

Forum Guide on Enforcement for Dossier Submitters

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1. Introduction

According to REACH article 77(4) h the Forum shall examine proposals for new restrictions in Annex XVII with a view to advising on enforceability. For this task the Forum has set up a working group (WG) on enforceability of proposals for restrictions with the mandate to elaborate this work and prepare draft Forum Advice, taking into account the comments of the Forum members.

It would be advantageous if MSCAs (Member State Competent Authorities) consult their national Forum member at the drafting stage (before the dossier is submitted to ECHA) and that the national Forum member cooperates with the MSCA during the drafting process.

This guidance gives advice on what to consider in elaborating a dossier and a restriction proposal from an enforcement perspective.

Forum will focus on the following chapters in the dossier:

- **The restriction proposal**
- **Effectiveness:** the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk.
- **Practicality:** the restriction must be implementable, enforceable and practicable.

Restrictions should be possible for the companies to comply with, and enforcers should manage to check compliance in a practical and efficient way. In particular the practicality of the proposal should be considered when preparing the Forum Advice on enforceability.

The Annex XV dossier proposing a restriction contains lots of background information on the proposed restriction that is necessary to analyse the proposal from an enforcement point of view. However, when the restriction has entered into force this information in the dossier will not be easily accessible by companies or the national enforcers. Thus the entry should be clear enough to be easily and unmistakably understood by those parties who need to comply with it.

Former Forum advices can be helpful for dossier submitters and can be provided to them on request.

In the following chapters Forum's intention is to give practical advice on enforcement issues to consider when elaborating an Annex XV dossier.

2. The scope of the proposed restriction

2.1 PLACING ON THE MARKET

Placing on the market for the first time puts the obligation solely on the first actor who supplies or makes substances, mixtures, articles available, whether in return for payment or free of charge, to a third party. This term, “for the first time” is not defined in Article 3 of the REACH Regulation. Any application of the term should be mentioned explicitly in the Annex XVII entry – e.g. in case the obligation does not apply to products that were already put on the market when the restriction enters into force.

2.2 SECOND HAND MARKET AND RECYCLED MATERIAL

When there is a need for an exemption of the second hand market or recycled material, the restriction text could reflect that.

As an example the wording from the European Commission Regulation on restriction of Chromium VI is welcomed by Forum, “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”

2.3 DEFINITIONS

Definitions are sometimes needed for specifying terms that are referred to in the restriction and to clarify what is included in the scope of the restriction. However, there is no need to propose definitions of common words where the normal dictionary definition is sufficient, e.g. keys, locks, padlocks. Instead advice on definitions should preferably be limited to the cases where terms in the proposal may create significant problems of interpretation/implementation (e.g. easily foreseen different interpretation among Member States). If, for example, it is not clear which product groups are covered by the restriction there may be uncertainties for the companies and the enforcers. In case of lack of clarity, because essential definitions are missing, different enforcers may address companies differently, thus jeopardising harmonisation for all actors.

For certain words, e.g. technical terms, thorough specification might be appropriate to prevent unclear translations, thus causing risk for differences between the Member States with regard to enforcement. One example was ‘outdoors’ in the DCB restriction – the term had a different scope in some Member State (some would exclude in vehicles, others would not).

However, it will not be possible to get clear definitions for every product group, and even if definitions are given, there still might be some grey areas. It should be kept in mind that it takes considerable time to develop new definitions. A solution could be to develop guidelines for companies and enforcers explaining what is or what is not meant regarding definitions. ECHA could develop such guidelines, on request of the Commission and with possible contribution from the Committees and the Forum, and keep the guidelines containing explanations up to date by inclusion and revision of ECHA’s website with Q&As: REACH Restrictions ECHA (<http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/restrictions>)

Examples of wordings in restrictions that Forum has approved in former advice are:

- “Direct or prolonged or repetitive contact” needs to be defined. The wording has been changed in the legislation text to “coming into contact” which is a better alternative.
- When the scope of the restriction is articles or any part of them whatever material: “Articles or any parts thereof”, instead of variations such as “homogenous parts” or “separate parts”

The wording from COM on restriction of Chromium VI was welcomed by Forum:

- When the article contains more than one material: “leather articles or articles containing leather parts”, instead of “leather articles and parts thereof”.

2.4 EXEMPTIONS

Exemptions might be needed for some restrictions. However, if the restriction includes too many or complex/interwoven exemptions the proposed restriction might lack clarity.

3. Sampling and preparation of probes for analysis

Sampling prior to analysis is an important issue with regard to reproducibility of the analytical result and thus important for enforcement. The Forum recommends that where possible, the dossier submitter assesses whether sampling can influence the results of analysis. Forum is in favour of either an existing sampling method or of having an indication in the dossier that one needs to be developed. If a sampling method is not available a sampling guidance is recommended to be provided in the Annex XV dossier, when necessary. Information regarding sampling guidance, if necessary and if existing, can be provided to companies and enforcers as a restriction Q&A on ECHA 's website (<http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/restrictions>). In some cases it could be relevant to create a method or standard method for sampling. An example of a sampling standard method is EN 326-1 for wood based panels.

