

**Committee for Risk Assessment (RAC)**

**Committee for Socio-economic Analysis (SEAC)**

**Response to comments document (RCOM)**

**on the Annex XV dossier**

**proposing restrictions on**

**Chromium VI in leather articles**

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

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

**Chromium VI**

**EC number: Not applicable**

**CAS number: Not applicable**

**9 November 2012**

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 **General comments**

| **Ref** | **Date Country/ Organisation/** **MSCA****Comment type** | **Comment** | **Response of the Dossier Submitter** | **RAC Rapporteurs comments** | **SEAC Rapporteurs comments** |
| --- | --- | --- | --- | --- | --- |
| **218** | 2012/09/14 17:12Germany / Company The proposal (A), Information on hazard and risk (B), Justification for action on a Community-wide basis (D), Why a restriction is the most appropriate Community-wide measure (E)  | 1) Lists of leather articles with skin exposure include coated articles where there is no potential exposure.2) Table 21 is not a valid scientific assessment of chromium dermatitis from leather3) References to chromium (VI) analytical Standards and analytical procedures are mixed up. | The coating with polyurethane or acrylic layer might be damaged and thereby exposure would be possible. The estimation on exposure is linked to the prevalence and the contribution from leather. Therefore it would not change the picture of exposed people if exposure from coated articles does not contribute. Overall, these type of articles are included in the scope of the restriction proposal.2) The test (rather limited as only 15 patients were involved) was carried out on patients already known to be allergic to chromium (VI). It is correct that other chemicals in principle could have influenced the result. However the purpose of reciting the study was to explore that the relationship between the level of content of chromium (VI) and Chromium (III) and number of people reacting. It is not correct that the set up of the study on exposure from certain products was based on an assumption that e.g. exposure from furniture was not relevant.3) In the Background document, it is clarified that CEN/TS 14495 and DIN 53314 both have been superseded by ISO 17075, and that EN 71-3 is being updated in order to be able to measure also Chromium (VI) and not only total chromium as in the present version. The 3 mg/kg as a limit value equal to the quantification limit of 17075. It does not provide an indication that content just below that is safe, but is chosen as a manageable value known from the 17075 and the levels in the legislation on personal protection.  | Thank you for your valuable comments. (1) We have not been provided with any analytical data regarding the potential release of chromium (VI) from coated articles. Although we accept that coatings will limit direct exposure to an extent, we agree with the Dossier Submitter that they should be included in the scope of the restriction proposal. The text of the Background Document (Section B2.2.7) and the opinion has been modified accordingly. (2). We have modified the text to further indicate the weaknesses of the study summarised in table 21.(3) We agree wth the Dossier Submitter  | We agree with RAC rapporteurs’ comments. |
| **217** | 2012/09/14 17:10 IrelandThe proposal (A), Justification for action on a Community-wide basis (D), Why a re­striction is the most appropriate Commu­nity­-wide measure (E)MSCA  | The Irish Competent Authority (IE CA) would like to thank the Danish CA for the work it has undertaken to prepare this Annex XV dossier to propose a restriction on chromium (VI) in leather articles and to complement the submitter on a well prepared dossier. The IE CA agrees with the conclusion that an EU wide restriction is the most appropriate Risk Management Option in order to reduce the risk associated with the presence of chromium (VI) in articles of leather. We have the following observations and comments to make. | The comments are all discussed in the revised Background document. | Please see the Background document.  | Thanks for the comments. As the request of the further consideration of RMO 3 we think this is not necessary.  |
| **216** | 2012/09/14 15:45Germany / Company  *The name of the company replaced with “Company X” in the comment field, as claimed as confidential.* | *Company X* welcomes the Proposal for a restriction based on the parameters given in the document (< 3ppm based on DIN ISO 17075) as the best conclusion that can be drawn with todays knowledge. However, there are three minor points we would like to address.  |  |  |  |
| Point 1, Page 11, quote: "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. see table 2 | Paragraph B.2.1. including Table 2 is deleted in the Background document, as the information was not considered relevant for the proposal. | As indicated by the Dossier Submitter, this part of the original proposal was not considered relevant to the proposal.  | We agree with the Dossier Submitter response backed by RAC Rapporteurs.  |
|  Sodium dichromate dihydrate (110.000 t) and sodium chromate (103.000 t) is a double-count, the latter being non-isolated intermediate for the first. As indicated correctly, this was the 1997 number from a 2005 document. In 2008 the one single plant producing this chemical was closed. In 2011 there was no dedicated plant left, production within Europe "close to zero", decreasing the total production of chromium (VI) chemicals by at least one order of magnitude. This most recent information is confirmed by the registration dossier. |  | As above |  |
| Point 2, Page 11, quote: The main chromium compound used for tanning of leather is chromium (III) hydroxide sulphate, Cr(OH)SO4 (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 classified in accordance with the CLP Regulation (CLP-Regulation (EC) No 1272/2008). |  | As above |  |
| During registration, a missing endpoint was identified and a study completed. The correct labelling according to CLP now is: chromium (III) hydroxy sulfate, EC 914-129-3; Acute Tox 4, H332The EC number was changed as a result of new substance identity definition in registration |  | As above |  |
| Point 3, Pages 7 & 78, quotes:" 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."  |  |  |  |
| 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." We would very much appreciate, if the clarification on consumer protection of chrome and chrome-free tanning systems from chapter C 3.3 could be repeated on page 7. It is a crucial statement on the comparison of both systems, and we are afraid it might not get the right attention if not mentioned in the summary.  | Our attempt was to make and precise summary as possible. The information cited from C.3.3. is not considered necessary in the summary as the approach is common for all restrictions. | As the Dossier Submitter has indicated, this change does not seem to be a critical matter. All the relevant information can be found in the Background document.  |  |
| Indeed, the very few studies that do a direct comparison of leathers tanned with vs. without chrome indicate, that the risk of skin sensitation is higher for chrome free leathers, based on the much higher content of organic tanning chemicals necessary to replace chrome.As such, RMO 1/RMO 2 are the only options that will guarantee a reduction of consumers risk based on scientific evidence. | According to Rietschell et al (2008) there are no reports of shoe dermatitis developing from glutaraldehyde-tanned shoes. Glutaraldehyde is the most common alternative to chrome tanning. | Those who are sensitive to chromium (VI) will be at risk from leather tanned with chrome. We agree that RM0 1/RM0 2, or similar, will produce a reduction in consumer risk.  |  |
| **215** | 2012/09/14 14:17Germany / Industry or trade association / TEGEWA   | We appreciate the suggested regulation for chromium (VI) in articles of leather. We would prefer that the international standard EN ISO 17075:2007 is mentioned in the text to clearly define the suitable test method.The standard is well established in the leather industry worldwide and is directly connected to the restriction limit. No other test method is available with the same preciseness to determine compliance with the suggested regulation. | There is a clear reference of the standard in the Background document with some technical details. Mentioning the standard in the wording of the restriction proposal is not a common regulatory approach.  | We agree that the analytical method is not normally mentioned in the legislative text. The Commission and Member States could possibly further reflect on the issue, during the decision making process. The Background document is clear that EN ISO 17075:2007 is the relevant international standard and that the limit in the proposed restriction is derived from this method. | We agree with the RAC Rapporteur’s response. |
| **214** | 2012/09/14 13:10Individual   | The 3 Tables referred to in my comments submitted on 13.9.2012 did not copy into your web form. My reference number for further communication is 8985a43f-c384-4645-983c-56a4bc5c0decI have now uploaded my full response, hopefully containing the 3 tables as an attachment. Please let me know if you have not received the doc with 3 tables.  | Please see response to comment number 213, below. | Please see response to comment number 213, below. | Please see response to comment number 213, below. |
| **213** | 2012/09/13 14:43 Individual Information on hazard and risk (B), Other information (H)  | I argue that this proposed restriction should not be introduced. I consider that the proposal for REACH to ban leather articles which contain more than 3 mg chromium (VI) /kg is grossly out of proportion to the problem of chrome allergies caused by leathers.  | Comment 213 is part of the document listed in comment 214. Observe that part of comment is found below under specific comments. | Thank you for your well-argued comments and perspectives. We agree that the question of proportionality is an important one; the restriction should only be introduced if it is proportionate. There are analyses provided by RAC and SEAC in the Opinion and the Background document indicating that the restriction is proportionate.  | We agree with the RAC Rapporteur’s response. |
| There should be considerable investigation into:• the expected effect of the restriction on chrome allergies • managing chrome allergies to leather items, • control of chromium (VI) formation in finished leather, • a viable substitute for chrome containing shoe leathers, • consequences of the restriction throughout the world. | The information submitted does not result in our view that a restriction is not proportional. | A similar restriction on the level of chromium (VI) in cement is widely considered to have had a positive effect through the reduction of chrome allergies in the EU. The expert advice and clinical data that we have received indicates that a similar restriction of chromium (VI) in leather articles can reasonably be expected to have a beneficial effect. We agree that a viable substitute for chrome-containing shoe leathers may not be available; this is one reason why we did not support “RM0 3” on the basis of the data presented in the Background document. Our assessment of the data we have been given is that techniques are sufficiently well developed to enable compliance of leather articles with the proposed restriction. Although some articles on the market have been found to contain high levels of chromium (VI), most would already appear to comply with the terms of the restriction.  |  |
| Approximately 80% of global leather production is tanned with chromium (III) salts. Over 0.2% of the population is sensitive to chromium but chrome tanned leather has been worn for over 100 years and this sensitivity has been known but managed. Some chromium (VI) must always have been present in chrome leathers. Tanners and others who are allergic to chromium use barrier creams made from ascorbic acid (vitamin C) and EDTA to control dermatitis. People allergic to shoes can wear barrier socks and those allergic to chromium can wear synthetics if necessary. | We do not agree that some chromium (VI) always will be present in chrome leathers.Ascorbic acid cream is widely considered to give some kind of possible protection. However this has never been clinical documented.  | The expert advice we have received from dermatologists has been in favour of the restriction. They report continued problems with leather articles (including shoes) for many sensitised people and also point to the positive impact of a similar restriction on chromium (VI) in cement. We understand that chromium (VI) may have been present in leather articles produced over the last 100 years.  |  |
| The best leathers for shoes and many other items are chrome tanned. When white tannages are used for shoes, they are usually retanned with chromium. Allergy to Chromium (VI) is a greater problem than allergy to Chromium (III), but Chromium (III) sensitivity is also a problem. Chromium (VI) sensitivity is caused by sodium dichromate and other compounds which are widely used; a REACH restriction on leathers will not overcome Chromium (VI) sensitivity. Also, it has not been demonstrated that elimination of Chromium VI in leather would overcome allergies to Chromium (III). | The purpose of this restriction is to restrict the allergy from the more potent Chromium (VI). | The proposed restriction would not ban chrome tanning. We have not been provided with any evidence showing that chromium (III) sensitivity is a problem. Reassuringly, chromium (III) in cement (in the absence of chromium (VI) does not seem to pose a significant problem.  |  |
| If Europe introduces this regulation then the world leather industry will be severely threatened. There is no viable alternative to chrome in shoe leather and there is no viable way to ensure elimination of Chromium (VI) from chrome tanned leather articles.  | The comment does not qualify why consequences would be severe. If optimized production procedures are used Chromium (VI) should not be a problem | As the Dossier Submitter indicates, we understand that there are production procedures that can be employed to ensure compliance with the proposed restriction.  |  |
| Peanut allergy is estimated to affect about 1% of children and adults word wide and is a far worse allergy than Chromium (VI). Peanut allergy is one of the most common causes of food-related death. However, peanuts are not banned but are avoided by those allergic to them. It is far more difficult to avoid eating peanuts than to avoid contact with chrome tanned leathers. | Peanut allergy is not relevant for this proposal. | We have been asked to comment on the scientific evidence supporting the proposal to restrict chromium (VI) in leather articles. This does not include an analysis of societal concerns or a comparison with risks posed by other allergens.  |  |
| **212** | 2012/09/12 17:53 / / SwedenMSCA  | *Due to technical difficulties, the attachment received by email on 2012/09/13 15:05*SE comments on Annex XV report on chromium (VI) compounds. SE welcomes the proposal to restrict the content of chromium (VI) compounds in articles of leather. It could be expected to have a significant impact on the exposure to chromium(VI) in leather, followed by reduced prevalence of chromium allergy in the population. Below, please find some Swedish data on chromium allergy in dermatitis patients as well as some comments on the content of the restriction itself. |  |  | Thank you for supporting the restriction proposal. |
| Swedish data on chromium allergy in dermatitis patients. Chromium belongs to one of the most common causes of contact allergy in Sweden as in other European countries. The frequency of allergy to chromium in patch tested dermatitis patients in 1973-1980, 1992, 2000, and 2008-2009 is shown in Figure 1 and Table 1. In sum­mary, the results show that the preva­lence of allergy to chromium has de­creased in male dermatitis patients since the period 1973-1980, and that it now is equally frequent in female and male pa­tients. A trend of increasing prevalence of allergy to chromium in women was noted between 1992 and 2000 (Lindberg et al. 2007). Further increase is indicated by da­­ta from 2008-2009 (Figure 1 and Table 1). The age (<40 and ≥40 years) when contact allergy to chromium was diagnosed is shown in Table 1. The results indicate that the onset of allergy to chromium, in both females and males, is at younger age now compared to previous decades.  | The following is added to footnote 11 at page 52: “It is important to note that a large group is induced before a age of 40 (Nardelli A(2005).” | We have added to the Background document that young people can become sensitised to chromium (VI). Some comments received from the public consultation have shown that children can be sensitive to chromium (VI) in leather articles. The reference of Nardelli is noted (inserted into footnote 9 on page 51).However, we prefer not to change the original EU-wide assumption that was provided about the average age of onset. There is no indication from the information available to us that the new data is more robust than that provided by the Dossier Submitter. |  |
|   Figure 1. Contact allergy to chromium in patch tested dermatitis patients in Sweden. 1973-1980 = data from two university hospital clinics in Stockholm; 1992 and 2000 = data from 9 university hospital clinics (Lindberg et al. 2007); 2008-2009 = data from six university hospital clinics (Swedish National Patch Test Register 2012).   = females,   = males  |  | These data help to confirm the prevalence estimates given in the Background Document. It is within the range we have described in the Opinion Document,  |  |
| Table 1. Contact allergy to chromium in patch tested dermatitis patients in Sweden

