



**EUROPEAN COMMISSION**

Directorate-General for Environment  
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**21st Meeting of Competent Authorities for REACH and CLP (CARACAL)**

**29 June – 1 July 2016**

**Open session**

**Room: 1D, Centre Albert Borschette**

**Rue Froissart 36**

**1040 Brussels, Belgium**

**Concerns:** Feedback on the public consultation on the potential restriction on CMRs 1a and 1b in textiles and next steps

**Agenda Point:** 6.1

**Action Requested:** Written comments on this document should be sent by 1 August 2016 to [valentina.bertato@ec.europa.eu](mailto:valentina.bertato@ec.europa.eu) and [karin.kilian@ec.europa.eu](mailto:karin.kilian@ec.europa.eu).

**The CARACAL are invited to take note of this document for discussion.**

**Background**

Article 68(2) of REACH provides a simplified procedure, which the Commission may use to restrict substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A and 1B on their own, in mixtures or in articles that could be used by consumers.

As discussed extensively at earlier CARACAL meetings, the Commission intends to use Art. 68(2) to target specific categories of consumer articles, aiming to restrict CMR substances (categories 1A and 1B) in them<sup>1</sup>. Textile articles and clothing were selected as a first test-case

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<sup>1</sup> [CA/102/2014 "Use of Article 68\(2\) for CMRs in articles"](#)

because of the high likelihood of prolonged – or multiple short-term – exposure of consumers to CMR substances being potentially present in those articles. The list of CMR substances (individual substances or groups) to be covered by this possible restriction would be added to Annex XVII to REACH and could be regularly updated following the same procedure, as appropriate.

The Commission, in collaboration with ECHA and Member States Competent Authorities, identified a preliminary list of CMR substances categories 1A and 1B potentially present in textile articles and clothing. In order to target relevant chemicals and articles and to consider the proportionality and enforceability of a possible restriction in this area, the Commission launched a public consultation, which lasted from 22 October 2015 to 22 March 2016. The main objectives of the public consultation were to collect information on:

- the presence or likelihood of presence of the identified CMR substances in relevant consumer articles and, in so far as is possible, also gather information on their concentration, function and on the availability of alternatives;
- the potential socio-economic impacts and the enforceability of the possible restriction.

### **Brief summary of the outcome of the public consultation**

The Commission received 120 contributions:

- 18 from individual citizens,
- 10 from Public Authorities
- 34 from companies,
- 40 from Industry or Trade Associations,
- 11 from Non-Governmental Organisations,
- 1 from a Trade Union,
- 1 from an Academic/Research Institute,
- 5 from other stakeholders.

Additionally, the Commission received 5 position papers from stakeholders' organisations.

While many of the associations' contributions presented general concerns about the application of Art. 68(2) to a wide category of articles such as textiles and clothing, some stakeholders submitted specific comments on the scope and the list of substances, including the function of the substances and analytical methods.

A summary of the main comments received and the Commission's answers are in Annex to this paper.

### **Proposed way forward**

As announced at the launch of the public consultation, the Commission intends to use this case as a test for the applicability of Art. 68(2) to specific CMRs category 1A and 1B found in a category of articles. Considering the many comments received in the public consultation,

the difficulty to define the wide and heterogeneous range of articles to be covered and the many CMRs that could potentially be present in this group of articles, the Commission considers that a stepwise approach is needed. The initial steps would be:

- limit the scope to articles that may come into direct contact with the skin;
- include the substances from the list of the CMRs subject to the public consultation that are most relevant for such articles.

A wider scope and inclusion of additional CMRs will be considered in a second step.

### Scope

To clarify the scope of the restriction, the Commission intends in a first stage to cover the articles where the exposure of consumers is potentially the most relevant: clothing, footwear and interior textiles articles (such as bed-linen) that may come into direct and prolonged contact with the skin. Clothing accessories (buttons, zippers, etc.), interior textiles with no or infrequent contact with skin and footwear made of real leather are going to be excluded.

By focusing on the function of the articles and not on the composition, also clothes with very low or no textile fibre content (i.e. raincoats, artificial leather) would be included.

Articles to be considered in a second step might include floor coverings, carpets, upholstery, clothing accessories and leather articles.

The text of the proposed restriction will include:

- identification of the substances;
- specific limit values based on the content;
- specification of the kind of articles that are covered;
- specific derogations;
- transitional period for the application of the restriction.

