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Concerns: **Use of article 68(2) for CMRs in articles**

Agenda Point: **Info 11**

Action Requested: **For information.**

N.B.: This document is a revision of CACS/13/2014.

Criteria and procedure for the implementation of Article 68(2) of REACH: restriction of CMRs 1A and 1B in consumer articles

1. Introduction

Why are criteria needed?

Article 68(2) of REACH provides a simplified procedure, which the Commission may use in relation to 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. The procedure differs from the standard restriction procedure of Articles 69 to 73, which requires the preparation of an Annex XV Dossier to initiate the restriction process, public consultation, opinions by RAC and SEAC and the consultation of Forum.

As already stated in the CARACAL paper CA/52/2011, it is important to recall that the right of initiative under Article 68(2) remains with the Commission, including the discretion whether to prevent the exposure of consumers to CMR substances exclusively under Article 68(2). If considered appropriate, the Commission could also act under Article 69(1) and ask ECHA to prepare a dossier that would be subject to the standard restriction procedure outlined in Articles 69 to 73.

For substances and **mixtures**, REACH (recital (75) in particular) suggests continuing with the long-established practice under Directive 76/769/EEC whereby each time new substances are classified as CMR Cat. 1A or 1B, the Commission proposes and, having obtained the opinion of the REACH Committee, adopts an amendment to entries 28-30 of Annex XVII to REACH to prohibit the sale and use of these newly classified substances and mixtures containing them for supply to the general public.

This is justified by the potential (even if in some cases theoretical) exposure that could result from a CMR substance or mixture supplied or made available to consumers and possible combined exposure from different sources.

For **articles** the situation is different in the sense that there was no equivalent practice of a semi-automatic restriction procedure under Directive 76/769/EEC. The main difference between articles and substances and mixtures is that there might be cases where there is no or very limited possibility of exposure of consumers to a CMR substance contained in an article and other cases for which exposure is comparable to that for mixtures (e.g., articles fulfilling the condition in Article 7(1)(b)). Despite some REACH provisions related to substances in articles (Articles 7 and 33), it is in general difficult to obtain information about the presence in and/or migration from articles of substances. For these reasons, the Commission considers that the (sometimes theoretical) exposure of consumers to substances or mixtures cannot in all cases be compared with potential exposure to CMR substances from articles. The approach for CMR substances in articles should therefore not be implemented in all cases in the same way as for substances on their own or in mixtures under entries 28-30 of Annex XVII. This means that a general prohibition of sale to or use by consumers of all articles containing classified CMR substances cannot be routinely applied in all cases and without prior considerations.

Article 68(2) does not provide details on how to implement the simplified restriction procedure in the specific case of articles. The first case of a restriction[1] adopted following this route showed that there is a need to develop criteria and a methodology to address:

- the cases when this procedure could be applied, considering the reduced scientific scrutiny and lack of socio-economic impact assessment explicitly required;
- the type of information and the level of detail needed in the documentation supporting the restriction proposal;
- the assessment to ensure that the draft restriction is scientifically sound and proportionate, including consultation of stakeholders and, where necessary, consultation of a scientific expert body .

The criteria and the procedure presented in this paper have different purposes:

- to help Member States thinking of asking the Commission to propose a restriction following Article 68(2) to decide whether this is the appropriate route;
- to guide the Commission when considering its own proposals for a restriction following the Article 68(2) route or when responding to such suggestions from the Member States ;
- to help the Commission define the scope and the conditions of the possible restriction.

Experience with the adoption of the first restriction for consumer articles via the Article 68(2) route showed that there are some important elements, including policy ones, to be considered:

- the difficulties encountered discussing a technically complex file (such as the PAH case) in the REACH Committee;
- the economic considerations linked to the proposed restriction;
- possible reactions from stakeholders, including WTO members.

In addition to consulting CARACAL, other relevant Commission services (e.g., SANCO, TRADE) will be consulted.

After having gained some experience with the first practical cases, the Commission will evaluate whether there is a need to revise the criteria and procedure presented in this paper.

