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Circular Economy and Green Growth
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Rue Froissart 36
1040 Brussels, Belgium**

Concerns: Reflection on the experience on the practical application of Art. 68(2) and possible future cases

Agenda Point: 8.1

Action Requested: For information and discussion.

Written comments on this document should be sent by 15 December 2017 to Valentina.BERTATO@ec.europa.eu, Ana-Maria.BLASS-RICO@ec.europa.eu, Karin.KILIAN@ec.europa.eu, GROW-CARACAL@ec.europa.eu, ENV-CARACAL@ec.europa.eu

In the paper CA 102/2014, the Commission presented the intended approach for the practical implementation of Art. 68(2) of REACH.

The Commission then applied this approach to the article category of textiles and clothing. The papers CA 46/2016 and CA 04/2017 presented the developments of the case and the approach followed in the preparation of the draft restriction proposal.

Now that this first case is in its final stages, the Commission believes it is the right time to review the experience with the first application of Art. 68(2) to a consumer article category, and to discuss the future approach and possible new cases.

Process followed to develop the restriction proposal

The case of the CMRs 1A and 1B in textiles and clothing falls under the approach of the restriction on a category of articles foreseen in the paper. This category of consumer articles was chosen as the use pattern of clothing and certain other textiles leads to direct contact with the human body and thus (typically dermal) exposure of consumers to substances contained in such articles has to be assumed.

The process used was aligned with the approach described in document CA/102/2014 and included the following steps:

- drawing up of a broad list of CMR Cat. 1A/1B substances that are potentially present in clothing, footwear and textiles, based on information in REACH dossiers and MS reports
- a public consultation to obtain more information on these substances in relation to their use, presence and function in textiles and the impact of a possible restriction
- a technical workshop with experts from MS, Industry, testing labs, certification schemes and NGOs to provide detailed input of a refined list of substances, feasible concentration limits and test methods
- a consultation of the ECHA Forum on the enforceability of the planned restriction

Overall, the Commission considers the experience with the chosen approach as positive. The continued communication with and involvement of stakeholders on technical matters related to the proposal on the one hand provided relevant and necessary information, and on the other hand ensured transparency of the process, thereby increasing acceptance by the concerned stakeholders.

The initial collection of information on possibly relevant substances for a certain article category can pose a considerable challenge. This is mainly due to the known limitations of information on uses in articles in REACH registration dossiers and the uncertainty about substances without EU uses that may be present in imported articles. In this case the work was helped by extensive work done in some MS. Identification of relevant substances was also supported by the significant level of self-regulation of the concerned industry, which provided information through e.g. Restricted Substance Lists or criteria used by certification schemes.

Concerning the possible need of substance-specific approach (as foreseen in document CA/102/2014), only one such case was identified among the substances included in the planned restriction. For formaldehyde, textile manufacturers pointed out that for certain applications the proposed concentration limits would not be sufficient to achieve the desired functionality. The Commission concluded that the existing information was not sufficient to decide on the same limit for these applications as for the other uses of formaldehyde in textiles and clothing. The feasibility of a stricter limit for these uses will be considered in the future Annex XV dossier for restriction covering formaldehyde in consumer articles.

Because of the continuous involvement of stakeholders in the process and the publication of all relevant information on the case¹, the Commission felt that there was no need to in addition publish a report as foreseen in the paper.

This first case showed that the main elements set out in CA/102/2014 for an Art. 68(2) restriction on a category of articles could be implemented in practice and ensured appropriate information collection and stakeholder involvement.

¹ http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299
http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9088

Therefore, for future cases, the Commission considers it appropriate to continue following the main elements of this procedure, including:

- Setting of an initial list of CMRs potentially present in the category of articles subject to the restriction. Possible information sources are ECHA database, other available databases and reports, industry voluntary initiatives.
- Conducting a public consultation on the scope of the restriction (i.e. articles to be covered) and on the list of substances including the availability of testing methods, with the objective to refine the restriction proposal.
- If needed, following up the public consultation with a technical workshop including stakeholders who provided relevant contributions in the public consultation, Member States and Forum representatives.
- Consultation of the Forum.
- Final feedback from stakeholders on the draft restriction proposal via the Feedback Mechanism foreseen by the Better Regulation Initiative² and the WTO TBT notification process.

Possible future cases for the application of Art. 68(2) to consumer articles

The Commission considers that, to start an Art. 68(2) restriction for CMRs 1A and 1B in consumer articles, the following conditions should be met:

- there is a concern for exposure of the general public (especially for vulnerable population, such as children), supported by scientific reports or equivalent information from the authorities or stakeholders.
- the concern is related to categories of articles to which consumers have frequent contact and that are not regulated by a specific legislation.

The Commission has identified the following potential future cases:

- Childcare products
While toys are covered by the Toys Safety Directive, childcare products are not specifically regulated. This is a very wide category, covering diverse products including sleeping/transportation articles, relaxation tools, feeding and hygiene articles. These products are also composed of different materials, making the identification of relevant CMRs 1A and 1B rather complex. A possible approach to this complex category could be to cover the different groups one by one and/or to select specific materials.
- Absorbent hygiene products (Feminine hygiene, children nappies, adult incontinence products)
Concerns about the safety of these products have been raised recently due to the claimed presence of hazardous chemicals. There is high potential for exposure because of the prolonged and frequent contact with skin and mucosae and they are not covered by specific legislation.
- Leather products: to complement the restriction on textiles
- Furniture
This category is only partially covered by the future restriction in textiles and clothing. Voluntary initiatives are on-going to limit the presence of hazardous flame retardants.
- Sport equipment

² http://ec.europa.eu/info/law/better-regulation/share-your-views_en

As in the case of childcare products, this category is very wide and would probably need to be refined on the basis of the typology of products and/or the materials.

Feedback from the members of CARACAL

The Commission would like to ask to CARACAL members to answer to the following questions:

1. Do you agree with the Commission assessment on process for the Art. 68(2) restriction on CMRs in textiles and clothing? Do you have suggestions to improve the process for future cases?
2. Among the product categories proposed by the Commission for a next case, which ones do you consider the most relevant/suitable for an Art. 68(2) restriction? Do you have additional suggestions for categories to be considered? Is there relevant information on the presence of CMR substances in such articles you can provide (e.g. analyses, reports, assessments etc.)?