**RESTRICTION EFFICIENCY TASK FORCE**

**SETTING A CLEAR SCOPE**

**A common understanding for a clear scope of Annex XV restriction proposals**

The scope of the Annex XV dossier is defined by the restrictions proposed in conjunction with the risk assessment performed by the dossier submitter, by the boundaries within which the assessment of risks has been performed and the analysis of the degree to which those risks are controlled.

This paper was discussed and agreed by the Restriction Efficiency Task Force (RETF) at its meeting of 8-9 October 2014.

☞ **Good practice tips: scope**

Please refer to Section 2.2 of the 'Fit for purpose dossiers – good practice guide', accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

## Dossier Submitter

### A. Why the DS should define a clear scope?

The boundaries of the risk assessment are determined by the dossier submitter on the basis of several considerations, including policy, and therefore do not need scientific justification; however, they need to be coherent from a scientific perspective because the scope of the Annex XV dossier in turn influences:

- **the harmonisation achieved by the restriction –** RAC will verify whether there is inadequately controlled risk and the Commission will decide whether there is unacceptable risk;
- **the efficiency of the measure –** SEAC will verify the proportionality of the measures and whether the exemptions based on socio-economic implications or lack of alternatives are well justified;
- **the possibility** for RAC and SEAC **to diverge from the restriction suggested** (within the limits of the restrictions proposed and the risk assessment provided) without having to launch a new restriction process;
- **the content of the public consultations**, which is crucial to enable all relevant stakeholders to participate in the process.

## B. What are the critical elements enabling a Dossier Submitter to suggest a clearly defined restriction?

As stated in its document to CARACAL CACS/23/2013 (page 5), the Commission believes that "*In order to develop a draft restriction proposal, the Commission needs to obtain clarity on the following items:*

- *the concern to be addressed ((eco-)toxicological effect of concern, human health/environmental effect; targeted population/environmental compartment);*
- *the objective (expected outcome/benefits of the implementation of the proposed measure);*
- *the proposed measure (scope and enforcement tools, where appropriate), […]".*

Enforcement is also an additional reason for requiring a clear scope.
As far as the proposed measure is concerned, the following elements are therefore critical for defining a clear scope in the proposed restriction and should be assessed in the risk assessment in the Annex XV dossier (also presented diagrammatically in Annex I):

B. 1. Identification of substances (column 1 in Annex XVII)

The Dossier Submitter:

- should preferably provide the EC (and/or CAS) number for each substance for which a restriction is proposed;
- can propose restrictions for an entire group of substances, for instance when the identified risk relates to a common chemical structure or degradation product of the substances (e.g. "X and its compounds");
- should, when a big group is targeted, try to identify it by using the chemical formula (example: CH3)P(OH)X with X equal to F, Cl, O, etc.).

All the substances for which a restriction is proposed should be assessed in the Annex XV dossier. If only some of them are assessed, the Dossier Submitter should justify why the results are valid for the others (justification for grouping).

B.2. Provisions (column 2 in Annex XVII)

### *1) Limit value for content/migration*

Any limit value proposed should, for threshold substances, be based on the DNEL/PNEC or another value if justified. When there is no DNEL/PNEC, the justification for the limit should, for example, make reference to the availability/reliability of testing methods or to the limit of detection of the best performing method, if the intention is to achieve 'zero content/migration'. When both values are considered, justification should be provided to avoid two divergent values.

### *2) Uses*

- The restriction can contain a (non-exhaustive) positive or negative list[1] of specific uses (e.g. in certain articles, type of articles, etc.);
- The restriction can target the function of one specific substance or a group of substances, e.g. flame retardants in articles supplied to the general public;
- The restriction can take the form of a total ban or a ban with exemptions;
- The restriction can be based on the substance being 'not present above a certain limit' in a specified category of articles/mixtures;
- The description of the uses or articles should relate to the target population (in terms of intended protection);
- Where relevant, the feasibility of referring to a production category should be examined (Eurostat PRODCOM Codes or CN (HS) code, or both).