|  |  |
| --- | --- |
| Age (yrs) | Pos. patch test to potassium dichromate (% of patch tested) |
| 1973-1980 | 1992 | 2000 | 2008-2009 |
| Femalen=1673 | Malen=1262 | Femalen=2371 | Malen=1291 | Femalen=2398 | Malen=1392 | Femalen=1993 | Malen=1119 |
| <40 | - | - | 2.4 | 2.8 | 3.3 | 2.5 | 4.8 | 4.1 |
| ≥40 | - | - | 4.0 | 6.7 | 5.0 | 5.7 | 5.9 | 5.1 |
| All | 6.3 | 10.1 | 3.2 | 4.6 | 4.2 | 4.1 | 5.4 | 4.6 |

 |  |  |  |
|  n = number of patch tested dermatitis patients, female and male respectively 1973-1980 = data from two university hospital clinics in Stockholm; 1992 and 2000 = data from 9 university hospital clinics (Lindberg et al. 2007); 2008-2009 = data from six university hospital clinics (Swedish National Patch Test Register 2012)  |  |  |  |
| A restriction of chromium (VI) in cement was introduced in Sweden in 1989. Iron sulfate has however since 1983 been added to all cement manufactured in Sweden, to reduce chromium (VI). This has contributed much to reducing chromium allergy in males. |  | Noted. |  |
|  Taken together, Swedish data show that chromium allergy is common in females and males, and that other exposure than to chromium VI in cement must be important causes. Some recently published scientific studies add further evidence in support of a restriction (Geier et al. 2011, Landeck et al. 2012, Thyssen et al. 2012, Uter et al. 2012).  |  | Thank you for this supportive information.  |  |
| References Geier J, Krautheim A, Uter W, Lessmann H, Schnuch A. Occupational contact allergy in the building trade in Germany: influence of preventive measures and changing exposure. Int Arch Occup Environ Health. 2011 Apr;84(4):403-11. Landeck L, Uter W, John SM. Patch test characteristics of patients referred for suspected contact allergy of the feet--retrospective 10-year cross-sectional study of the IVDK data. Contact Dermatitis. 2012 May;66(5):271-8. |  |  |  |
|  Lindberg M, Edman B, Fischer T, Stenberg B. Time trends in Swedish patch test data from 1992 to 2000. A multi-centre study based on age- and sex-adjusted results of the Swedish standard series. Contact Dermatitis. 2007 Apr;56(4):205-10. Thyssen JP, Strandesen M, Poulsen PB, Menne T, Johansen JD. Chromium in leather footwear - risk assessment of chromium allergy and dermatitis. Contact Dermatitis. 2012 May;66(5):279-85. Uter W, Aberer W, Armario-Hita JC, Fernandez-Vozmediano JM, Ayala F, Balato A, et al. Current patch test results with the European baseline series and extensions to it from the 'European Surveillance System on Contact Allergy' network, 2007-2008. Contact Dermatitis. 2012 Jul;67(1):9-19. |  |  |  |
| **Comments on the content of the proposed restriction**. “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.”  |  |  |  |
| • “Direct“ contact with the skin seems redundant; it is also a risk that it could be misunderstood or misused. For example, a thin lining of the soles or upper leather of shoes may prevent direct contact with the skin. The same applies if manufacturers recommend wearing socks in the shoes. However, such measures are not protective enough to avoid migration of chromium in leather to skin. With the purpose to avoid attempts to get round the restriction SE proposes to delete the word “direct”.  | “direct” is deleted from the wording of the restriction proposal. However, the scope does also cover leather shoes even if the leather is separated from the skin by a thin lining. Justification is provided in the Background document. | Agree with the response of the Dossier Submitter.  | Noted  |
| • “Prolonged or repetitive contact with the skin” is not used consequently throughout the Annex XV Report. SE considers both “prolonged” and “repetitive” to be adequate wordings in the restriction; however their meaning needs to be defined.  | “Prolonged and repetitive” is deleted from the wording of the restriction proposal. Justification provided in the Background document and the draft opinion. | In view of comments received from the Forum, and expert advice received about the nature of the risk posed by chromium (VI) in leather, it was agreed with the Dossier Submitter not to include “prolonged and repetitive”.  |  |
| • In the Annex XV Report there is much focus on consumers. As professional exposure to chromium tanned leather is common, e.g. in personal protective equipment, it is important to also include professional use in the restriction.  | The proposal does also include articles for professional use. | As noted by the Dossier Submitter, the proposal does include the use of leather articles (including boots, shoes, aprons, etc) by workers  |  |
| **208** | 2012/06/01 16:22 GermanyThe proposal (A), Information on hazard and risk (B), Why a restriction is the most appropriate Community-wide measure (E), Socio-economic Assessment of Proposed Restriction (F), Other information (H)MSCA  | The Danish restriction proposal concerning chromium (VI) in leather is highly wel-comed. DE has some remarks concerning the document which are listed in the following: |  | Thank you for the comments.  | Thank you for the support. |
| Driver for the restriction is the allergenic potential of chromium (VI) and the fact that human exposure to chromium (VI) from articles of leather coming into direct prolonged or repetitive contact with the skin might be higher than a DMEL of 0.02 µg/m2 over two days which was derived from a MET10% (minimum elicitation threshold). | Se responses below on specific questions.  | See below. |  |
| The appropriateness of the application of a DMEL is questioned, because according to Chapter R8 of the REACH guidance document on information requirements and chemical safety assessment, DNELs are used for threshold endpoints whereas DMELs are used for non-threshold endpoints. As the MET10% value, on which the restriction dossier is based, is a threshold value, it should form the basis of a DNEL and not of a DMEL. When the MET10% is used as a starting point for DN(M)EL-derivation, then all the possible assessment factors (AFs) should be considered and it should be made transparently in case they are not ap-plied. | We agree that skin sensitisation caused by chromium (VI)exposure is regarded as a threshold effect with dose-response relationships for both the induction and elicitation phase. However, the dataset only gives information for the MET10% (minimum elicitation threshold) and provides a basis for estimating LOAEL/DMEL for elicitation.  | We agree that sensitisation is a threshold phenomenon. Use of the DMEL methodology would be inappropriate here. A comparison of MET10% values (LOAELs) with modelled exposure values has been included in the Background Document. This is for illustrative purposes; the main basis for the re­striction is, rather, the observation of EU citizens suffering from allergic contact dermatitis due to chromium (VI)exposure from leather articles. |  |
| In section B 5.11 it is stated that “setting a DNEL in relation to risk assessment may therefore be difficult since individual susceptibility and other factors influence the induction and elicitation thresholds”. However, as factors alleged by the authors to make setting of a DNEL difficult, are addressed in the DNEL derivation (e.g. by applying AFs for e.g. individual susceptibility), we encourage to derive a DNEL value for chromium (VI)according to Chapter R8 of the REACH guidance document on information requirements and chemical safety assesment. | We think that deriving a DNEL in relation to risk assessment would be difficult and furthermore misleading for several reasons. 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 exposure below the elicitation threshold should therefore protect against sensitisation. Therefore a DMEL was set to be equal with the LOAEL from MET10% (0.02µg/cm2). To use the EC3 value in risk assessment with appropriate assessment factors is too unsure and as we do have human data, it would be misleading. And the value would assess the induction of chromium (VI). The purpose is also to protect for elicitation.  | As above; and note the response from the Dossier Submitter.  |  |
| Having set a properly derived DNEL, a risk characterisation ratio (RCR) should be derived and it should clearly become evident, that exposure to chromium (VI)from leather exceeds the derived DNEL. A wording as used in section 9.3.2 (e.g. on p. 63 – under “Hypothetical expo-sure scenario with leather shoes”: “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.” might be too weak and vague to justify the necessity of the restriction.Concerning the three different risk management options (RMOs) which are discussed in the document, it is not clear to the reader, why RMO option 1 should be preferred. In contrast to RMO 1, RMO 2 is only marginally discussed. However, as there might arise problems when discerning or defining articles which are in prolonged or repeated contact with human skin on one hand from those which are in shorter contact, it is suggested (when comparing RMO1 and 2) to give preference to option 2: it is a well known fact that consumer behaviour is incalculable. Thus, it cannot be excluded that articles intended to be used short-term will be used in a prolonged or repetitive manner. | The risk characterisation clearly shows that exposure to chromium (VI) exceeds the DMEL (for elicitation). And clinical data on new dermatitis patients show that there is a current and tangible risk today. The toxicological data are used additionally to asses the risk. | The calculation was included for illustrative purposes, and not to provide a formal justification for the restriction. It shows how factors such as chromium (VI) release rates and chromium (VI) detection limits might impact on the risk. As indicated above, there is already human experience and clinical data, which is more meaningful. However, an improved exposure scenario (including exposure and risk assessment) has been introduced into the Background document. |  |
| We think RMO 1 gives a high effectiveness as described in E.2.3.1RMO 3 is mostly rejected due to feasibility of alternatives.  | Taking into account all the received comments, including from the Forum, we have proposed a simplified wording for a restriction that would be somewhat Dossier Submitter wider in scope compared with RM01 but quite similar in terms of risk characterisation.The comment of the Dossier Submitter in relation to RM03 is noted. |  |
| In contrast to RMOs 1 and 2, RMO 3 concerns banning all articles containing chrome tanned leather. From a consumer protection point of view, this is the preferred option based on dif-ferent grounds: (1) it is stated in the document that by ageing or e.g. by UV-light, chromium (VI) can be formed in leather articles. Thus, when being used by consumers, chromium (VI) content in articles might increase, even when the article had concentrations below 3 mg/kg when sold or pro-duced. (2) It is stated in the document that elicitation can occur at even lower levels than the given MET10% value. Thus, a slight increase in chromium (VI) content by ageing might lead to a con-siderable increase of cases of chromium allergy. (3) It is stated in the document, that also chromium (VI)can elicit allergic reactions. Even when the prevention of chromium (VI) led to significant decreases of the number of incidences for chromium allergy in cement workers, this must not necessar-ily be the case for the whole population. |  | It is acknowledged that RMO 1 and RMO 2 (and the modified RAC proposal) may not (in theory) be 100% protective. However, as the Dossier Submitterhas indicated, they appear to be the most feasible. Further information has been added to the Background document that relates to points (1) to (3), and they are also addressed in the RAC opinion. In short:(1) post-formation of chromium (VI) can be avoided(2) see (1)(3) the potency of chromium (III) in leather articles is very much lower (almost negligible) compared with chromium (VI).  |  |
| The scoring of the three discussed RMOs (Table 38) is not very transparent. Each score given in the table should become evident from the text, i.e. the score derived should become clear from the respective text passages. | The purpose of the table should be to ease the understanding.  | We did not consider it appropriate or necessary to modify the table.  | We find the scoring clear and not consider any changes needed. |
| **207** | 2012/06/01 15:44Sweden / Company / Ahlsell AB The proposal (A)  | Restriction Option RMO2 could have been split into to options: A. chromium (VI) <3mg/kg for all leather articles B. chromium (VI) < detection level for all leather articles. | Response provided to specific questions (see later part of table). | A complex “tiered approach” is proposed: if RMO 1 doesn’t work after a period of monitoring (3 years) “automatically” RMO 3 will take over, coming into force 5 years later (market can adjust).We agree that the restriction could be reviewed after a period of some years, but defer to the Commission.  | We thank you for the proposal to evaluate the effectiveness of the restriction after three years. However, decision on the review and related following actions are not evaluated under this proposal. |
| **206** | 2012/05/31 23:56Denmark / Academic institution / The Danish Contact Dermatitis Group   | Exposure to chromium (VI) in cement and concrete was earlier the maincourse for developing chromium allergy. Chronic hand eczema, due to chromium allergy among workers in the building industry was a highly serious problem until the EU legislation came through. Thereby the chromium (VI) content in cement was reduced to values below 2 ppm. After a decade the work-related chromium (VI) induced chronic hand eczema decreased. During the last 10 years a new group of chromium allergic patients has increased in number. These patients have developed chromium allergy due to exposure to chromium tanned leather. An intervention reducing the CrVI in leather to values below 2 ppm may have the same benefit as did the reduction of chromium (VI) in cement. Therefore we highly recommend the reduction of chromium (VI) in leather articles. On behalf of The Danish Contact Dermatitis Group, President Christian Avnstorp, Specialist in dermatology, MD,PhD,DMsc | The comment supports the proposed restriction.  | The comment supports the proposed restriction. Recommendation of 2 ppm instead of 3 ppm cannot be followed as the corresponding analytical methods differ from each other. |  |