Forum has given the following advice when there has been no information on sampling in the dossier.

- A sampling and preparation method is in practice available/needed but is not (clearly) given in the background document of the restriction proposal.

For restrictions that apply to parts of articles, there might be a need for sampling guidance within the Annex XVII entry because many articles consist of different parts and the substance is rarely equally present in the whole article. Under these circumstances, the entry may need to state particular parts of articles that the restriction is intended to control (and therefore which parts are to be sampled).

For example, restriction of PAH in tyres requires sampling of rubber from both the tyre-wall and the tread because they have different compositions to suit their function. The entry may include specific reference that would provide guidance about which parts of an article to include in a composite sample; for example: "... any plasticised part thereof,...any flame retarded part thereof"

In general samples of substances, mixtures or articles have to be prepared according to laboratory procedures for getting them in a state suitable for analysis. Analytical methods commonly prescribe preparation procedures regarding the analyte¹ of interest. The reported procedures might be applicable to only distinct matrices, e.g. water or soil. The dossier submitter should propose analytical methods covering all the materials - especially articles or parts of them- which are affected by the proposed restriction.

¹ From Wikipedia: An analyte, or component (in clinical chemistry), is a substance or chemical constituent that is of interest in an analytical procedure. Grammatically speaking, experiments always seek to measure properties of analytes—analytes themselves cannot be measured.

4. Analysis of restricted substance

4.1 ANALYTICAL METHODS

Forum recommends that for restricted substances there is at least one reliable analytical method available to check compliance with the restriction. Forum recommends that the Annex XV dossier includes information about the availability of reliable analytical methods especially if an accredited/established method exists (National level, CEN or ISO).

If no method is available and not mentioned in the dossier, the Forum recommends that a method that fits for the purposes of the restriction needs to be identified or developed for the restriction to be enforceable.

Guidance and recommendations for suitable analytical methods are essential for assessing enforceability and information needs to be available for companies and enforcers in one way or another (entry, recital, Q and A or guidance). The Forum Compendium of recommended analytical methods could be used as a reference information source by a candidate dossier submitter. Recommended analytical methods should preferably be standardised methods (EN/ISO etc.).

Including a reference to the analytical method in the entry has to be a case by case decision depending on each restriction.

Using an “analytical method” (i.e. “sampling” and “sample preparation” and “analysis”) can be expensive, and on occasion prohibitively so. The Forum could advise that harmonised and widespread enforcement may be problematic due of potential lack of resources needed for control. Some NEAs might apply the analytical method to gather material evidence, while some might not and limit themselves to assessment of existing documents. The restriction proposal dossier submitter may wish to suggest an analytical method that is practical and not leading to excessive costs.

4.2 SCREENING METHOD

For enforcement sometimes screening methods are used, to identify restricted substance. For instance most elements, preferably metals, can be detected by XRF-technique². Screening methods may also be considered with regards to monitorability of a restriction proposal. Forum may ask if screening methods are available and appropriate.

4.3 LIMIT VALUE AND RELATION TO DETECTION & QUANTIFICATION VALUE

The proposed limit value for a restricted substance needs to exceed the limit for detection. The dossier submitter may wish to address this issue.

4.4 LIMIT VALUES REFERRING TO CONTENTS OR MIGRATION OR OTHER RELEASE

Limit values for a restricted substance can refer to the content or migration or emission – for example, as it was proposed for the restriction on ammonium salts – of the substance concerned. Analysing the migration of a substance might sometimes seem to be more adequate for the risk that is intended to be reduced.

² XRF (X-RAY Fluorescence) is an analysing technique

However, analytical methods for migration are less practicable than methods for analysing the composition of a substance. Methods for analysis of migration are destructive and more costly, both for companies and enforcers. Experience has shown that reproducibility of migration tests can be poor. Furthermore emission tests need special costly equipment going beyond routine enforcement and therefore are performed only by specialised laboratories. Therefore, Forum in general prefers to have limits for content.

4.5 LIMIT VALUES (AREA, WEIGHT OR VOLUME)

Limit values referring to surface area are in general difficult to check since the surface might be difficult to estimate depending on the structure and irregularities. Therefore weight or volume is recommended to use as the suitable reference parameter.

5. Clear wording, logic relations between the aspects in the proposal

The wording of the restriction needs to be clear to avoid the risk for multi interpretation or misunderstanding. The relations between the aspects of the restriction are recommended to be clear and logical.

Usually Forum shall not formulate new wording proposals, unless it might support understanding or that Forum is invited to do so from dossier submitters, RAC, SEAC or the European Commission.

6. Practicality and General conclusions on enforcement

To be able to check compliance with the restrictions the national enforcers may have to pay for sampling products/mixtures/articles, and there may also be difficulties with the storage of large objects that are under certain restrictions. Such practical issues for enforcement could compromise the capacity of enforcement agencies in executing surveillance and enforcement activities.

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