The scoping study for the application of Article 68(2)

DG Enterprise and Industry commissioned ICF International and AMEC to undertake a study on "*The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles - Scoping study for the application of Article 68(2) of REACH to CMR substances requiring*

[1] Commission Regulation N. 1272/2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons

priority action" between December 2012 and November 2013. The objectives of the study were threefold:

- To collect and analyse information on CMR substances potentially present in consumer articles, looking at uses, market information, market players, and possible alternatives;
- To provide a scoping assessment of the socio-economic impacts of a potential restriction for a short list of 13 CMR substances in consumer articles; and
- Based on experience gathered from these activities, to provide advice on the factors to consider in deciding whether to use the Article 68(2) simplified restrictions procedure for CMR substances in consumer articles.

The CMR substances considered in the study were chosen on the basis of:

- possible use/presence in consumer articles, on the basis of information in the registration dossiers;
- CMR substances already included in the candidate list and known to be present in articles;
- different scales of potential socio-economic relevance.

The selected substances were used as case studies to help in elaborating a set of potential criteria. The information collected could also be a useful starting point for possible future regulatory proposals for some of the substances considered in the study. The two stakeholder consultations conducted by the consultant showed how difficult it is to establish with certainty whether a substance is still used in articles inside or outside the EU, or, where use/production of articles containing the substance in the EU had potentially ceased, or whether the substance is present in imported articles.

The study is publicly available on the DG Enterprise and Industry website[2] and the results were presented at the CARACAL meeting in November 2013.

The Commission has used the conclusion of the study as thought starter for this paper.

2. Fundamental Approaches

Article 68(2) could be applied by the Commission in different ways:

- Targeting individual CMR substance or groups of substances with a similar structure/mode of action, present in potentially different categories of consumer articles.
- Targeting specific categories of consumer articles and aiming at restricting the potential presence or migration of CMR substances in them.
- Targeting individual CMR substance known to be not yet used in consumer articles, with a view to avoiding the development of new uses.

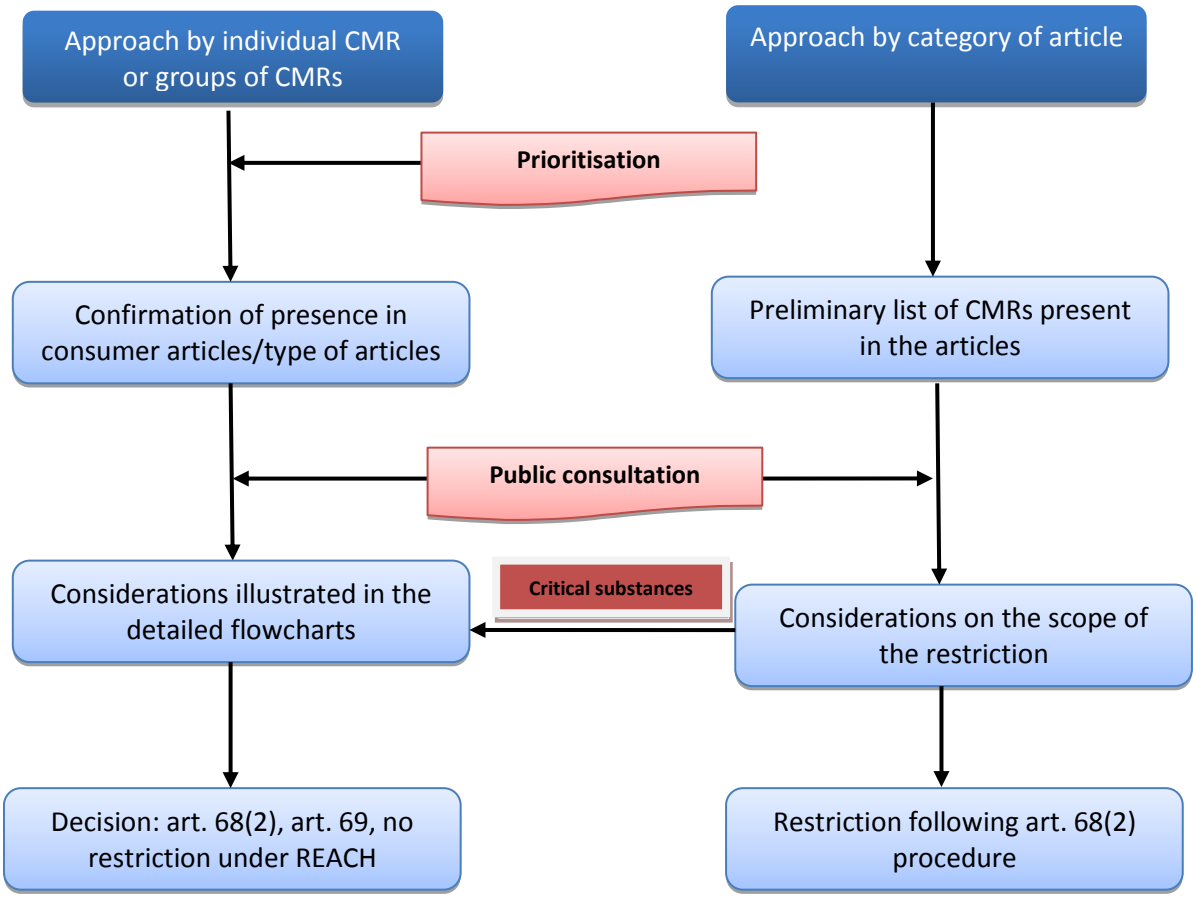
[2] http://ec.europa.eu/enterprise/sectors/chemicals/files/docs_studies/final-report-cmr-1a-1b-in-art_en.pdf