| **205** | 2012/05/31 22:26Belgium / Other contributor / EU Social Sectoral Dialogue Committee "Leather/Tanning" The proposal (A), Justification for action on a Community-wide basis (D), Socio-economic Assessment of Proposed Restriction (F), Stakeholder consultation (G), Other information (H) | The Social Partners of the European Leather Sector welcome the proposed restriction provided that the EN ISO Standard 17075 specific for the testing of chromium (VI) in leather is used as the referenced test method for ensuring an uniform application of the restriction and that a mechanism is established for ensuring that non-complying imported products cannot cross Customs Controls and be placed on the EU market. | The aim of the proposed restriction is to avoid that chromium (VI) can be found in leather in quantifiable levels. The proposed restriction is linked to EN ISO Standard 17075.REACH obliges MS to take all measures necessary to ensure that the provisions of REACH is implemented.  | The Background document includes this standard as the referenced test method. The comment about Customs is outside the remit of RAC to address.  | Thank you for the support. |
| **204** | 2012/05/30 19:16Spain / Industry or trade association / CEOE. Confederation of Employers and Industries of Spain   | CEOE COMMENTS FOR ANNEX XV restriction Dossier Cr VI in leather articles. Substance name: chromium VI in leather articles.Further to the enquiry on the proposal for the restriction of Chromium VI in leather articles, below you will find our feedback:  |  | Thank you.  |  |
| -For the Spanish footwear the restriction of chromium (VI) (limited to less than 3 ppm) in leather articles in the whole of the European Union would not imply a major change in their way of working. Consequently, the harmonisation of this restriction would state this measure in a clear and transparent way, this measure being already imposed by some EU member states and certain footwear buying groups.  | The comment supports the proposal.  | Comment supports the proposed restriction.  | Noted.  |
| -Footwear manufacturers do not use chromium (VI) in the footwear manufacturing process. They just buy the materials and components, including leather and leather-made components, from different suppliers and assemble them by different methods (sewing, riveting, cementing, etc.) to produce footwear. Therefore, should chromium (VI) be found in footwear, this would originate from chrome-tanned leather used as a raw material for footwear production.  | Information in line with the information given in the dossier. | Noted; the focus on preventing chromium (VI) formation lies at the early, tanning stage of production. Accordingly, we have proposed that **“**Leather articles or leather parts of articles, coming into contact with the skin…” should be restricted.  |  |
| -Footwear manufacturers do not wish to have problems in marketing their products; they just want to use safe materials complying with regulations and market safety requirements and meeting the demands of footwear distributors and brands.  | Appreciated.  | Noted. |  |
| -Footwear made in Spain, and footwear made in Europe on the whole, is mostly sold in the European Union, this being one of the most demanding markets in terms of health and safety regulations.  |  | Noted. |  |
| -In general, large footwear distributors and brands require footwear manufacturers to provide footwear in which chromium (VI) cannot be detected in leather components (less than 3 ppm), given that they operate in international markets in some of which, like Germany, chromium VI is already statutorily limited.  | The comment supports the argumentation in the dossier. | Comment supports the proposed restriction.  |  |
| -chromium VI restriction in the EU should clearly specify that the test method to be used to determine chromium (VI) content in leather articles shall be the standard EN ISO 17075:2007 “Leather. Chemical tests. Determination of Chromium (VI) content” and no reference should be made to sample pre-treatment methods that have not been harmonised and enforced as EN or ISO standards. | The reference to sample treatment methods is part of ISO 17075:2007. In 17075 it is said that the methods should only be used when appropriate.And that is normally not the case for articles. | Comment supports the proposed restriction.  |  |
| -Similarly, it should be specified that the restriction for leather articles only applies to leather intended to come “in direct and prolonged contact with the user’s skin.”  |  The wording of the restriction proposal has been modified as reflected in the Background document.  | It is evident that footwear poses a problem, regardless of whether an individual wears socks or stockings, therefore, strictly, direct contact between the skin and the article is not always necessary. Regarding the proposed scope of the restriction, please refer to the final recommendation made by RAC and SEAC.  | We follow the information on exposures provided by RAC Rapporteurs. |
| -All measures aimed at ensuring the compliance with this restriction, either by import inspection or market surveillance, should be taken to guarantee fair competition, at least as far as this issue is concerned.  |  | Outside of the task for RAC; no comment.  | We agree that sufficient measures to enforce the restriction are needed. |
| **203** | 2012/05/29 14:26 NorwayThe proposal (A)MSCA  | *Please see specific comments.* |  |  |  |
| **202** | 2012/05/31 10:46United KingdomThe proposal (A), Information on hazard and risk (B), Available information on alternatives (C), Why a restriction is the most appropriate Community-wide measure (E), Socio-economic Assessment of Proposed Restriction (F)MSCA  | The authors are to be commended for the production of this proposal for the placing on the market of articles of leather containing chromium (VI).On the basis of the evidence presented, the dossier concludes that there is an unacceptable risk to health from chromium (VI) in leather articles and that a restriction is the most appropriate community wide measure to reduce this risk. Although the dossier in general appears to provide a good deal of evidence to support this restriction, further evidence and justification (as outlined below) would help clarify the risks and benefits. |  | With the help of the Dossier Submitter, we sought additional evidence and improved the justification.  |  |
| **201** | 2012/05/16 11:56Germany / International organisation / European Society of Contact Dermatitis   |  “Allergic contact dermatitis from Chromium in footwear is a frequent finding in a dermatological practice (cf. infra). The eczema lesions are in most cases very severe at the contact sites and often accompanied by spreading to other body parts, even generalized.  | We agree to the comment on the severe character of Chromium allergy.  | Comment supports the proposal.  |  |
| Wearing stockings by women does not prevent sensitization nor do socks from relapses of dermatitis. Contact allergy to chromium compounds in footwear is an important cause of disability, since alternatives are hardly available. Even so-called 'hypoallergenic&quot; leathers that should contain less (or no?) chromium are not tolerated by most of the chromium-sensitized subjects. Last but not least, because of the damaged skin barrier and the inflammation, chromium-allergic patients frequently develop subsequent sensitizations to other components in footwear, such as resins in glues, rubber additives or coloring agents.Some data regarding the frequency of chromium contact allergies: |  Table-16 has been adjusted to indicate that lining is not preventing exposure.  | These comments illustrate the importance of preventing new cases of sensitisation and support the proposed restriction.  |  |
| - in Portugal out of 2872 patients tested for contact allergies in 2009 and 2846 in 2008, 7.3% and 8.2% reacted to potassium dichromate in the baseline series, respectively. About half were due to leather in footwear. Moreover, in Coimbra, in 2010 and 2011, the respective percentages were 5.4 and 6.2 out of 292 and 276 subjects tested, with 1/3 due to shoes. | The levels are higher than found in Denmark (2.96%) which is used in justification for the proposed restriction. In the socio-economic estimation in the dossier 45% of the cases were linked to shoes. The data confirm the need for a restriction. | These data from Portugal, Spain and Belgium are useful as they illustrate the prominence of leather articles in the causation of allergic contact dermatitis in people who are sensitised to chromium (VI). They also help to show the relevance of the data from Denmark to the rest of the EU. These data have been acknowledged in the Opinion and Background document.  |  |
| - in Barcelona (Spain), the percentages of chromium allergies in 2009 was 4.9 and in 2010 it was 5.6, respectively, with many cases due to shoes.- In Leuven (Belgium), 626 (4.7%) out of 13.257 patients tested between 2000 and 2011 presented with a contact allergy to potassium dichromate, of which 536 (86% of the positives) due to footwear.” |  |  |  |
| **200** | 2012/05/10 12:24Italy / Industry or trade association / AssOSafety The proposal (A) | This proposal to restrict chromium (VI)in leather to <3ppm is a logic proposal. This will align other markets to what already in place as per the PPE Directive (89/686/EEC), where any materials used in the PPE may not be adversely affect the user's hygiene or health.  | This restriction proposal aims also at covering the leather articles used by professionals at work (e.g. protective gloves, shoes)The limit cannot go lower than 3ppm as (limit of quantification with the ISO 17075 standards) due to technical limitations that are presented in the Background document. However, practically the proposal aims at resulting at lower than 3ppm concentrations of Cr VI in the finished article.  | We agree with the response of the Dossier Submitter. |  |
| It's already largely prooven that Cr(VI) is ineed carconogenic, allergenic and toxic, and therefore needs to be restricted indeed, better would be to ban it. In the glove standards (which provides presumption of conformity with the PPE legislation), this restriction has already been defined at <3ppm in for example the EN420. This was actually a required from the European Commission (initially 10ppm was defined but not accepted by them) because higher then 3ppm was considered as unsafe. Hence, in order to be aligned with the PPE |  | The proposed limit of 3ppm is determined by the analytical method (EN ISO 17075) that is used to detect chromium (VI) in leather. |  |
|  Directive, I guess it makes much sense to align REACH with this requirement as well and define this <3ppm.  |  |  |  |
| I also suggest to start an EU campaign to perform Customs controls on leather products, in particular on working gloves as low level/cheap products (no liner, direct contact with the hand skin) shouldn't be difficult. Most of them are imported from Pakistan India and China. Concerning safety shoes, where again the basic models has no lining, check those imported from China. | Initiating a general campaign on control of leather is outside the scope of this restriction proposal.  | Outside of the task for RAC; no comment. |  |
| **199** | 2012/05/02 13:08IndividualThe proposal (A)  | This proposal to restrict chromium (VI)in leather to <3ppm is a logic proposal. As per PPE Directive (89/686/EEC) any materials used in the PPE may not be adversely affect the user's hygiene or health. Guess that is it already largely prooven that chromium (VI) is ineed carconogenic, allergenic and toxic, and therefore needs to be restricted indeed.  | Thank you for the comments. | The comments support the proposal. The proposed limit of 3ppm is determined by the analytical method (EN ISO 17075) that is used to detect chromium (VI) in leather. |  |
| In the glove standards (which provides presumption of conformity with the PPE legislation), this restriction has already been defined at <3ppm in for example the EN420. This was actually a required from the European Commission (initially 10ppm was defined but not accepted by them) because higher then 3ppm was considered as unsafe. Hence, in order to be aligned with the PPE Directive, I guess it makes much sense to align REACH with this requirement as well and define this <3ppm.  |  |  |  |
| Start a EU campaign to perform Customs controls on leather products, in particular on working gloves (cheap products, no liner, direct contact with the hand skin) ... shouldn't be difficult ... most of them are imported from Pakistan and India, while safety shoes from China. | Initiating a general campaign on control of leather is outside the scope of this restriction proposal.  | Outside of the task for RAC; no comment. |  |
| **198** | 2012/03/21 09:54 IndividualThe proposal (A), Information on hazard and risk (B)  | My daughter and I have very severe dermal allergies with contact of some leathers. Having worked in the lab of a tannery, I was convinced long ago that this was allergies to chromium (VI). I'm very surprised that this CMR product is still allowed to process leathers that are used in contact with skin. I suggest that chromium (VI) is prohibited in the tanning of all leathers. | The comment supports the proposal.  | Comment supports the proposal to restrict chromium (VI) in leather articles. The option to ban the use of chromium (III)itself has been considered. As the Background document explains, it is chromium (III) (not a “CMR”) that is used in the tanning of leathers. Techniques are available to prevent conversion of this chromium (III)into chromium (VI), therefore a total ban may not be necessary.  | Thanks for your comment.The proposed restriction is targeted to the risk to consumers (and workers) of skin sensitization of chromium (VI), The formation of chromium (VI) in chrome tanned leather can be effectively prevented by application of the appropriate techniques. This risk management option seems to be sufficient. |