### *3) Exemptions*

- When the Dossier Submitter proposes exemptions, this must be on the basis of the risk assessment, a socio-economic assessment or other justified considerations included in the Annex XV dossier for this purpose;
- All proposed exemptions should be presented in the public consultation with the justification from Annex XV;
- All proposed exemptions must be reviewed and assessed by RAC and SEAC;
- When the exposure scenario is based on the worst case, the Dossier Submitter should clearly define any articles to be included in the restriction and how the extrapolation from this scenario was done for these articles and, if some articles have been excluded, suitable justification should be provided;
- The difficulties that arise when the target of the exposure scenario is a particular sub-population which is then extrapolated to a larger one need to be further discussed.

### *4) Conditions*

- The terms "direct" or "indirect" relating to contact should be avoided unless fully described in the Annex XV dossier;
- The term 'intended for' in terms of use should be avoided (cf DCB example);
- Vague terms relating to the frequency of contact such as short, repetitive, long term, prolonged etc. should be avoided, if at all possible, as there is a need to quantify contact and even if the frequency of contact is quantified in the exposure scenario, this is difficult to enforce; moreover, if we look at the case of Nickel, ECHA took two years to provide a scientific quantification that still needs to be 'translated' into more practical guidance;

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[1] The Annex XV Dossier should also consider this positive or negative list of articles.

- ECHA should provide mini guidance on the general principles of certain methodologies, with a list of examples dealt with so far by RAC (e.g. phthalates and lead for "mouthing time");
- "Normal and reasonably foreseeable conditions of use";
- Misuse: if targeted by the Dossier Submitter, may exceptionally be considered in the Annex XV dossier if it relates to known or reasonably foreseeable exposure and creates concern for human health or the environment to be addressed at Union level, and there is no other appropriate EU legislation to tackle the problem.

**RAC and SEAC**

**A. Question from the conformity check template: "Does the Annex XV dossier specify the scope of the restriction proposed in sufficient detail?"**

In order to reply positively to this question, the Rapporteur should consider that the following elements are included in the Annex XV dossier:

- All the relevant elements discussed in the previous point shall be observed (in particular the relevant elements under 'B. 1. Identification of substances' and 'B.2. Provisions');
- The risk assessment done by the Dossier Submitter concludes that control of the risks identified is either adequate or inadequate (either through RCR>1, or other methods in case of non-threshold substances);
- Exemptions (based on adequate control of risk) – any such exemptions must have been fully assessed in the risk assessment;
- Exemptions (based on socio-economic implications) – any such exemptions must be based on comprehensive socio-economic analysis (e.g. indicating severe consequences for certain sectors or society; or indicating that certain sectors/ products would be disproportionately affected; or indicating that the net costs to industry, DUs, consumer or society clearly outweigh the net benefits to human health and environment).

**B. How to assess whether the scope is clear at the conformity check?**

As stated in its document to CARACAL CACS/23/2013 (page 10), the Commission believes that if the scope of the suggested restriction is not clear to the ECHA Committees, then the dossier cannot be considered to be in conformity with the requirements of Annex XV[2].

The clarity of the suggested restrictions should be read within the general meaning of "the scope' as described at the beginning of this paper. The suggested restriction must be coherent with the risk assessment of the Annex XV dossier; in the case of restrictions targeted at a specific product group, it should be simple for the two Committees to verify that the proposed restriction corresponds to the risk assessment. The situation can be a bit complex for restrictions with a more general scope In this case RAC and SEAC should carefully compare the proposed restriction with the range of products covered by the risk assessment of the Annex XV dossier and check that the scope of the proposed restriction is coherent and fully assessed. If it is not the case, RAC and SEAC should not consider the dossier "in conformity" and may try to clarify this aspect with the Dossier Submitter. This

[2] This issue was not agreed by all members of the RETF.

is crucial before launching the public consultation in order to provide information for the public consultation which is fully in line with the scope.