For the third scenario, the Commission believes that it is currently not possible to use Article 68(2) because of the very low level of knowledge on the presence/absence of CMRs in consumer articles.

The Commission proposes to apply Article 68(2) in the two first cases, with different information requirements, combining both scenarios where appropriate. The objective is to achieve a balance between simplifying the procedure compared to the standard one and ensuring that the proposed restriction is proportionate and enforceable.

For both approaches, restriction of consumer-related CMR substances in articles can be divided into three phases:

- Phase 1: COM to consider possible restrictions via Article 68(2) of a CMR substance or group of substances present in all consumer articles or of CMR substances in specific categories of consumer articles,
- Phase 2: Preparation of the restriction proposal, including public consultation and underlining discussions, and
- Phase 3: Discussion of and decision on the proposal according to the Comitology procedure.



Approach by individual CMR substance

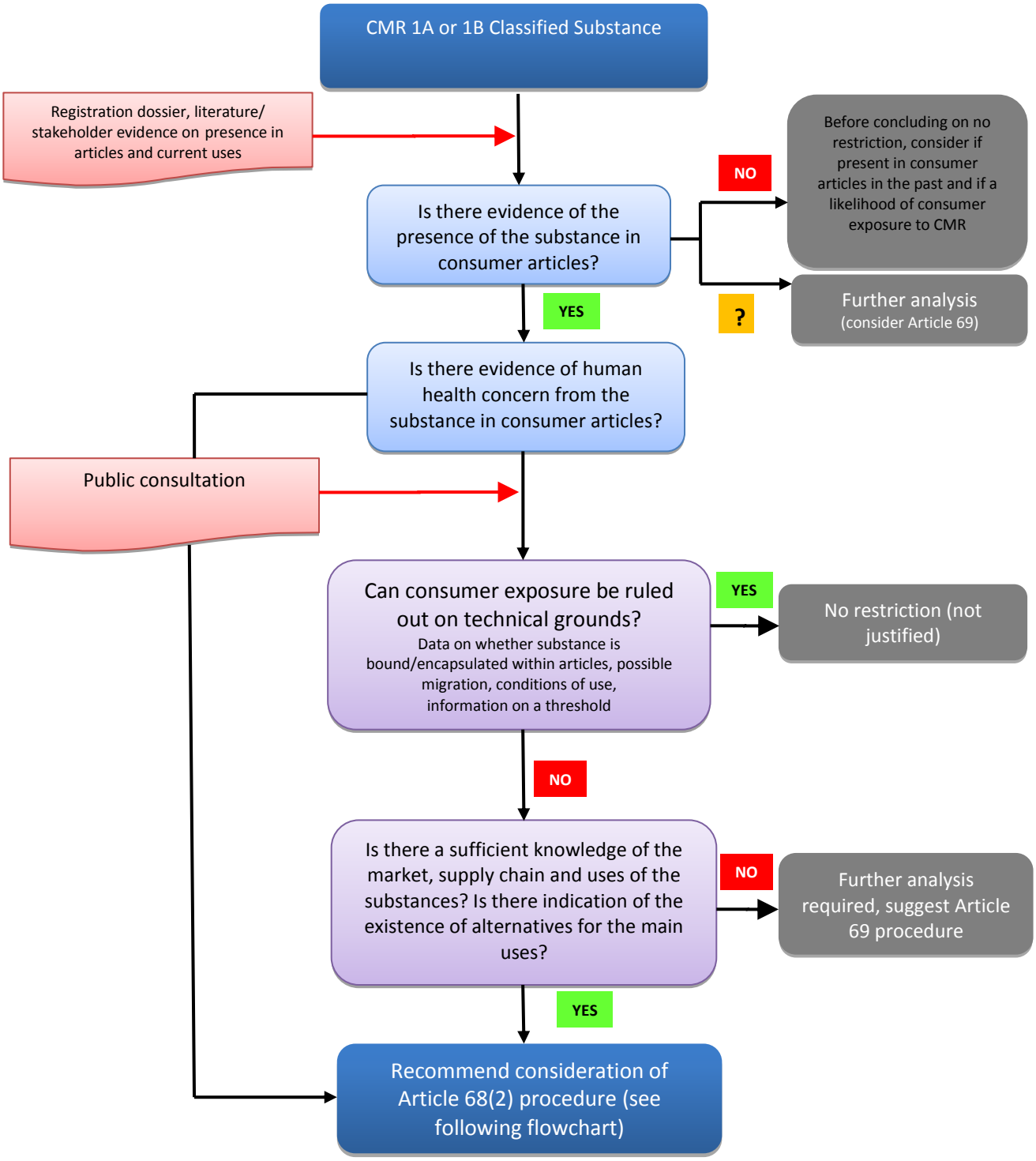
This approach would apply when the substance is considered to be potentially present in different consumer articles, because it has a specific function or because it can be considered as residual of the production process or be generated in the article following a transformation of its constituents and therefore still present in the articles.