**Specific comments**

| **Ref** | **Date Country/ Organisation/** **MSCA****Comment type** | **Comment** | **Response of the Dossier Submitter** | **RAC Rapporteurs comments** | **SEAC Rapporteurs comments** |
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| **213** | 2012/09/13 14:43 Individual Information on hazard and risk (B), Other information (H)  | The extensive Warshaw study of allergic contact dermatitis (ACD) found that only 17.5% of patients allergic to shoes were allergic to chromium (VI). (Warshaw et al., 2007). | The restriction address risk to chromium (VI)and not ACD in general. | Noted, but we focus on the evidence relating to chromium (VI) allergy.  |  |
| The North American Contact Dermatitis Group (NACDG) patch-tested 10,061 patients between 2001 and 2004. Among the 109 NACDG patients with dermatitis of the foot, and a shoe source of allergens, the adhesive p-tertiary butylphenol formaldehyde resin was the most common allergen, accounting for 24.7% of positive patch-test results, followed by potassium dichromate chromium (VI). (17.5%) and carba mix (11.7%). When the data were examined according to groups of allergens, rubber chemicals (40.4%) were the most frequent allergens, followed by adhesives (32.5%), and leather components (20.1%)  | We observe that chromium (VI)is “responsible” for 17.5% of the ACD, which seems to be a rather significant level.  | We have tried to quantify the number of EU citizens who develop allergic contact dermatitis associated with exposure to chromium (VI) from skin contact with leather articles. It is for SEAC to judge the scale of this problem on socio-economic grounds.  |  |
| This study found that about 1% of ACD patients were allergic to shoes and 0.2% were allergic to leather components with 0.175% being allergic to chromium (VI). ACD is a major problem but chromium (VI) in leathers was found to affect about 1 in 500 ACD patients. As reported, chromium (VI) is only one of several shoe allergens. Fungicides can also be shoe allergens. | Surveillance data from Denmark shows that 2-3 % of eczema is allergic to chromium. Higher prevalence is found in other parts of Europe (table 23 in Background document).  | Chromium (VI) is a common cause of contact dermatitis in the EU. It is possible that the prevalence rate is greater in the EU than in the US.  |  |
| Hansen’s trials have shown that the proposal of chromium (VI) < 3 mg/kg is unlikely to overcome the dermatitis problem with chrome tanned leather.In the Hansen 2006 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 both chromium (VI) < 3 mg/kg, and soluble Chromium III, 12mg/kg, (Hansen et al., 2006 a).Five patients reacted to leathers which contained less than 3mg chromium (VI)/kg and no patients reacted to the two leathers with the highest chromium (VI) contents. Therefore, the proposed restriction is unlikely to control the ACD problem with chrome tanned leather. | The Hansen trial is based on 15 patients. The study is described in B.5.5.1, page 46, where the authors referred for saying that 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). | We would agree that there will be some sensitive individuals at risk of acute contact dermatitis from the low-level exposures that could occur with some leather articles that contain less than 3 mg/kg chromium (VI). As a consequence it is acknowledged in the Background document, that the proposed restriction will not be 100% effective. As commented by the Dossier Submitter, there appear to have been problems with the quantitative analysis of chromium (VI)and chromium(III) in this study.   |  |
| **Controlling Cr VI in leathers**Considerable research has determined processes to be used to produce leather containing less than 3mg chromium (VI)/kg, and these processes are now used in Europe. However, chromium (VI)can be generated in these leathers during storage and use. Chromium (VI)is formed in chrome tanned leathers during manufacture of articles, exposure to heat, low humidity, daylight and UV light. Ageing tests are available but do not simulate the real ageing of leather over months rather than days. | When applying the recommended measures mentioned in the Background document,  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 agents. The issue of post- production of Cr VI during the life cycle of the leather products has been considered in the Background document. | From the data we have been provided with, it appears that extreme, unrealistic combinations of conditions are needed for higher levels of chromium (VI) to develop after the production of articles using the best available technology.  |  |
| **Replacement of chrome tannages** There are now a range of alternative tannages but chrome tanned leathers are usually superior, less expensive and more versatile. This is why 80% of leather is chrome tanned. When white tannages are used for shoes, they are usually retanned with chromium. | In line with the information in Background document. | Noted. |  |
| **Prevention of formation of chromium (VI) in the further processing and storage of leather** There are serious problems with this section of the ECHA proposal. It appears that there is not yet a proven, acceptable method to control chromium (VI) formation during storage, transport and ageing of leathers, manufacture of footwear and ageing of manufactured products. Antioxidants have been used but it is known that ascorbic acid causes unacceptable discolouration of aged leathers. Problems with the proposed systems are demonstrated in studies cited in the ECHA proposal.For example see page 71, and Table 30 below for problems with antioxidant treatment.Although the antioxidants lowered the chromium (VI) content in these leathers, this may increase to detectable levels with longer ageing at different temperatures and humidity and longer UV irradiation. This will be the case with many leathers in retail conditions and in use. It should also be noted that the antioxidants greatly increased the soluble chromium in the leathers and levels over 700 and 1500 mg/kg may cause skin reactions (Hanson et al. 2006 b). Also, chromium (VI) could be generated from this soluble chromiumIII during subsequent storage. | None of the references mentioned in the Background document give an absolutely reliable method of how to avoid the formation of chromium (VI) in leather or leather products. However, for avoiding chromium (VI) it is recommended: i) not to use natural products such as fish oilsii) to employ vegetable retaining agentsiii) to properly adjust pH values in neutralisation andiv) to avoid ammonia as a wetting agent before dyeing and instead, use agents with reducing abilities.The positive effect of vegetable retanning agents and the neutral effect of synthetic fatliquors can also be confirmed. | Your concerns are expressed very clearly, and we respect them. However, the data we have seen, and other comments received, appear to indicate that it will be possible from a technical perspective for industry to comply with this restriction.  |  |
| It is stated, page 72 in the ECHA proposal, that 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). This statement is very misleading as shown in the Congzheng paper, Table III below: all the chromium (VI) levels achieved are above 10 mg/kg. |  |  |  |
|  The fatliquor NF3, found to give the lowest chromium (VI) content in the leather, resulted in 14.16 mg chromium (VI)/kg. This level was only lowered to 10.83 after 2 weeks at 100% humidity and increased to 66.25 at 12% humidity. The high chromium (VI) contents in leathers stored at low humidity show the possibility of chromium (VI) formation in just 2 weeks storage. The study and findings were impractical and leather stored at high humidity would require fungicides which may also cause allergies. |  |  |  |
| There is not yet a proven, acceptable method to control chromium (VI) formation during storage, transport and ageing of leathers, manufacture of footwear and ageing and use of manufactured products. Any chrome tanned product, whether produced in Europe or elsewhere, could generate chromium (VI) during storage and wear, even after an antioxidant treatment. |  |  |  |
| **208** | 2012/06/01 16:22 GermanyThe proposal (A), Information on hazard and risk (B), Why a restriction is the most appropriate Community-wide measure (E), Socio-economic Assessment of Proposed Restriction (F), Other information (H)MSCA  | ● Suggested restriction (A)The suggested concentration limit of 3 mg/kg is based on the current analytical detection limit. |  | Correct, no action required.  |  |
| The Annex XV report derives a surface concentration of 0.02 µg/cm2 over two days of exposure as a LOAEL (DMEL, MET10%). The hypothetical exposure scenario with leather shoes (see chapter B.9.3.2.2) predicts – by assuming a chromium (VI) content of 3 mg/kg and a 100 % release as a worst-case scenario – a surface exposure concentration of 0.45 µg/cm2, which exceeds the LOAEL considerably. The suggested concentration limit of 3 mg/kg is therefore not sufficient to protect especially sensitised individuals from contact dermatitis. Therefore, Germany did not set a fixed concentration limit but implemented a ban of production procedures resulting in detectable concentrations of chromium (VI)based on a specific harmonized analytical procedure (LFGB; B 82.02-11) as defined in the German Consumer Goods Ordinance(Bedarfsgegenständeverordnung).  | In principle we agree that the limit should be set to the limit of quantification in ISO 17075.  | We agree with the Dossier Submitter. The Background document has been modified accordingly. |  |
| The current detection limit of this analytical method is 3 mg/kg. As soon as this analytical method enables lower detection limits, there will be an adaptation of the maximum permissible concentration without amendment of the legal regulation. | In order to ensure legal certainty we inserted the current limit of quantification in the proposal.  | We agree with the Dossier Submitter. The limit could be lowered when the appropriate methods are available.  |  |
| The Annex XV report for the restriction of PAK similarly links the ban to the detection limit of the analytical procedure. It is therefore suggested to handle the restriction for chromium (VI)under REACH in an analogous manner.  | We assume that PAK refers to the German proposal on PAH. In this proposal the restriction is linked to limit of quantification (LOQ) as defined in entry proposal.Our aim is the same but was chosen because of legal clarity. We leave it to the Commission to propose an appropriate wording the text of the Annex XVII entry. | We have tried to address this in our opinion, but also agree with the Dossier Submitter. |  |
| ● Information on hazard and risk (B)Section B.2.2.2“A considerable influence on the formation of chromium (VI) in leather could be attributed to ageing and UV irradiation.” If chromium (III) can oxidise to chromium (VI) at a later stage, it is not clear how consumers can be protected only by avoiding oxidation during the tanning process.Section B.2.2.8  | We agree that under certain conditions the chromium (III) can be transformed to chromium (VI).Some reducing agents were effective when applied in the finishing part of the leather production process as after-treatment or as an after-spray.  | The evidence available to RAC indicates that anti-oxidants can be effective in preventing formation of chromium (VI)in articles.  |  |
| The German Consumer Goods Ordinance (Bedarfsgegenständeverordnung) restricts the content of chromium (VI)in consumer products of leather intended to come into direct and prolonged contact with the human skin, especially in consumer products such as clothing, watchstrap, bags and bagpacks, chair covers, purses and leather toys. This list is not exclusive, but exemplary. In an analogous manner, the Annex XV report should list the leather articles coming into prolonged contact with the human skin (Table 16) as examples rather than exclusive product categories. | Tables 16 and 17 have been updated. These are indicative and not exhaustive lists of leather articles.  | We note the useful nature of such a list. In addition the tables have been updated to reflect the alternative wording proposed by RAC. | We agree with the RACRapporteur’s response. |
| Section B.5.1.Quantitative figures (percentages) should be given for the amount of excretion via urine and faeces.Dermal absorption should be described into more detail, because this is important for an understanding of the allergic process. As chromium (VI)is an ion, one would anticipate limited dermal absorption, however, there are several publications demonstrating dermal absorption of chromium (VI)an overview is given in the German MAK document dated 2012 (http://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb1854029stad0048/pdf)) and these should be integrated here for a better understanding of the subsequent chapters. | Chromium is primarily excreted in the urine via the kidneys (ca.60%, Ryan et al.2000 and up to 80% Armstrong et al. 1981), with some additional excretion in the bile, faces, sweat, hair, nails and breast milk. However this is of minor relevance for the effect targeted by the proposal.The allergic process is described in section B5.5. Thank you for the link to the German MAK document. | We agree with the Dossier Submitter  and have not amended the documentation further.  |  |
|  |  |
| Section B 5.5.1 Sensitisation to chromium (VI):Mechanisms of contact allergy: reference should be given to dermal absorption of chromium compounds in the toxicokinetics section. | Noted and added to the Background document. | Noted. |  |
| p.50: it is unclear why the extrapolation for the EU was made only on data basis from Denmark. The extrapolation method of 50,000 new cases per year is also unclear. The assumption made “onset of allergy happens on average at 40-year old” should be explained. | The extrapolation is made using a specific prevalence which is not high compared to figures in table 23. The assumption on average of 40 years is an expert judgement. The estimate is conservative. Actually in Nardelli A, Taveirne M, Drieghe J, Carbonez A, Degreef H, Goossens, A. (2005) report that a mean age of 36 years of patients with allergic contact dermatitis to shoes.  | We have provided our own estimate of the number of new cases, based on the data from Denmark. Please see the Opinion and Background document.  |  |
| Section B.5.5.2 Sensitisation to chromium (III):There are publications dealing with dermal absorption of chromium (III) compounds (an overview is given in the German MAK document on chromium (III), http://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb1606583verd0046/pdf), which should be integrated into this section. Sensitisation to chromium (III) should be described into more detail. | Thanks for the link. We think the section B.5.5.2 describes the sensitisation to chromium (III) adequate. We will include the link to the German MAK report in this and other relevant sections. | Noted. We are content with the information provided by the Dossier Submitter.  |  |
| Section B.5.6 Repeated dose toxicity: It should become clear from this section, that there are no data on repeated dose toxicity from dermal exposure; in all study descriptions of this section, the route of application should be given.Section B.5.9 Toxicity for reproduction:  | The routes of exposure in the studies are indicated. In last sentence of B.5.6 it is mentioned that no repeated dermal studies are available. | Noted. |  |
| It should become clear from this section, that there are no data on fertility and development from dermal exposure; in all study descriptions, the route of application should be given. The type of the studies should be better described (e.g. for fertility studies whether 1 - or 2 generation studies had been performed). 6th para: it should be described into more detail, in which parts of the animals (e.g. blood, organs) chromium was detected.Section B.5.11 Derivation of DNEL(s)/DMEL(s):See general remarks. | Noted. The routes of administrations are applied in the report. The Danish EPA is not aware of any multi generation studies. In last sentence of B.5.9 it is mentioned that no reproductive toxicity studies are available suing the inhalation or dermal routes of exposure. | Noted. |  |
| Section B.9.2.1 Occupational exposure: Possible positive effects for workers were not considered and these were seen as “not relevant” for this restriction proposal in context with substance manufacturing. However, the use of Chromium (VI) compounds in leather tanning industries could pose occupational dermal exposure and hence risk for workers in this sector. | Available information suggests that in Europe chromium (VI) agents are not used for the tanning of leather. | The BREF report states that chromium (VI)compounds are not used in leather tanning today (at least in the EU).  |  |