### C. How to consider additional risk management options within the scope proposed by the Dossier Submitter?

The Dossier Submitter usually proposes the preferred option as the "suggested restriction", RAC and SEAC should evaluate other options mentioned in the Annex XV dossier in a separate or combined way and therefore all these options should be part of the public consultation so that relevant information is collected and affected stakeholders participate on time.

Unless other options are only an adaptation of the suggested restriction or come from the public consultation and are fully documented, options not included in the Annex XV dossier should not be assessed by RAC and SEAC. Such "non-assessed options" may be part of the background document (following the boxes approach), if RAC and SEAC are of the opinion that it could/would constitute the best option. It would be difficult for the Commission to further process these "non-assessed options" that were not part of the public consultation.

Annex II contains some examples of previous restrictions discussing the scope and how the scope evolved during the opinion making.

## Public consultation

### How to define clear the scope before launching the public consultation?

In its document CARACAL CACS/23/2013, the Commission considered the public consultation as a crucial step during the opinion making process and this has also been discussed within the task force.

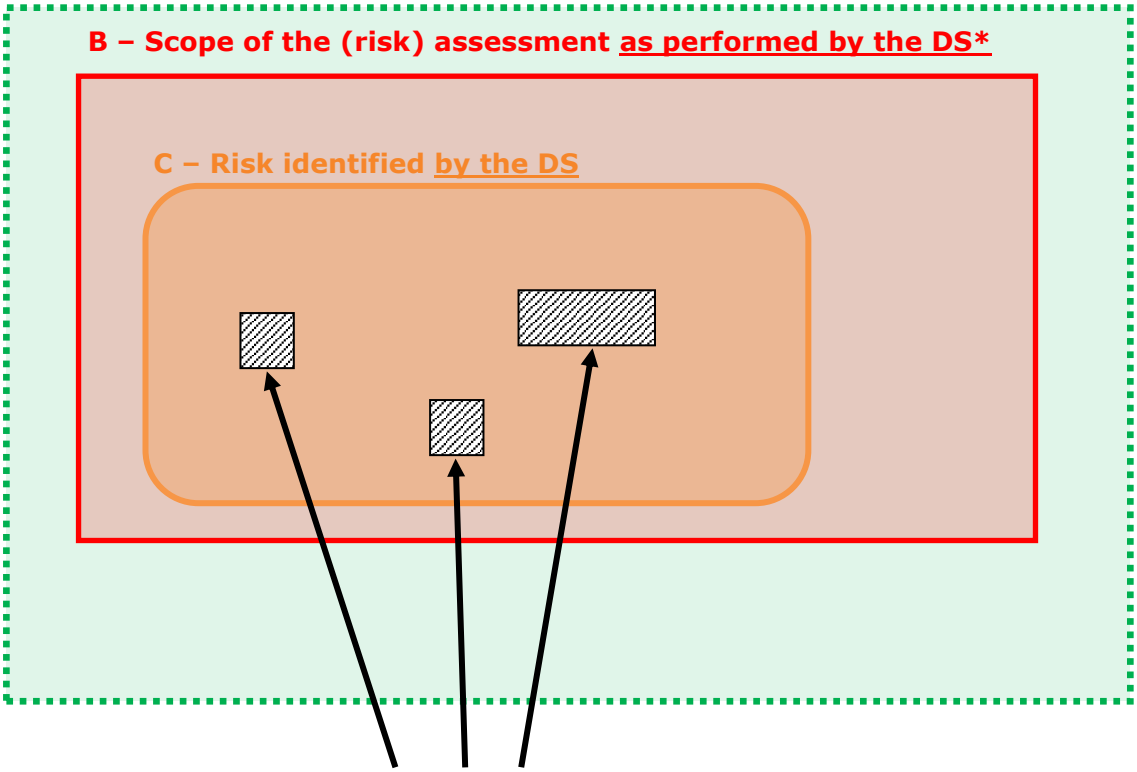
In order to obtain the right contribution from the public consultation, before launching it, there is a need to clarify the scope at the conformity check. We would like to avoid comments which are not targeting the proposed restrictions.

The proposed restriction should be part of the public consultation within the meaning of the clarification in column 1 and 2 of Annex XVII which includes conditions, exemptions, etc.