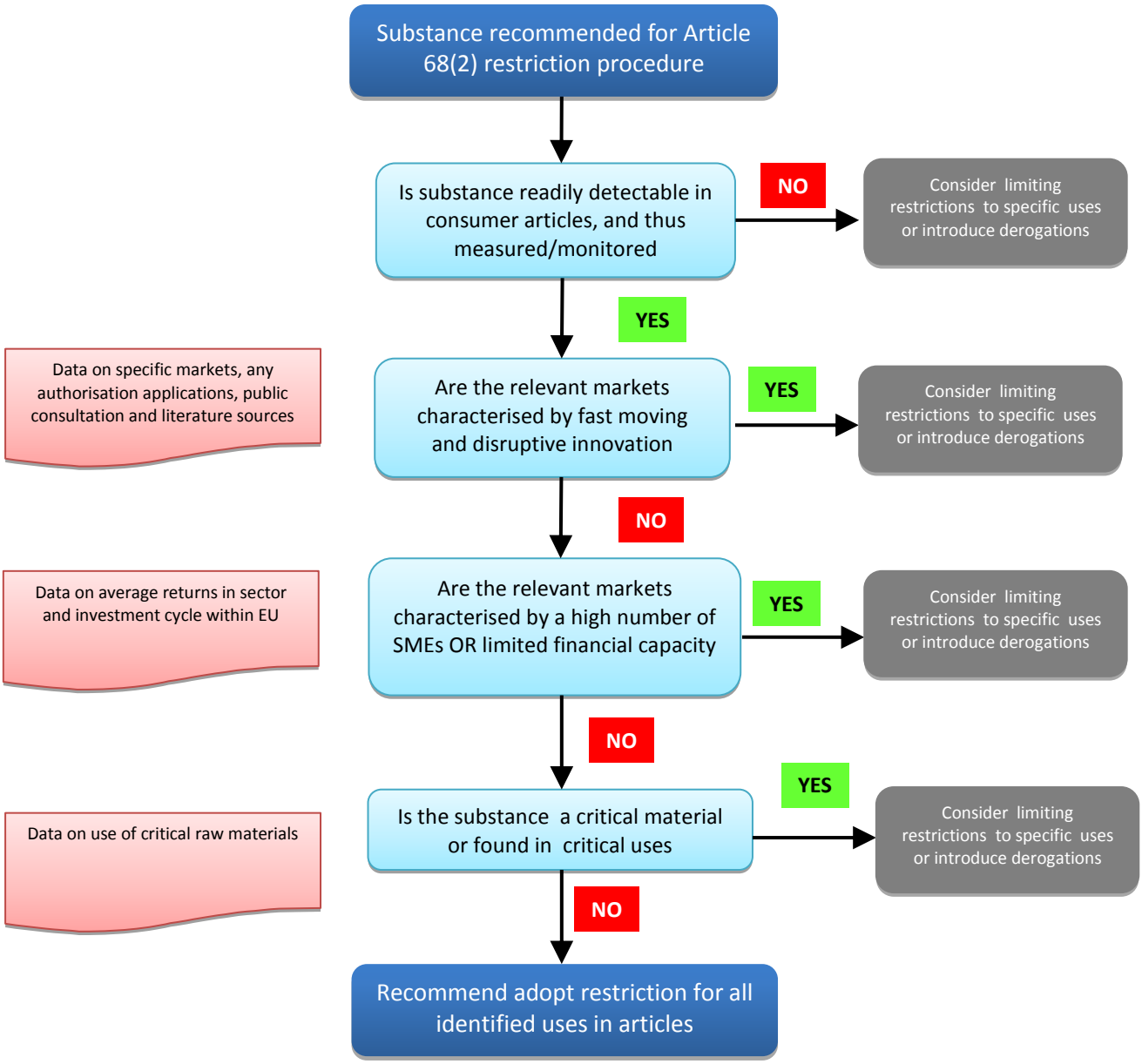
This approach would imply a two-step verification:

- Decision criteria: is the Article 68(2) procedure the best regulatory option?
- Additional criteria (when decision criteria confirm 68(2) as the most appropriate regulatory option): to define the scope or other elements of the restriction.

These criteria are meant to be guiding-criteria for the Commission in order to facilitate a decision whether the use of the procedure in Art. 68(2) for CMRs in consumer articles is the most appropriate. Experience gained with the first practical cases will indicate if these criteria are feasible or there is a need for revision in the future.

This approach is illustrated in two flowcharts.


CMR 1A or 1B Classified Substance
Registration dossier, literature/ stakeholder evidence on presence in articles and current uses
Is there evidence of the presence of the substance in consumer articles?
NO
Before concluding on no restriction, consider if present in consumer articles in the past and if a likelihood of consumer exposure to CMR
?
Further analysis (consider Article 69)
YES
Is there evidence of human health concern from the substance in consumer articles?
Public consultation
Can consumer exposure be ruled out on technical grounds?
Data on whether substance is bound/encapsulated within articles, possible migration, conditions of use, information on a threshold
YES
No restriction (not justified)
NO
Is there a sufficient knowledge of the market, supply chain and uses of the substances? Is there indication of the existence of alternatives for the main uses?
NO
Further analysis required, suggest Article 69 procedure
YES
Recommend consideration of Article 68(2) procedure (see following flowchart)