### List of substances

The Commission received around 20 contributions on the proposed list of substances, providing specific information on the presence of the substances in textiles and clothing, on the function, on the concentration and on the limits. On the basis of these comments, the Commission is going to establish 4 lists of CMR, Categories 1a and 1b substances:

- substances that are potentially present in clothing and are relevant for the restriction;
- substances that are less likely to be present in clothing or less likely to be released, to be further assessed in a second step;
- substances that are not present in clothing;
- substances that were not present in the initial list, suggested during the public consultation, to be further assessed in a second step.

The following substances will not be considered in the restriction in a first step:

- substances only present in accessories;
- substances bound to the matrix and not released;
- petroleum and coal stream derivatives;
- substances that might be present only as impurities at very low levels (i.e. below detection limit).

The Commission will be mindful of the cases of specific categories of substances where restrictions under REACH are already in place or planned (i.e. certain azodyes and phthalates) in order to avoid inconsistencies and duplications.

Concentration limits will be specified in the restriction. There will be two types of limit values:

- values that are technologically and analytically feasible (detection limits) for those substances that can be eliminated from the articles;
- values based on hazard (e.g. CLP specific limit values, DNELs) and/or lowest achievable concentration for those substances that cannot be eliminated from the articles.

### **Consultation of experts and stakeholders**

Before finalising the restriction, the Commission intends to consult:

- the Forum, on the scope and wording of the restriction, on the availability of testing methods and on the enforceability of the conditions;
- ECHA, on the specific concentration limits of some substances;
- a group of experts, including those who provided relevant comments in the public consultation, on the scope and on the limit values, by organising a technical workshop.

The Commission will launch a second, shorter public consultation on the draft amendment of Annex XVII before the proposal is discussed in the REACH Committee, as foreseen in the Better Regulation Guidelines.

## **Public consultation on a possible restriction on CMRs in textiles articles and clothing for consumer use under Article 68(2) of REACH: summary of comments and answers**

COM would like to thank all the stakeholders who submitted comments in the public consultation. The general comments on the possible restriction and on the scope are summarised and addressed in this document. The specific comments on the list of substances proposed, the function, the relevance for the restriction, the analytical methods, the concentration limits and potential socio-economic impacts will be used to select the most relevant substances for the restriction proposal.

### **1. General comments on the restriction and on the application of Art. 68(2) procedure**

*1.1. Many comments expressed concern about the complexity of the scope and the number of substances included.*

COM acknowledges that the scope as presented in the public consultation was wide and that many substances were included. The main objective of the public consultation was to collect all the elements to refine the scope and to select the most relevant substances for the restriction. As explained above, COM is going to use the comments received to clarify the scope of the restriction and to select the substances that are more relevant for the restriction in view of their expected presence in clothing and likely consumer exposure.

*1.2. The public consultation length was not sufficient, and a second public consultation is needed. It was suggested that an industry expert group could be created to provide advice.*

COM believes that the length of the public consultation (5 months) was appropriate for its objectives. Once COM has completed the analysis of the detailed comments received, stakeholders, as well as ECHA and the Forum, will be consulted on a revised (narrower) scope and on a new (more limited) list of substances. Furthermore, as foreseen in the Better Regulation Guidelines, a public consultation on the draft amendment of Annex XVII will be launched before the discussion of the draft restriction in the REACH Committee.

*1.3. Art. 68(2) procedure is not appropriate for such a complex case. Instead, the full restriction procedure should be envisaged, including a risk assessment and a socio-economic assessment.*

As explained in the paper on the application of Art. 68(2) (CA/102/2014) that was extensively discussed in CARACAL, for CMRs, Categories 1a and 1b in articles that can be used by consumers, REACH provides COM with the possibility to apply a simplified procedure. COM believes that such a procedure is appropriate for the case of CMRs, Categories 1a and 1b in textile articles and clothing because of the potential for consumer exposure and the high number of different substances potentially present, which makes the full restriction procedure lengthy and cumbersome to apply. Even though Art. 68(2) does not require any of the elements of the normal restriction procedure, COM decided to include some of them, such as public consultations and consultation of experts (both in ECHA and among stakeholders) to ensure that the restriction is implementable and enforceable.