**Annex I: Scope of the risk assessment and the proposed restriction as submitted by DS and assessed by RAC/SEAC**

**1. As submitted by DS**

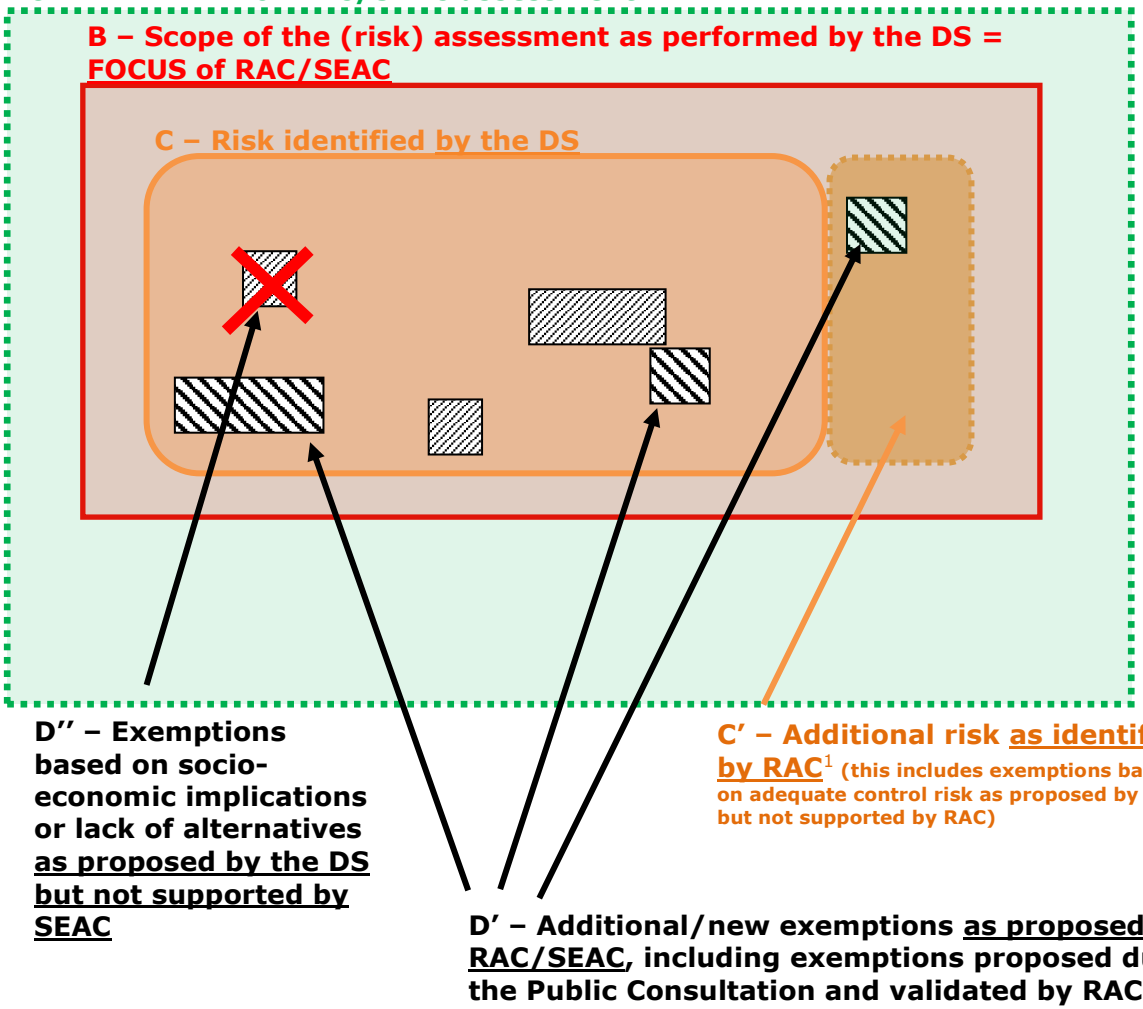
**A – "Full scope" of assessment for the chemical substance (all uses, all exposures)**




**D – Exemptions based on socio-economic implications or lack of alternatives as proposed by the DS**

***Exemptions based on adequate control of the risk are included in B**

**2. As assessed and amended by RAC/SEAC**




[1]: Note that RAC can express different views than the DS in both directions, i.e. either wider or narrower scope, but within the limits of the scope of the risk assessment as performed by the DS.