| Furthermore, in general, the use of leather protection gloves by workers, which could contain chromium (VI)also pose a dermal risks for workers.  | Leather protection gloves are already covered by EU legislation.  | Agree with Dossier Submitter, and leather gloves are included in the proposed restriction.  |  |
| This consideration can be linked to Part F: Thus, the proposed restriction would have a positive impact on tannery workers in EU as well outside of the EU, if chromium (VI) compounds will not be used in tanneries anymore. In socio-economic assessment this positive benefit has not been taken into account, yet. A consideration of preventive effect on workers would increase the benefit of proposed restriction.  | Agree that the restriction would have positive effect in non EU countries both for workers and for consumers. No need to adjust Background document. | Chromium (VI)compounds are not used in the tanning industry in the EU. Agree that the proposed restriction could have a positive impact outside the EU.  | We agree with the consideration as well as with the Dossier Submitter and and RAC Rapporteurs’ responses. |
| Following information from Germany about sensitization unadjusted prevalence, caused by potassium dichromate by shoemakers and tanners which were affected and indicate allergy symptoms is available to us (Uter, W.; Gefeller, O.; Geier, J.; Lessmann, H.; Pfahlberg, A.; Schnuch, A.:Untersuchungen zur Abhängigkeit der Sensibilisierung gegen wichtige Allergene von arbeitsbedingten sowie individuellen Faktoren. 1. Auflage. Bremerhaven: Wirtschaftsverlag NW Verlag für neue Wissenschaft GmbH 2002. (Schriftenreihe der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin: Forschungsbericht, Fb 949) ISBN: 3-89701-819-5, 172 Seiten, Projektnummer: F 5156, Papier http://www.baua.de/de/Publikationen/Forschungsberichte/2002/Fb949.html): Tests made: 124 workersPositive reaction: 8 -&gt; Quote: 6.45%Textiles and leather workersTests made: 645Positive reaction: 34 -&gt; Quote: 5.27% |  | These studies were done with financial support of BAuA some years ago. They deal with workers sensitised not only but also to chromium (VI). The main message from these studies is: workers in direct contact with leather (leather and fur production and cobblers / shoemakers) have a slightly higher risk than other professions to develop a chromium (VI)allergy. But, the most often suffering professions are in the construction area. |  |
| It should be emphasized that these quotes excess an average quote of 4.21% (total 75.449 patients tested from several occupations and 3174 person indicate a positive allergic reaction towards potassium chromate). Furthermore the small amount of working teams depends on structure of leather-processing industry.  | The quotes confirm that the 2.96 as prevalence used in the proposal is conservative. | The figures are not unsurprising for chromium (VI) allergy and are consistent with the information we have based our opinion on.  |  |
| Another source (Dickel, H.; Uter, W.; Schmidt, A.; Kuss, O.; Schnuch, A.; Diepgen, T. L.: Auswertung von Datenbanken bzw. Registern von Hauttestergebnissen zur Relevanz arbeitsbedingter Faktoren. 1. Auflage. Bremerhaven: Wirtschaftsverlag NW Verlag für neue Wissenschaft GmbH 2001. (Schriftenreihe der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin: Forschungsbericht, Fb 939) ISBN: 3-89701-790-3, 132 Seiten, Papier http://www.baua.de/de/Publikationen/Forschungsberichte/2001/Fb939.html?nn=668500) indicates potassium chromate allergy by affected workers in leather and fur processes. |  | The workers were shown in patch tests to be sensitive to sodium chromate. However, this is not used in tanneries in the EU.  |  |
| Tests made: 23 Positive reaction: 3 ->; Quote: 13%It should be emphasized that potassium chromate is the most known allergen in tannery industries. |  | We note that a large number of workers were tested (75449, 3174 = 4,21% positive) all of them in dermatological hospitals because they had one or the other skin problem. They didn’t come necessarily because of a chromium (VI) allergy suspicion but also because of other skin problems. So the patch tests were done together with several other potential allergens. |  |
| Section B.9.3.2.2 Consumer exposure, 1st para:In absence of measured exposure values for consumers (normal case) exposure estimates based on one or more sentinel exposure scenarios (e.g. dermal exposure to Cr (VI) from wearing shoes as chosen in the dossier) are common for probabilistic or deterministic exposure calculations. Algorithm of ecetoc tra or Krätke &amp; Platzek 2004 (Migrationsverfahren und Modelle zur Abschätzung einer möglichen Exposition mit Textilhilfsmitteln und -farbmitteln aus Bekleidungstextilien unter Anwendungsbedingungen. Aus dem Arbeitskreis „Gesundheitliche Bewertung von Textilhilfsmitteln und -farbmitteln“ der Arbeitsgruppe „Textilien“ des BfR. Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 47, 810-813.) can be used. The variability in human populations, the lack of knowledge about consumer behaviour and other exposure data like concentration/migration can be expressed by distributions. Such calculations can be easily carried out and allows the comparison with the DNEL if available. | We believe that the clinical data combined with the exposure considerations used in this report provides a sufficient the basis for the restriction proposal. Imposing additional exposure estimates and scenarios would qualify the estimations further, but would not alter the conclusion. | We agree with the Dossier Submitter.  |  |
| Section B.9.3.2.2. Consumer exposure, 2nd para:Sentence should be checked. | Corrected. | This editorial error has been corrected.  |  |
| Section B.10.1.1.2 Risk characterisation –Consumers:See also general remarks: a DNEL should be applied according to the REACH guidance document. The DNEL should be compared with exposure in order to derive a risk characterisation ratio which clearly demonstrates that RCR is > 1. Wording such as “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” might be too weak to support the restriction proposal. |  | As it is explained in the Background document and opinion, the references to DNELs and DMELs have been removed to avoid misunderstandings. Instead, the lowest MET10% (LOEAL) values have been used for the risk characterisation. |  |
| Section B.11. Summary on hazard and risk:It should become clear from the test, that for toxicological endpoints such as reproductive toxicity, no dermal data are available. | Only sensitisation has been demonstrated as a critical effect by dermal administration. No repeated dose toxicity studies is available, but if it turned out that another endpoint was critical via dermal administration, it would not change the proposed limit of chromium (VI) which is the detection limit.  | We agree with the Dossier Submitter.  |  |
| ● Why a restriction is the most appropriate EU-wide measure (E)As the dossier submitter is in favour of RMO 1, it should be elaborated more thoroughly and supported by data, that chromium (VI) is a much more potent allergen than chromium (III). The possibility of formation of chromium (VI)from chromium (III)under post-marketing conditions (i.e. in the process of leather ageing under consumer use) should also be discussed. | The comment does not contain specific information. The issue is discussed in B.5.5.1 and B.5.5.2 | RAC concluded that CrVI is significantly more potent than CrIII. All the patients who have shown sensitivity to chromium (III) were also sensitive to chromium (VI). Provided the best available technology is used to minimise Cr(VI) formation, it appears that “post-formation” should not be a major concern.  |  |
| ● Socio-economic Assessment of proposed restriction (F)Section F.1: Human health and environmental impactsp.108-110: The estimation method of direct, indirect costs of illness is not quite comprehensive. It is unclear if different health systems within the European Union, thus different health care costs within the Member States have been taken into account. The estimation method of a EU27 average is unclear. The direct costs units seem to be low estimated. The costs of establishing the diagnosis were not taken into account for the costs per case calculation.  | The evaluation of cost is illustrative and we think it to this regard is sufficient for the justification of the proposal.The cost of establishing the diagnosis has been taken into account for the cost per case calculation (cost over lifetime). | For SEAC Rapporteurs. | We agree with the response of the Dossier Submitter. |
| For example, according to experiences from Germany , medical rehabilitation costs in average 1069.23 € (registered cases in the time period 1986-2006) of one occupational disease (cement dermatitis /allergic contact eczema) caused by chromiumVI in cement. In the same time period, occupational rehabilitation costs in average 8996 € per case. However, the average expenditures by German accident insurance (DGUV) are estimated at 4794 € per case. The estimation is based on data of registered cases in the period 1986-2006. | The comment does not contain information on how the data has been derived, what the accident insurance covers and how it is calculated etc. It is unclear e.g. if the rehabilitation costs in average given annually, over the period or the estimated life time? What is meant by rehabilitation cost for a decease that can not be cured? | For SEAC Rapporteurs. | The valuation of the health impacts in the Background document includes four well based cost elements (see BD section F1.1.1). No further assessment is considered necessary for the case. |
| Another source from German Institute for Medical Documentation and Information (DIMDI) provides data on costs of illness by occurrence of atopic dermatitis, which is similar in effects to contact dermatitis. The health unit costs (direct, indirect and private costs) vary depended on source, land and time period. The direct medical unit costs vary between 687 € (for year 1992) and 1449 (N/A) €. The indirect unit costs are estimated in average at 1541 € (for year 1992) and 1843€. The private costs are estimated at 239 € and 1128€. The difference of the amount of health care costs is obviously within the MS. For example in UK the direct costs are estimated at 51 and 97 GBP (1995/1996) and private costs at 25 and 153 GBP (1995/ 1996).  | The data in the dossier shows direct annual costs (health care and medi­cation to be 472 € pr case. Both the German and the UK data seem to indicate higher direct costs underlining that the proposal is justified. We do not see any reason for adjusting the text as the strength of the proportionality is clearly demonstrated in (section E and F). | For SEAC Rapporteurs. | Thanks for the data on costs which show potential underestimate by the Dossier Submitter. |
| Before discounting of future expenses for health care, these should be adjusted on future expected price increases due to inflation rate.Before discounting of future production losses, these should be adjusted on expected salary increases due to inflation in the future. | We count in 2010 prices – so therefore the expenses should not be adjusted further. The annual discount rate of 4% is quite high. | For SEAC Rapporteurs. | We agree with the Dossier Submitter. |
| Section F.3. Social impacts:If the positive effects (of the proposed restriction) on workers in tanneries / shoe industry would be taken into account, the negative social effects on workers could be avoided in the future. This aspect is justified by possibility of job losses and loss of social status of the affected workers, if the occupational disability occurs due to chromiumVI exposure and accordingly severe skin disease. | In principle we agree. However such benefits are (in principle) covered by the indirect costs and welfare loss. | For SEAC Rapporteurs. | We agree with the Dossier Submitter. |
| ● Other information (H)The paper by Hansen, Johansen and Menne (Contact Dermatitis 2003, 49, 206–212), which addresses the (documented) sensitizing properties of chromium (III) and its considerably higher content in leather, proposes a restriction of soluble chromium (III) in leather products in addition to chromium (VI). | The paper is included in the list of references and cited in B.5.5.2 | Noted. The paper provides MET10% data showing that CrVI is more potent than chromium (III).  |  |
| **207** | 2012/06/01 15:44Sweden / Company / Ahlsell AB The proposal (A)  | Ahlsell AB proposes a restriction as follows:Restriction option 1 (RMO 1) The restriction takes the form of a regulation, which has direct effect all over the EU. This will make it easier to monitor the compliance of the restriction and sends a strong signal to stakeholders outside EU. • Evaluation of the effectiveness of the restriction is made after three years.• If the content of chromium VI stays below the limit, RMO 1 stays in force and its effectiveness is monitored and evaluated with 3 yrs interval.• If the above problems are shown not to be solved, and measured levels of chromium VI in leather products are found not to be reduced as expected, then;Restriction option 3 (RMO 3) enter into force five years later. | We agree that the restriction should be evaluated after a period. This could be further considered during the decision making process. | Agree that the restriction could be reviewed. It will be for policy makers to initiate any further proposals. | We agree with the RAC Rapporteur’s response.  |
| **203** | 2012/05/29 14:26NorwayThe proposal (A)MSCA  | Norway welcomes the Danish initiative to propose a restriction under REACH on hexavalent chromium in articles of leather, coming into direct and prolonged or repetitive contact with the skin. | Thank you for the positive comments.  |  |  |
| This proposal concerns chromium (VI) formed unintentionally in leather tanned by the use of chromium (III) compounds as tanning agents, and will apply to both imported articles and articles manufactured within the EU.  |
| We fully agree with Denmark that there is a need for reduction of the risk of allergy due to exposure from chromium (VI). However, we are concerned whether the proposed limit value of 3 mg/ kg is low enough to reduce the risk based on the information that elicitation of chromium allergy can occur at low levels of chromium in leather and even below existing detection limits in standard analysis.  | Consideration for the proposed restriction limit are presented in the Background document. The possibility of including a review clause could be considered in the decision making process. | It is possible that levels of chromium (VI) below 3 mg/kg could elicit responses in some sensitive people. However, it is anticipated that the protective measures will actually reduce levels well below 3 mg/kg. |  |
| On this basis we will propose that a review clause is added to the restriction in order to consider reducing the limit value further when the detection limit of the analytical methods is lowered.  | We agree that the restriction could be responsive to any technical advances that enable a lower detection limit to be applied reliably. |  |
| According to the Annex XV document three alternative restriction options RMO 1, 2 and 3 were considered. As the risk management options addresses prolonged skin exposure caused by releases of chromium (VI) from articles of leather, we find the RMO 1 most appropriate and targeted. However, from an the enforcement point of view, RMO 2, restriction of chromium (VI) in all articles of leather, is more enforceable and will probably not have any practical impact compared to RMO 1. Hence, Norway could also support the RMO 2. RMO 2 may provide a slightly better consumer protection, but will 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 considered to be higher than the ratio for RMO 1. | The comment supports the proposal.  | Noted. | Thank for your support. |
|  | If RM02 were proposed, some articles may need to be exempted. However, the alternative wording and scope proposed by RAC should enhance the enforceability as also confirmed by the the advices of the Forum on the restriction proposal | 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. Our opinion is that including in the scope of the restriction articles which do not present a mentionable risk cannot be supported. |
| RMO 3 is in practice a ban of chrome tanned leather. Compared to RMO 1 and RMO 2 the costs of compliance would be significantly higher. We do not support this option. |  | Noted. |  |
| Conclusion Norway supports the Danish proposal for a future restriction on hexavalent chromium in articles of leather, coming into direct and prolonged or repetitive contact with the skin. We could also support a restriction on chromium (VI) in all leather products (RMO 2). |  | Noted. |  |