Substance recommended for Article 68(2) restriction procedure
Is substance readily detectable in consumer articles, and thus measured/monitored
NO
Consider limiting restrictions to specific uses or introduce derogations
YES
Data on specific markets, any authorisation applications, public consultation and literature sources
Are the relevant markets characterised by fast moving and disruptive innovation
YES
Consider limiting restrictions to specific uses or introduce derogations
NO
Data on average returns in sector and investment cycle within EU
Are the relevant markets characterised by a high number of SMEs OR limited financial capacity
YES
Consider limiting restrictions to specific uses or introduce derogations
NO
Data on use of critical raw materials
Is the substance a critical material or found in critical uses
YES
Consider limiting restrictions to specific uses or introduce derogations
NO
Recommend adopt restriction for all identified uses in articles

Information to be collected via literature search and public consultation

Evidence of exposure: is there evidence of human health exposure to EU citizens from the substance in consumer articles? Elements to be considered are:

- Evidence of the presence of the substance in the articles (including the presence in the articles in the past) and indication of category of articles. Has the substance a function, or is it present as a residue of the production process or can it be present in/released from the article following a transformation of its constituents (e.g., formaldehyde in construction products)? Can the presence (and/or release) of the substance be measured (validated analytical method available)?
- The physical-chemical properties of the substance (e.g. Kow, volatility, solubility or molecular weight) or of the matrix of the article in which the substance is present. Is there any indication that the substance may migrate / leak from the article, for example, because the substance is not bound tightly into the matrix? (e.g. PAHs in rubber). Or, on the contrary, is there an indication of no migration potential, because the substance is well bound into the matrix (e.g. Cr in steel, borates in glass) or of no direct consumer exposure because the substance is encapsulated in the article (e.g. gallium arsenide in transistors included in electronic devices).
- A likelihood of dermal, oral or inhalation exposure due to the normal/reasonably foreseeable conditions of use and disposal of the consumer article (e.g. cutting/grinding related to inhalation exposure, likely mouthing of children, long period of dermal contact expected such as for gardening tools or clothing).

Additional elements that could be considered:

- Indication of a non-threshold effect for the substance
- Any application for authorisation
- Complexity of the supply chain
- Volume and value of market, data on specific markets
- Types of uses
- Added value of the substance for categories of articles
- Suitable alternatives for categories of articles/critical uses
- Magnitude of cost of substitution/ abatement cost

Approach by category of articles

In this approach, the Commission would address one or several categor(y)ies of consumer articles where, because of the nature of the article, there is a likelihood of (prolonged – or multiple short-

term) exposure of the consumer to relevant CMR substances potentially present in the articles. It would also take special account of the potential exposure of vulnerable population groups (such as children, pregnant women, the elderly). When applying this approach, coherence with sector-specific legislation would have to be ensured in order to avoid possible overlaps.

The categories of consumer articles need to be identified and prioritised in cooperation with MSCAs, ECHA and stakeholders, looking also at possible legislative gaps against the background of existing sector-specific legislation. As a start, the following groups could be considered:

- Textile articles (clothing and footwear)
- Childcare articles
- Sports and leisure articles
- Articles constituting constructive elements and decorative furnishings used in the home (flooring, textile, furniture) or other confined spaces (car, public transport).

The definition of the category of consumer articles is important in this context and, when possible, definitions in existing legislation (for example, Toy Safety Directive) should be used.

The list of CMR substances (individual substances or groups) covered by the restriction would be added as a specific appendix to Annex XVII to REACH and could be regularly updated with additional substances, as appropriate.

Information required

In this case, the information needed on the specific substances is less extensive than in the previous case, but it should include at least:

- Justification of the potential consumer exposure for the specific category of articles.
- List of CMR 1A and 1B substances (individual substances or groups) potentially present in the article category.
- Additional elements similar to those mentioned for the other approach; the objective is
    - To define the scope of the restriction (including exemptions, if needed)
    - To identify possible cases where there is a need to follow a “substance specific” approach because of a higher complexity of the case (for example, critical substance with no alternatives).

3. Procedure

The elements to support the proposal should be collected looking first at available information and then complemented/verified via a specific public consultation as appropriate. The length of the

public consultation could be decided on a case by case basis, but it should be at least 3 months. The public consultation should clearly indicate a list of elements on which stakeholders should comment, depending on the approach chosen.