**Annex II: Examples of scope modifications/changes from previous restrictions**

### *1. DMFu*

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| Dimethylfumarate<br>Dimethyl (E)-butenedioate<br>CAS 624-49-7<br>EC 210-849-0<br>There were no changes to the Column 1 entry from the initial proposed restriction. | 1. Shall not be used in articles in concentration greater than 0.1 mg/kg.<br>2. Articles containing dimethylfumarate in concentration greater than 0.1 mg/kg shall not be placed on the market. | 1. Shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg<br>2. Articles or any parts thereof containing DMFu in concentrations greater than 0.1 mg/kg shall not be placed on the market | No derogations were identified in the Annex XV report.<br>No major changes were made to the proposed restriction during the opinion making process. However, the exact wording was further clarified, e.g. to ensure that the restriction applies to all individual parts of an article. |
| **Final proposal** | | | |
| Dimethylfumarate<br>Dimethyl (E)-butenedioate<br>CAS 624-49-7<br>EC 210-849-0 | Shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg. Articles or any parts thereof containing DMF in concentrations greater than 0.1 mg/kg shall not be placed on the market. | | - |

## 2. Phenylmercury compounds

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| Phenylmercury acetate (CAS 62-38-4, EC 200-532-5)<br><br>Phenylmercury propionate (CAS No 103-27-5, EC No 203-094-3)<br><br>Phenylmercury 2-ethylhexanoate (CAS No 13302-00-6, EC No 236-326-7)<br><br>Phenylmercuric octanoate, (CAS No 13864-38-5, EC No na*)<br><br>Phenylmercury neodecanoate (CAS No 26545-49-3, EC No 247-783-7)<br><br>In addition, RAC considered that if the five substances mentioned above | 1. Shall not be manufactured, placed on the market, or used, as a substance or in mixtures in a concentration above 0.01 % Hg weight by weight (w/w) after [5 years of the entry into force].<br><br>2. Articles, or homogenous parts of articles, containing the substance(s) in a concentration above 0.01 % Hg weight by weight (w/w) shall not be placed on the market [5 years of the entry into force]. | <u>RAC</u><br><br>1. Shall not be manufactured, placed on the market, or used, as a substance or in mixtures after 3 years of the entry into force*.<br><br>2. Articles, or parts of articles, containing the substance(s) shall not be placed on the market after 3 years of the entry into force*.<br><br>*The provisions referred to in paragraphs 1 and 2 above concerning mixtures and articles are not applicable if the concentration in a mixture or in articles or any parts thereof does not exceed 0.01 % weight by weight (w/w) mercury.<br><br><u>SEAC</u><br><br>1. Shall not be manufactured, placed on the market, or used, as a substance or in mixtures after 5 years of the entry into force. | The precise wording of the restriction was changed during the opinion forming process to take into account the comments in the first and second advice from the Forum. This did not affect the scope, however.<br><br>In addition, in the RAC opinion, the implementation time was changed from 5 years to 3 years. The use of phenylmercury substances was, as stated in the Annex XV restriction report, assumed to decline every year. RAC therefore was of the opinion that the sooner the restriction enters into force, the higher the impact of the restriction on reducing the global mercury pool. RAC considered, however, that a shorter phase out than 3 years might lead to a switch to other mercury containing alternatives.<br><br>All the elements were assessed in the Annex XV report and in the two RMOs presented therein. |