| As there is doubt whether the proposed limit value is low enough to protect the most sensitive individuals we will propose that a review clause is added to the restriction in order to consider reducing the limit value further when the detection limit of the analytical methods is lowered.  | We would support such a review clause | The issue of the review of the restriction could be further considered in the decision making process by the policy makers.” | We agree with the RAC response. |
| for existing **202** | 2012/05/31 10:46United KingdomThe proposal (A), Information on hazard and risk (B), Available information on alternatives (C), Why a restriction is the most appropriate Community-wide measure (E), Socio-economic Assessment of Proposed Restriction (F)MSCA  | A.1.2 It would be helpful if further clarification were provided on some of the terms used, e.g. direct, prolonged and repetitive to aid enforceability.  | Revised versions of indicative lists for leather articles in short/prolonged contact with the skin are given in the tables 16 and 17 of the Background document. However, this is not relevant given the modified wording of the proposal that does not include such terms  | We have proposed an alternative wording that does not include these imprecise terms, especially to aid enforceability and also in line with the Forum advice on the restriction proposal.   | We agree with the RAC Rapporteurs’ alternative wording, that should not require further clarification of terms.  |
| Is it proposed to tie the restriction to a specific analytical technique (EN ISO 17075:2007)? How will technological advances in measurement methodology be taken into account, e.g. newer methodology with a lower detection limit? | It is up to the Commission to propose changes to the Entry, e.g. in a review clause covering both the detection limit and evaluation of effectiveness of the restriction. | Yes, this standard is specified in the Background document and opinion. As indicated also by the Dossier Submitter, we defer to the Commission for the question about new methods.  |  |
| A.2.3 It would be helpful if the basis on which the effectiveness of the restriction would be judged could be explained more.It is clear that reducing the formation of chromium (VI) during leather processing is possible and this is the focus of the restriction but what is not clear is how this restriction will address reducing Cr VI that is formed post-production. More information on the stability and lifetime of the antoxidants would be helpful. | We agree that more information on the stability and lifetime of antioxidants would be helpful. The issue is discussed in C.2.2. | RAC noted that there are some antioxidising agents that can be applied on uncut leather or finished products (Section C2.2). There is no evidence from the clinical data that old, well used articles can suddenly become allergenic, but this possibility cannot be excluded. |  |
| A.2.4 More justification on why ‘swift’ regulatory action is needed now would be useful.More evidence supporting the need for the restriction would be useful; e.g. there is no correlation between chromium (VI) content and induction of dermatitis in chromium (VI) allergen-positive patients (Table 21). Furthermore the response of these sensitised patients (n=15) was restricted to 5 of the 14 samples (a hit rate of 10 out of 210 so 3mg/kg levels identified in many leather items for sale as reported by studies conducted in Denmark and Germany. Therefore further information is required to determine whether restriction of chromium (VI)following leather processing alone is sufficient to prevent chromium (VI)content in finished leather goods. | 5 out of the 15 chrome allergic patients reacted when exposed to leather in the patch test. There was no clear relationship between the content of Cr(VI) in the leather and the number of patients reacting. This underlines the need completely to avoid Cr(VI) in leather.  | Clinical observations indicate the scale of the problem. There is already a comparable restriction in Germany. The restriction would target imported articles as well as those produced in the EU. Technology is available to minimise “post-formation” of CrVI in leather articles.  |  |
| B.2.2.3. Other sources of chromium (VI)in leather. A concern is the potential to use chrome based pigments in imported leather articles. The use in the EU falls under Annex XIV listing but this will not affect use in imported articles. Has this use of other chromium (VI) compounds in pigments been taken into account in the calculation of prevalence and incidence rates for chromium (VI) sensitisation? | The Annex XIV inclusion does not address risk related to imported articles which cover the majority of leather articles on the EU market (B.2.2.5).The proposal addresses the risk related to chromium (VI) in leather, including if the chromium (VI) arises from pigments. | We agree with the Dossier Submitter’s response.  |  |
| B.5.5.1 Table 22 states that the overall mean occurrence of chromium allergy among patients with eczema is 2.96% and that this is used for the socioeconomic evaluation. It is unclear how this is used in the socioeconomic evaluation and in what way it is relevant for the socioeconomic evaluation. Further explanation is needed to validate the use of this figure.  | At p. 50 it is described how the 2.96 is used in one of methods used for the calculation of the number of new cases per year – resulting in 50,000 new cases per year in Europe. Actually it is other method (prevalence method) – resulting in 44,000 new cases that is used in the socioeconomic evaluation. Of the 44,000 cases it is estimated that 45% = 20,000 cases are related to chromium in leather. The sentence under table 22 has been clarified. | The expert advice we have received is that nearly all those who suffer from chromium allergy in Denmark will attend a clinic. As such, using data from Denmark, it has been possible to calculate the prevalence and number of new cases of chromium allergy in the general population. Our approach is described in the background document and the opinion. |  |
| B.5.5.1 It is unclear how the representativeness of the prevalence of chromium allergy in the general population of Denmark (0.37%) relates to the rest of the EU. Although the figures for Germany (0.2-0.7%) are similar, it is unclear how representative these figures are for the rest of the EU.  | It is our best estimate. Also here we are conservative as the prevalence in other parts of Europe seems to be higher (table 23) and comment mentioned above (REF. 201– European Society of Contact Dermititis). | Noted. Table 23 and the information from ESCD appear to address this point. We think that the prevalence might be highest in parts of the EU with a hot climate (exposure to chromium (VI) in footwear thought to be most problematic here).  |  |
| B.9.3.2.2. The conclusion that 35% of products contained chromium (VI)only reflects articles containing greater than 3 mg/kg. The percentage could have been higher if articles containing smaller quantities were included. | Correct but we don’t know, as the 3 percent is the established quantification limit. | Noted. |  |
| Johansen et al, 2011 – aimed to clarify whether chromium (VI) and chromium (III) compounds are released from shoes in Denmark in an amount that could cause allergic reactions. The results given in this dossier relate to chromium (VI) content of shoes rather than the amount released. Were any migration studies performed? We would like to see more justification of the use of 45.5% as the percentage of leather exposure as causative agent for Chromium contact dermatitis. This figure is 45.5% of patients at Gentofte Hospital in Denmark with ACD due to chromium who reported leather as a source of exposure. It is not clear if the profile of patients at Gentofte is typical for the profile of patients in other EU countries. The uncertainty surrounding this value needs to be explicitly stated to use this value for SEA cost benefit analysis. | The 45% is supported by Ref 201 - in Portugal out of 2872 patients tested for contact allergies in 2009 and 2846 in 2008, 7.3% and 8.2% reacted to potassium dichromate in the baseline series, respectively. About half were due to leather in footwear. Moreover, in Coimbra, in 2010 and 2011, the respective percentages were 5.4 and 6.2 out of 292 and 276 subjects tested, with 1/3 due to shoes.- in Barcelona (Spain), the percenta­ges of chromium allergies in 2009 was 4.9 and in 2010 it was 5.6, respectively, with many cases due to shoes.- - In Leuven (Belgium), 626 (4.7%) out of 13.257 patients tested. Between 2000 and 2011 presented with a contact allergy to potassium dichromate, of which 536 (86% of the positives) due to footwear | Although the data are still relatively limited, the figures obtained from the public consultation indicate the general relevance of the 45.5% value given in the Thyssen study.  |  |
| We accept that it is not possible to quantify skin exposure to chromium (VI)from leather based on current information but think that the value given in the hypothetical ES is an overestimate. The expectation that all of the chromium (VI) content in a leather article is released seems overly conservative. Also the shoe being worn wet is worst case. Given the uncertainties it may be preferable to use a qualitative approach. Also given that the limit for the restriction is based on limitations of analytical technique rather than on health grounds. There is likely to be a residual risk at the proposed limit of 3 mg/kg. | The hypothetical ES has been replaced by a box with considerations regarding an exposure scenario for leather articles. A migration rate of 30% is used instead. | The calculation has been refined (see Background document). It illustrates the possible risk in the continued absence of the restriction. It is agreed that there is likely to be a residual risk at 3 mg/kg, but it is anticipated that the restriction will provoke protective measures that reduce chromium (VI) levels below this.  |  |
|  B.11 The suggestion that the restriction will have an effect on 36% of sensitised individuals needs further clarification. Does this mean 36% of individuals with ACD due to chromium will benefit from this proposal? The 45 and 36% values are very speculative and do not provide a robust basis for an SEA assessment. More information on the uncertainties surrounding these estimates needs to be provided. | It is the best estimate. 36% is derived from en expected effect of 80% of leather related chromium allergy and that leather allergy counts for 45% of chromium allergy cases. | We accept this to be the best estimate, given the available data and the expert advice given to the Dossier Submitter.  |  |
| B.10.1.1.2 The dossier states that the suggested limit is expected to protect approximately 80% of sensitized individuals against manifestation of the disease. The 80% figure is according to “expert judgment”. The rationale used in this expert judgement needs to be described, otherwise it is unclear how much the credible and robust the 80% figure is. | The 80% is based on experience from cement where nearly all allergy cases disappeared when a limit value of 2 ppm introduced. But there is uncertainty related to (illegal) direct consumer import of leather articles, use of leather which is not covered by the restriction for purposes that makes the leather come in contact with the skin, possible contribution from chromium (III) and the fact that the MET10 value might be below the proposed 3 ppm (Ref hypothetical exposure scenario at page 64). In F.6 a sensitivity analysis assuming a “protection rate” of 40% is carried out. | We have nothing to add to the response from the Dossier Submitter.  |  |
| C.2.2. Are the antioxidising agents referred to here substances that have to be used during the tanning process or is there scope for treatment of processed leather and finished articles. For treatments that can be applied to finished articles, is the effect permanent or would reapplications be necessary?It would be useful to have some information on results of TEGEWA work on prevention of chromium (VI) formation during the storage of leather. | Some of the agents are to be used in the last part of the leather production process, while others are said to be used on final articles. | We understand from the Dossier Submitterthat anti-oxidants can be applied during the production process and on final articles to minimise the potential for chromium (VI) formation. Further information has been introduced into the Background document.  |  |
| C.2.5 The information on the total (and additional) costs of manufacturing leather in which chromium (VI) is prevented is insufficient to assess its credibility and robustness. The dossier presents only an “expert estimate” that the extra costs are thought to be in the order of magnitude of 2-10% for chemicals, which equates to less than 1% of the total costs for the production of leather. All evidence that was used to come up with the expert estimate of 2-10% needs to be presented so that it can be properly assessed.  | We think information is sufficiently for taking a decision. C.2.5. gives an overall description of the cost structure. The expert is COWI. As mentioned in the text the statement is also based on information from several chemical suppliers. | For SEAC Rapporteurs.  | We agree with the Dossier Submitter, that information is sufficient. In addition, based on information provided to Dossier submitter by TEGEWA, we note that the additional chemical costs to avoid the formation of chromium (VI), may vary more between different suppliers than between different chemicals. |
| C3. The evidence suggests that there will be no significant exposure to glutaraldehyde residues in tanned leather but there may be concerns for worker safety. |  | Noted.  |  |
| The methodology available for the restriction of chromium (VI) formation during tanning is well established within the EU, is effective and would represent minimal additional cost to the producers. Consequently adopting these protocols, including the use of antioxidants to prevent post-production chromium (VI)formation, would represent a major step in decreasing chromium (VI) content in leather, occupation exposure to chromium (VI) in the tanning industry and post-manufacture formation of chromium (VI) under UV induced oxidation.  |  | Noted. | Thank you for the information. |
| E.1.3 In table 35, the possibility of using labelling as a risk management option is considered but discarded. The examination of this option should be reconsidered.  | The comment fails to indicate why the explanation is not sufficient. | We note the response of the Dossier Submitter and have received no evidence to suggest that labelling would be effective.  | In addition to RAC Rapporteur’s response, we add that labelling may be ineffective to protect persons who do not currently have Chromium allergy.  |
| E2 Given that there may be practical enforcement issues related to RMO 1 and the need to explain the meaning of ‘direct, prolonged and repetitive’ it would be helpful to have more argumentation related to the relative enforceability of the different options. | Forum has given advices on the enforceability in line with which the wording of the restriction proposal has been modified (with no reference to direct/prolonged/repetitive terms) | In light of all comments, the restriction proposal has been modified.  |  |
| E.2.1.1.1. The statement that the restriction will lead to a reduction in 80% of new cases is at odds with earlier which suggests that the limit will protect the majority of population against induction and around 80% of sensitised individuals from elicitation.The uncertainties surrounding the 20,000 cases per year need to be stated explicitly. Also days off work is based on assumptions which have not been described. | It is correct that the limit related to induction is higher than the limit related to elicitation, and therefore more than 80% of new cases are considered to be avoided. However for the cost-benefit calculations the 80 % is used – and in the sensitivity analysis an assumption of 40% is used. | For SEAC Rapporteurs. | We agree with Dossier Submitter that the assumptions used in the cost-benefit calculations are on the safe-side. Prof. Menné has extensive experience of patients with chrome allergy, and in a meeting with the rapporteurs he confirmed that an average of 7 days per year off work seemed reasonable. |