*1.4. Some of the substances included in the public consultation are already restricted, will be soon restricted or are undergoing the RMOA process. There might be overlaps and inconsistencies with the Toy Safety Directive.*

COM is fully aware that some of the substances are already subject to restrictions or of the restriction proposals for some others. COM is also closely following the RMOA process. COM is committed to avoid double regulation for the same substance and use. The interface with other legislations (including the Toy Safety Directive) will also be carefully considered.

*1.5. For most of the substances, there are no recognised test methods available.*

Some contributors sent information on available test methods for the substances considered in the public consultation. Forum will be consulted, also to investigate the possibility to prove compliance with methods different from routine testing.

*1.6. This restriction is a good way to harmonise the requirements of different standards and legislations related to chemical content in textiles and clothing.*

COM agrees with the harmonisation potential of this restriction.

## **2. General comments on the list of substances and the limit values**

*2.1. The list of substances was too long to be able to send detailed comments, especially concerning the socio-economic aspects. Only substances that are likely to be present in textiles and clothing should be part of the restriction*

Please see answer to comment 1.1. Stakeholders will have additional possibilities to provide specific contributions on a shorter list of substances.

*2.2. Some substances that could be present in textile and clothing articles were not in the list.*

Additional substances suggested during the public consultation will be considered for future possible amendments of the restriction after its adoption (together with newly classified CMRs).

*2.3. It is not appropriate to use a generic limit of 50 mg/kg for many substances with different hazard profile. The limits used in the Oeko-Tex standard could be used. The limits should be agreed by specialists.*

COM agrees with the general principle to adopt specific limit values for different substances or groups of substances. The limit of 50 mg/kg was an initial proposal for the purpose of the public consultation and the objective was to collect information on possible specific limits. The intention is to have specific limits in the restriction proposal and to consult experts (both from stakeholders and from authorities) to define them. The limits of the Oeko-Tex standard, as well as other voluntary standards, will be considered when appropriate.

## **3. Scope of the restriction: is it clear what articles are covered by the restriction? Is the range of articles covered appropriate?**

*3.1. Contradictory comments were received on the definition of the scope on the basis of the material used and in particular the reference to textile articles under EU Regulation 1007/2001. Some stakeholders were supporting it, because it is a well-recognised definition, also used in the*

*Ecolabel criteria for textile articles. Some others were against it, because of articles potentially excluded (for example, raincoats made exclusively of plastic, artificial leather, etc).*

COM proposal is to simplify the scope of the possible restriction, by referring to clothing and not referring to textile fibres in the definition of the scope. This would allow to cover all materials, and to focus on articles with the highest potential for consumer exposure.

*3.2. Some comments were pointing to the need to cover the whole textile article and the individual parts of the article, mentioning the recent judgment of the European Court of Justice on the definition of article in the context of REACH. Some other comments suggested to cover only textile parts and exclude parts made of other materials (i.e. zips and buttons).*

COM proposal is to focus on clothing and exclude the accessories such as zips and buttons. The wording of the restriction will be redrafted and consulted with the Forum to ensure that it is clear what is covered.

*3.3. Some stakeholders considered that the inclusion of raw, unfinished and semi-finished goods could have unintended consequences, such as applying the restriction also to textiles meant for workers and to cases where the CMR concentration is above the limit in the unfinished article, but below in the finished articles to which the consumer is exposed.*

As explained above, COM proposal is to cover finished clothing only.

*3.4. Some exemptions were proposed, including for*

- *Recycled and disposable textiles;*
- *Articles that have a protective/safety function for workers;*
- *Footwear;*
- *Textile articles where no contact with the skin is expected (i.e. curtains)*
- *Toys.*

COM intends to cover clothing for consumer use and home textiles with comparable exposure potential (i.e. bed linen). Clothing intended to be used by workers are not going to be part of the restriction because Art. 68(2) can only be used for consumer articles. An exemption for recycled clothing will be considered. COM intends to cover footwear, with the exception of natural leather. COM does not intend to exclude toys, in order to cover clothing that is also defined as toy (such as disguise costumes).

*3.5. Some stakeholders proposed to add fur, hides and natural leather*

COM did not include such materials because their manufacturing process is substantially different from textile-based articles and, therefore, relevant substances might not have been included in the list prepared for the public consultation.

*3.6. Some stakeholders proposed to include other categories of consumer articles (such as childcare articles).*

Since this is a test case for the application of Art. 68(2) to a category of articles, COM intends to take a stepwise approach. Childcare articles could be considered for a future restriction, as already indicated in the paper on the implementation of Art. 68(2) (CA/102/2014).