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| were to be replaced by other organomercury compounds this restriction could become ineffective. Therefore, in addition to the conditions mentioned above, RAC recommended considering necessary measures for verifying and controlling that other organomercury compounds (their general formula was also given) are not used as alternative to the restricted substances. | | 2. Articles, or parts of articles, containing the substance(s) shall not be placed on the market after 5 years of the entry into force.<br><br>The provisions referred to in paragraphs 1 and 2 above concerning mixtures and articles are not applicable if the concentration in a mixture or in articles or any parts thereof does not exceed 0.01 % weight by weight (w/w) mercury. | |
| **Final proposal** | | | |

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| Phenylmercury acetate (CAS 62-38-4, EC 200-532-5)<br>Phenylmercury propionate (CAS No 103-27-5, EC No 203-094-3)<br>Phenylmercury 2-ethylhexanoate (CAS No 13302-00-6, EC No 236-326-7)<br>Phenylmercury octanoate, (CAS No 13864-38-5, EC No na*)<br>Phenylmercury neodecanoate (CAS No 26545-49-3, EC No 247-783-7) | 1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0.01 % by weight.<br>Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01 % by weight.’ | | |

### 3. 1,4-Dichlorobenzene (p-dichlorobenzene)

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| 1,4-dichlorobenzene<br>EC No. 203-400-5,<br>CAS No. 106-46-7<br>The text in column 1 remained constant through the opinion making process from the original proposal | Shall not be placed on the market or used in:<br>1. Toilet blocks<br>2. Air fresheners to be used in toilets or other domestic or public indoor areas, or offices.<br>The proposed restriction will apply 12 months after the amendment of the REACH Annex XVII comes into force. | Proposal by RAC<br>1. Shall not be placed on the market, or used, as a substance or constituent of mixtures in a concentration equal to or greater than 1 % by weight where the substance or the mixture is intended to be used as an air freshener or to de-odourise toilets, homes, offices and other indoor public areas.<br>2. Paragraph 1 shall apply from {date corresponding to 12 months after the Commission Regulation amending Annex XVII to REACH Regulation enters into force}.<br>Proposal by SEAC<br>1. Shall not be placed on the market, or used, as a substance or constituent of mixtures in a concentration equal to or greater than 1 % by weight where the | The Forum working group on enforceability of restrictions suggested to replace the phrase "to de-odourise" with "deodoriser" to clarify that the restriction applies to air fresheners (or deodorisers) with a specific use (i.e. in toilets, homes, offices or other indoor public areas) and not e.g. to all air fresheners irrespective of their use, and the word "and" was replaced by "or" (in the phrase "or" other indoor public areas) to clarify that the phrase "indoor public areas" is not meant to include "toilets, homes and offices" but it applies in addition to those. |

| Changes in column 1 | Changes in column 2 | | |
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| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| | | substance or the mixture is intended to be used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas.<br>2. Paragraph 1 shall apply from {***date*** corresponding to 12 months after the Commission Regulation amending Annex XVII to REACH Regulation enters into force}.<br>The proposed restriction should apply 12 months after the amendment of the REACH Annex XVII comes into force to allow distributors and suppliers to sell products in stock. | |
| **Final proposal** | | | |
| 1,4-dichlorobenzene<br>EC No. 203-400-5,<br>CAS No. 106-46-7 | Shall not be placed on the market or used, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1 % by weight, where the substance or the mixture is placed on the market for use or used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas.' | | . |

## 4. Chromium VI in leather articles

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| Chromium (VI) compounds<br>IUPAC name not applicable<br>EC number not applicable<br>CAS number not applicable<br>There were no changes to Column 1. | Articles or any parts thereof containing leather, coming into direct and prolonged 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. | RAC<br>• Leather articles, or leather parts of articles, coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) in concentrations equal to or higher than 3 mg/kg (0,0003%) chromium VI of the total dry weight of the leather.<br>SEAC<br>In addition:<br>• By way of derogation, the restriction shall not apply to leather articles placed on the market for the first time before [12 months after the amendment of the REACH Annex XVII enters into force]<br>• The proposed restriction will apply 12 months after the amendment of the REACH Annex XVII enters into force. | The wording of the restriction proposal was modified during the opinion forming. RAC extended the scope of the restriction, in agreement with SEAC, to cover all leather articles that come into contact with the skin. In the original proposal, only articles "in direct and prolonged contact" with the skin were covered. This change stemmed from (a) considerations on enforceability of the restriction, based on the Forum advice and (b) ECHA's on-going work on defining the "prolonged contact with the skin", which although it focuses on nickel, also evaluated corresponding scientific evidence relevant for chromium (VI). |