| E.2.1.1.2.2 A transitional period of 12 months is proposed to enable the market to adjust. The rationale for proposing 12 months is not well justified in terms of actual market evidence conditions. Rather it seems to be based on very little specific information related to this market, and justified on the basis that some transition is necessary for the market to adjust, but that this should not be very long in order to minimise exposure time. In accordance with the argumentation given in the dossier it would be just as reasonable to propose a 24 month transitional period.  | 12 months is often used and we do not see any reason to have a longer period, taking into account the health benefits. | We note the absence of any other comments on this subject, especially from the relevant industry sector.  | We agree with the response of the Dossier Submitter, as well as the observation of RAC rapporteurs. |
| E.2.1.1.2.1. The technical feasibility has not considered the issue that imported leathers that may have low levels of chromium (VI) at the point of import may develop higher levels during storage/processing. Is it feasible to treat such articles?  | The most likely scenario is that importers demand articles in compliance. Information in C.2 suggests that antioxidants to be used on finished products as shoes are available.  | The Dossier Submitter’ response is noted. We conclude that it should be possible for importers to comply with this restriction.  | We agree with the response of the Dossier Submitter. |
| E.2.3.1.2.2 It is stated that the costs related to chemical and new investments of implementing RMO 3 are likely to be 5-10 time higher than the costs of RMO 1 and RMO 2. No basis for how this was estimated/calculated is given hence it is not possible to consider the credibility and robustness of this assertion. It should also be noted that in section E.2.2.1.2.2 there is no information on what the total additional costs would be of RMO 2 as compared to RMO 1. | The cost related to RMO3 is uncertain as described in C.3.5. However a producer might choose to use non chrome tanning as a way also to comply with the requirements of RMO1.It is reasonable to believe that there are some additional costs related to including leather articles which are not coming into contact with the skin to the scope of the restriction (moving from RMO 1 to RMO 2). If the tonnage difference between these two options is 10%, the difference in total costs would as a maximum be at the same level. As described in the Background document, it is not reasonable to assume that all tanneries would separate the production lines for leather batches used in the articles inside or outside the scope of the restriction.  | For SEAC Rapporteurs. | We agree that 5-10 time higher cost estimation for RMO 3 is a rough estimate. Taking into account that the shoes industry would completely need to change the technology to produce Chromium free leather to comply with the RMO 3, the cost might be of this order of magnitude. The slightly higher costs for RMO 2 compared to RMO 1 may cover e. g. the extra testing. |
| E3 Table 38 It is not clear how the values given were reached and what criteria were used. | The purpose of the table is to ease the understanding related to the text. Some use +, ++, we use 1,2,3. | For SEAC Rapporteurs. | The response of the Dossier Submitter is noted. |
| F.1.1.1 The costs presented in table 39 (costs of establishing the diagnosis and one years treatment) do not appear to have been further taken into account in estimating the aggregate costs per case (table 41). If these costs are included in table 41 by virtue of their inclusion in the annual treatment costs shown in table 40, then it would be necessary to take into account the fact that some of the costs are one-off and not recurring every year. Moreover, this latter point about one-off and recurring costs needs to be considered more generally in relation to the health costs estimation exercise. This is because in deriving the lifetime costs associated with direct, indirect and welfare losses, it as assumed that the annual costs for each element are incurred every year for 42 years. In other words it assumes that there is no adaptation or avoidance behaviour taking place by individuals to avoid exposures and hence avoid the costs associated with exposure.  | The costs in table 39 are included in table 41, 3rd column. | For SEAC Rapporteurs. | We agree with the response of the Dossier Submitter.  |
| Such avoidance does not appear to have been taken into account in the individual figures for costs per case (discounted over life time) shown in table 41. Whilst this does not appear to be a problem in table 42 for avoided new cases, which are only based on 1 years costs, it does appear to be a problem for the costs from existing cases (since these include welfare losses associated avoided symptom days each and every year for 42 years, without any consideration that avoidance/adaptation may be taking place to avoid such symptoms). This would imply a potentially significant overestimation of the saved costs of avoided symptom days for existing cases –since these are the main component of total health benefits, then there is potentially a large overestimation of these benefits. | For the welfare loss, it is assumed that the number of symptom days is declining from 200 to 100 days during the first 20 years, and thereafter remains at 100 days for the remaining 20 years. (p.111). The average value, i.e. 125 days, is used in table 41. Furthermore 63 days is used in the sensitivity analysis. | For SEAC Rapporteurs. | To avoid potential overestimation of the benefits, the number of avoided symptom days for existing cases is assumed to be zero in the modified benefit calculations by SEAC rapporteurs. To estimate benefits for patients, the “consumer surplus” approach is applied. This change is based on an assumption that patients with chromium allergy are able to avoid symptoms caused by the exposure to leather. However, the updated cost-benefit analysis demonstrates that the monetised health benefits are significantly higher than the costs of the restriction and the net benefits are growing over time.  |
| F.1.1.1 Please provide details of expert estimates (and what they are based on) that a person with contact allergy is absent for 7 days on average per year.  | It is a judgement of Professor Menné. A Danish survey on worker related contact allergy (also for non metal) in 2001 for 181 women found an extra average absent rate of 1.6 days per year. This is regarded as too low. 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. | Prof Menné has extensive experience of patients with chrome allergy, and in a meeting with the rapporteurs he confirmed that an average of 7 days per year seemed reasonable given the severity of this disease.  |  |
| F.1.1.1 The valuation of a symptom day appears to come from a study which was looking at air pollution. In fact the symptom day that the study was looking at was characterised by the following symptoms: “mildly red watering itchy eyes and runny nose”. It is unclear therefore that this study is particularly relevant to the case of contact allergy whose primary symptoms are skin related. Furthermore, the number of symptom days in the COWI (2004) study (73 days or 20% of the year) does not appear to be based on any hard evidence, but rather is an arbitrary assumption. Given this the reassessment of the number of symptom days in the dossier, which is based on the COWI figures, would also appear to be unsupported by evidence (Although the dossier states that on the basis of Danish experience it is assumed that the number of symptoms days will gradually reduce from 200 to 100 days – but the dossier does not produce or say what this Danish experience is, i.e., it does not provide any evidence).  | 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 lifeAs described in the dossier the estimate is uncertain and not hard evidence.  | We note that the figures represent the best estimation that the Dossier Submitter can make, having consulted an expert clinical dermatologist with experience of patients with chrome allergy. Information provided during public consultation by allergy sufferers seem to point in the same direction. | The valuation of a symptom day (WTP €15) by the Dossier Submitter comes indeed from COWI (2009). SEAC compared this value with information in the study “The Importance of Skin Disease as assessed by Willingnes-To-Pay” (Lauren Parks, Rajesh Balkrishnan, Line Hamel-Gariépy and Steven R. Feldman; in the *Journal of Cutaneous Medicine and Surgery*, Volume 7, October 2003). The values in that study for various skin diseases vary between €6 and €12 (when recalculated to present value per day). Considering that chromium allergy is a particularly severe contact allergy, the figure used by the Dossier Submitter seems realistic. |
| As a result, it is unclear what, if any, validity the number of symptom days used in the dossier has. Moreover, the number of symptom days is reduced by 50% for those already diagnosed with chromium allergy (see p112) resulting in them having 63 days with allergic symptoms. Again, the reduction by 50% does not appear to be justified beyond a referral to an assumption based on expert judgement – no indication of the basis of the expert judgement is provided. | The 50% reduction reflects that only 50% of allergy cases were related to exposure from leather.  | As above, we have clarified that this is the best possible estimate the Dossier Submitter can make and that valuable expert advice has been provided by Prof Menné.  | In the updated calculations by SEAC, we used different approach based on consumer surplus for estimating the benefits of the existing patients, and the 63 days are not used in that calculation any more. Furthermore, sensitivity calculations are carried out with lower assumption on avoided symptom days for new cases. |
| F.1.1.1 Another potentially significant problem with the benefits analysis is the fact that it forgot to take into account the fact that even if the restriction is introduced, there will still be very many leather articles in circulation in society (stock versus flow issue) and hence the health impacts will continue both in term of continuing to generate new cases and inducing symptoms in those existing cases. In other words the health benefits given in table 42 will not materialise because this would require that all exposures (including to articles already in circulation) would stop. Since the Dossier does not discuss the number of articles in circulation, nor the number of new leather articles sold each year, it is not possible to say what, if any, effect the restriction might have. | Taken the overwhelming data it is surprising for us that anyone can doubt that the restriction will have any effect at all.A large part of leather articles is renewed every year, e.g. shoes. In any case it is a transitional issue. | It is clear that this restriction principally targets new leather articles. Items such as shoes and belts are purchased in high volumes every year across the EU and the aim is to limit the risks they pose both to already sensitised individuals and people who are not yet sensitised. Like the Dossier Submitter, we see this as a transitional issue.  |  |
| F.1.1.1 There does not appear to be any account taken in the total additional testing costs of the impact on import prices of testing costs. | The total cost of testing is estimated last line in F.2.1. The testing cost is app. 6-15% of the total additional cost for all articles (5 respective 15/(8 respective 15+70+5-15)). The impact on specific import prices of articles depends on the testing frequency, confidence in the supply chain etc. The impact on specific import prices of articles depends on the testing frequency, confidence in the supply chain etc. We also refer to the comment in REF. 204 (In general, large footwear distributors and brands require footwear manufacturers to provide footwear in which Chromium VI cannot be detected in leather components (less than 3 ppm), given that they operate in international markets in some of which, like Germany, Chromium VI is already statutorily limited.) | For SEAC Rapporteurs. | We agree with the Dossier Submitter’ response. |
| F.2.1 In table 43 please clarify what is meant by unit turnover. It is unclear that this is the same as total production costs. Hence it is unclear if the basis of the cost increase per m2 of tanned leather is correctly specified. More generally on the issue of the cost estimates provided in this section, it is unclear whether the cost impacts include things like costs related to the process change (e.g. improvements to control chromium (VI) throughout product chain, etc), familiarity costs. Whilst these may (or may not) be insignificant in terms of increases to prices of leather articles, the relevant comparison needs to be made in terms of opportunity costs to society in total (and not just in terms of the price of the article). | As indicated below table 43, the turnover estimate per m2 of tanned leather is based on the data from COTANCE (Table 11. (5,246,740/(131,453+42,693)).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 Most European tanneries have already made the changes to their production process (C.2.5)We think it is relevant to consider the effect on prices. The opportunity cost issue related to the next best use of scarce resources is in our view linking benefit to cost. Taking the limited costs for ensuring avoidance of chromium (VI) for the society as such, we think the considerations in chapter F are sufficient. | For SEAC Rapporteurs. | We agree with the Dossier Submitter’ response. |
| F.2.1 The cost of compliance control is estimated to be in the order of magnitude of euro 15 million. Based on the figures on test frequency and price per test, this estimate would appear to be rather conservative since it would imply that sales of leather would on average in the EU be around 1.2 articles of leather per year per person (((euro15 million / 250 euro [price per test]) x 10,000 [test frequency])/500 million [population of EU]. | The estimate is based on experience from Germany. | For SEAC Rapporteurs.  | We understand that there is some uncertainty in this estimate. We also note that the figure includes costs of “voluntary” tests, that would and are taking place regardless of the restriction, and actually does not include potential testing by enforcement authorities, as it has not yet been carried out. All in all we agree on the order of magnitude of costs estimated by the Dossier Submitter.  |
| F2.2 Regarding the loss of export revenue, the dossier asserts that it is unlikely that there will be any affect of the export of leather of leather goods since EU export is mainly of high quality products where the price of the article is not the main parameter. This seems to be at odds with conventional economic wisdom regarding Price elasticity of demand – in the case of such high quality products (in other words luxury goods), the price elasticity is > 1 and hence such products have greater sensitivity to price changes, such that exports will indeed be affected, contrary to what the dossier asserts. | Most European tanneries have already made the changes to their production process, so no changes in prices can be expected. Actually it can also be used as a sale parameter that the strict EU rules to protect health apply on articles produced in EU and thereby give an advantage in the competition in the different segments of the marked – especially the luxury part.Even that the price elasticity in general – but not always - is higher for luxury products, compe­tition is often related to other parameters than just the price.Furthermore even if the price elasticity is higher it should be kept in mind that the change in price is lower for high end products than for low end products, as cost related to ensuring elimination of chromium (VI) are the same.Therefore as indicated in F.3.1, EU production for the internal market will gain a bit in relation to imported articles. However, in practice we consider the changes as negligible. | For SEAC Rapporteurs. | We agree with the Dossier Submitter. |
| **200** | 2012/05/10 12:24Italy / Industry or trade association / AssOSafety The proposal (A) | Why not bring the limit to 0 (zero) or to a value below the current detectable limit (with a certain lab equipment)?So far the EU raw leather is guarantee and certified for chromium (VI) contents by EU laboratories, this allow EU (PPE) manufacturers to deliver articles that comply with the EN standards, should be the same for imported leather products! | For enforcement reasons the limit of quantification with the standard analytical method is used as the restriction threshold. This approach was supported by Forum.  | In agreement with the Dossier Submitter. |  |
| **199** | 2012/05/02 13:08 / / IndividualThe proposal (A)  | Bring the limit to 0 (zero) or to a value below what can be detected (with a certain lab equipment). | What is actually proposed as the limit is the limit of quantification of the testing method. | In agreement with the Dossier Submitter. |  |