The public consultation should be a Commission consultation, supported technically by ECHA.

The Commission proposes a stepwise approach:

1. A list of articles where a given CMR might be present or have been present in the past (in the substance approach) or a list of CMRs (individual substances or groups) potentially present in the chosen category of consumer articles (in the category of article approach) should be drawn up, on the basis of:
    - Results of national enforcement activities
    - National, EU and international databases/studies
    - RAPEX notifications
    - Notifications to ECHA on the basis of Article 7(2) of REACH
    - Any relevant authorisation applications for article service life
    - Any information obtained by consumers (or authorities) under Article 33 of REACH (if available)
2. The Commission would then launch a public consultation for the identified articles / CMR substances, requesting information on their presence or likelihood of presence in the specified consumer articles and, to the extent possible, their concentration/migration, their function, the frequency of contact with the article, the availability of alternatives, possible socio-economic impacts of a ban/restriction and enforceability of the possible restriction. There could also be a general question on the presence of the given substance in other articles or of other CMR 1A and 1B in a chosen category of consumer articles.
3. When necessary, the Commission could also consult the appropriate Scientific Committees. For example, in case of a restriction on childcare article, the Toy Safety Committee could be consulted, if necessary.
4. For substances for which the initially envisaged restriction via categories of articles appears to be problematic: the individual substance approach will be used. When effects are identified (e.g. where alternatives do not appear to be technically or economically feasible), additional information could show that the substance should be restricted following the Article 68(2) procedure, or there is a need for a restriction procedure under Article 69, or there is no need for a restriction, or there is a need for another risk management approach.
5. For substances/articles for which the consultation did not reveal any insurmountable problems the Commission would then formally start the Article 68(2) restriction procedure.

A comparable procedure is currently being used by the State of California in its "Safer consumer products" programme and some aspects, such as the choice of priority products and priority substances, could be used as an example[3].

The information collected should be presented in a report. The structure of the report could be the following:

- List of articles or categories of articles concerned, information on identity of the substance/substances classified as CMR 1A or 1B (potentially) therein and, to the extent possible –the use and/or function of the substance(s)
- Information on hazard and exposure: existence/absence of a threshold, use, likelihood for exposure/exposure potential, potential for presence of the substance in article
- Information on stakeholders consultation
- Information on alternatives
- Socio-economic elements
- Information on enforceability
- Conclusion: initial proposal for a restriction suggesting the appropriate route and approach to take (i.e., the application of Article 68(2) or 69 based on the individual substance (categories of substances) approach or based on a category of articles approach or a combination of the two), the proposed scope including the conditions, the time of application, the limit values as and if appropriate.

The level of detail will depend on the specific case.

4. Next steps

Criteria to prioritise and select relevant substances/categories of articles for an Art. 68(2) restriction procedure might include:

[3] http://www.dtsc.ca.gov/SCP/index.cfm

It should be noted that this procedure does not lead to bans/restrictions adopted by the State authorities, but rather obliges economic operators to conduct extensive alternative analyses and then adopt one (or several) possible 'regulatory responses', which can include substitution of the identified priority substances in the priority articles concerned. Also the scope of substances or articles concerned is much narrower. In March 2014, California released the first priority list, which includes one childcare article (children's foam-padded sleeping products that contain the flame retardant TDCPP).

- Possible/detected/known/widespread use of the substance in consumer articles, including past uses;
- Articles where there is a possibility of consumer exposure (for example, contact with the skin);
- Articles used by vulnerable groups (e.g. children, pregnant women);
- Migration potential of the substance;
- Non-threshold CMR.

The Commission intends to start working on a restriction for CMRs in consumer articles under Art. 68(2) using the category of articles approach. After consultation with Member States Competent Authorities, textile and clothing articles were selected as a first, test case. In addition to the characteristic that they come into contact with the skin, there is currently no comprehensive product specific legislation for these articles. The Commission, with the support of ECHA, is currently collecting information on CMRs 1A and 1B that can be present in textile and clothing articles, including their possible maximum concentration limits. A public consultation will be launched in the first half of 2015.

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