the proposal of the Dossier Submitter might be difficult to implement from an enforcement perspective.

(ii) A more explicit description of the test method proposed to quantify chromium (VI) in leather. It is stated that the limit of 3 mg/kg represents the current quantification limit, presenting the opportunity to reduce the limit described in the restriction should the technology improve.

Basis for the opinion of SEAC

The main changes introduced in the restriction suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by Denmark are as

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follows:

(i) A modest increase in scope, such that the restriction covers all articles of leather coming into direct or indirect contact with the skin, and not just those with direct and prolonged skin contact.

(ii) A more explicit description of the test method proposed to quantify chromium (VI) in leather.

(iii) The trantsitional period of 12 months added to the suggested restriction. In the Annex XV restriction report, it was only justified in Part E.

(iv) A derogation for the second hand markets and stocks.

The Committee for Socio-economic Analyses has no information to question changes (i) and (ii) proposed by RAC.

In addition to the changes introduced in the restriction the Committee for Socio-economic assessment introduced a different approach to estimate benefits for people currently having chromium (VI) allergy. The basis for this change is described in the SEAC part of the chapter "Proportionality to the risk".

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