**Specific question 1**

Please provide quantitative information on Cr(VI) exposure to human skin (e.g. data on relationships between the levels of Cr(VI) in leather articles that may reach the skin and the causation of allergic contact dermatitis).

| **Ref** | **Date Country/ Organisation/** **MSCA****Comment type** | **Comment** | **Response of the Dossier Submitter** | **RAC Rapporteurs comments** | **SEAC Rapporteurs comments** |
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| **207** | 2012/06/01 15:44Sweden / Company / Ahlsell AB The proposal (A)  | How do you define contact with human skin? I a jacket with leather on the outside only in contact with human skin, a belt, a shoe whit synthetic inside? | The updated restriction proposal concerns all leather articleswhich can release chromium (VI) to the skin upon use, no matter what the mode of the contact may be (e.g. direct/indirect, short/prolonged). The indicated articles are covered by the proposed restriction as they are handled when put on/taken off and thus come in to contact with the skin.  | We agree with the Dossier Submitter. | We agree with the Dossier Submitter.  |

**Specific question 2**

Please provide any additional information on costs of implementation of the proposed restriction.

| **Ref** | **Date Country/ Organisation/** **MSCA****Comment type** | **Comment** | **Response of the Dossier Submitter** | **RAC Rapporteurs comments** | **SEAC Rapporteurs comments** |
| --- | --- | --- | --- | --- | --- |
| **207** | 2012/06/01 15:44Sweden / Company / Ahlsell AB  The proposal (A) | We have not analysed this. |  | Noted. |  |
| **200** | 2012/05/10 12:24Italy / Industry or trade association / AssOSafety The proposal (A) | Concerning PPE's made of leather no extra costs ... because the limit should be already less than 3ppm!Add the results of non-compliant PPE's, not only those found at the consumer level (GDO, DIY) test into the RAPEX system so consumers will be alerted in time. | Correct that no extra cost for PPE, as already covered by EU legislation.The Rapex system does also apply on PPE’s. | Noted. |  |
| **199** | 2012/05/02 13:08IndividualThe proposal (A)  | Concerning PPE's made of leather no extra costs ... because the limit should be already less than 3ppm. |  | Noted. |  |

**Specific questions 3**

Please provide any information or expert opinion on:

1. the typical age of onset of skin allergies caused by Cr(VI);
2. the number of days absent per year from work of an average person suffering from such skin allergies;
3. the number of symptom days per year of an average person suffering from chromium allergy.

| **Ref** | **Date Country/ Org./ MSCA Comment type** | **Comment** | **Response of the Dossier Submitter** | **RAC Rapporteurs comments** | **SEAC Rapporteurs comments** |
| --- | --- | --- | --- | --- | --- |
| **207** | 2012/06/01 15:44Sweden / Company / Ahlsell AB  The proposal (A) | We do not have information regarding this. Customers who experience problem with our product typically contacts our salesperson who contacts the productmanager who contacts me. |  | Noted. |  |
| **198** | 2012/03/21 09:54IndividualThe proposal (A), Information on hazard and risk (B) | Appearance of these symptoms in both childhood and into adulthood. In fact, from the first contact with leather.Symptoms appear from exposure and last for at least a week. | Agree. Furthermore the symptoms in general get worse for each new exposure. | Noted. |  |