| Changes in column 1 | Changes in column 2 | | |
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| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| **Final proposal** | | | |
| Chromium (VI) compounds<br>IUPAC name not applicable<br>EC number not applicable<br>CAS number not applicable | 5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0.0003 % by weight) of the total dry weight of the leather.<br>6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0.0003 % by weight) of the total dry weight of that leather part.<br>Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015. | | - |

## 5. Lead and its compounds

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| Lead<br>CAS No 7439-92-1<br>EC No 231-100-4<br>and its compounds<br>There were no changes to column 1 | 1. Shall not be used in jewellery articles if the lead migration rate from such articles is greater than 0.09 µg/cm²/hr.<br>2. Articles which are the subject of paragraph 1 | RAC<br>Shall not be used or placed on the market in<br>i. Metallic and non-metallic parts of jewellery articles if the lead concentration is equal to or greater than | The restriction proposal in the opinions of RAC and SEAC were different compared to the original proposal by France. The proposals of RAC and SEAC also differ from each other. The original proposal proposed a migration limit and to restrict placing on the market such jewellery articles which do not conform to that limit value. The proposed migration limit value was associated with a DMEL, which |

| Changes in column 1 | Changes in column 2 | | |
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| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| | shall not be placed on the market unless they conform to the requirements set out in that paragraph.<br>3. The measure of the migration rate specified in paragraph 1 should be performed under the acidic conditions, the temperature and the duration specified in EN 71-3 standard. | 0.05% by weight of the part;<br>. The paragraph above does not apply when it can be demonstrated that the rate of lead release from the jewellery article or any part thereof does not exceed 0.05 µg/cm2/hr (0.05 µg/g per hr).<br>SEAC<br>1. Shall not be used or placed on the market jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of any part of the jewellery article.<br>2. By way of derogation, paragraph 1 shall not apply to<br>i) "Full lead Crystal" and "Lead Crystal" as defined in Annex I in Council Directive 69/493/EEC). | was based on analytical measurement error. RAC analysed the possibility to use a content limit value as a basis for limiting lead in and considered that due to lack of validated methods for measuring migration which mimics mouthing, a restriction based on content is more practicable for implementation and enforcement. Nevertheless, and independently of the lead content, RAC considered that the restriction should not apply when it can be demonstrated that the relevant lead migration rate is not exceeded. |

| Changes in column 1 | Changes in column 2 | | |
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| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| | | ii) Precious and semiprecious stones (CN code8 7103) unless they have been treated with lead or its compounds or mixtures containing these substances.<br><br>3. By way of derogation, paragraphs 1 shall not apply to jewellery articles placed on the market before [[12-18] months after the entry into force] and jewellery more than 50 years old on [the date specified in the restriction on cadmium]. | |
| **Final proposal** | | | |
| Lead<br>CAS No 7439-92-1<br>EC No 231-100-4<br>and its compounds | 1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight.<br><br>2. For the purposes of paragraph 1:<br><br>a. (i) "jewellery articles" shall include jewellery and imitation jewellery articles and hair accessories, | | |

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| | including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks;<br>b. (ii) "any individual part" shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles.<br>3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making.<br>4. By way of derogation, paragraph 1 shall not apply to:<br>a. crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*);<br>b. (b) internal components of watch timepieces inaccessible to consumers;<br>c. (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances;<br>d. (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.<br>5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. | | |

| Changes in column 1 | Changes in column 2 | | |
|---|---|---|---|
| | Original scope | Changes during Committee | |
| | | Entry | Comments |
| | 6. By 9 October 2017, the Commission shall re-evaluate this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly. | | |