

Brussels, 10 November 2020

## Orgalim comments on the 2020 draft Blue Guide

### Introduction

Orgalim welcomes the update of the Blue Guide and remains convinced that the New Approach and the New Legislative Framework are the best tools to support the proper functioning of the European Single Market for Goods. We greatly appreciate the amount of work the European Commission has done to accommodate the industry's need for additional guidance when it comes to the application of NLF.

Orgalim is, however, opposed to any modification of the Blue Guide that would impose new constraints or provisions other than those laid down in the European legislation (e.g. the introduction of a new definition for remanufacturing<sup>1</sup>) or even propose provisions arising from too strict an interpretation of the regulations.

Orgalim considers all the additions and modifications related to standardisation and harmonised standards under section 4.2 *Conformity with the essential requirements: harmonised standards* to be problematic. We feel the need to stress once more the importance of ensuring sufficient flexibility for the standardisation system. We propose that either the revision of the Blue Guide should be delayed, or section 4.2 should be maintained as in the edition published in 2016, unless a suitable solution has been found.

Finally, Orgalim would propose further developments of the Blue Guide draft, and we stand ready to support the Commission in the improvement of this Guide.

### 1. The Blue Guide should not impose new constraints or provisions other than those laid down in the European regulations

Orgalim is concerned that some of the new definitions and guidance included in the document could extend the existing legal framework – which should not be the case.

Considering the intention of the proposed new version of the Blue Guide to also cover the provisions of the new Regulation on market surveillance and product compliance (2019/1020/EU), it is imperative that the interested parties first reach a common understanding of these provisions before embarking on a revision of the Blue Guide, as the provisions of the new Regulation have a major bearing on a number of its chapters. Therefore, it is necessary first to discuss and make progress on the draft guidelines on the implementation of Article 4 of the new Regulation, which the Commission put forward in December 2019.

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<sup>1</sup> Please note that this comment as formulated is not supported by VDMA. As mentioned in this paper, Orgalim is in the process of further assessing and discussing definitions related to the circular economy, in view of reaching a common understanding across the whole membership.

When it comes to the guidance regarding online sales and the roles and responsibilities foreseen for economic operators we can cite the example of making CE information obligatory on a website. This would be an unjustified administrative burden. Making this information digitally available is not required according to any regulation, and thus not appropriate in a guidance document explaining the existing rules. Moreover, as this cannot be enforced for online sales platforms that operate from non-EU countries this unbalances the level playing field between EU-based platforms and non-EU platforms.

Furthermore, the draft (section 2.1) mentions the notion of “new product” and various modifications to products including “remanufacturing”. Orgalim believes that these definitions are important in the effort to anchor the activities of the circular economy in the regulatory framework; however, the sections of the Guide do not serve the purpose of providing more clarity. Orgalim is currently working on a paper to establish our views on the interface between NLF and how various potential modifications of products could be treated within this framework.

## 2. Legal position of harmonised standards and development process

As mentioned in the introduction, Orgalim does not believe that the Blue Guide can be published with section 4.2 in its present form. This is due to the Commission’s new interpretation of the standardisation regulation that will undermine the standardisation system as we know it, with serious consequences for the functioning of the internal market, European competitiveness and innovation. In particular, the proposals with regard to standardisation requests, expiry dates, closed lists of standards to be revised or developed, lack of a streamlined process for the revision of standards etc. would radically modify the way harmonised standards will be developed in the future. Furthermore, we believe it will leave the EU unable to achieve its goal of green and digital transitions, which Orgalim fully supports.

21 European industry associations have in a [joint letter](#) encouraged the completion of an independent assessment of the Commission’s interpretation and the consequences the interpretation will have for those who develop and apply standards. The results of such an assessment should be awaited before this section of the guidance can be changed.

The German presidency has recently published a [legal assessment](#) of the European system of harmonised standards. This opinion shows that it is reasonable to question the Commission’s interpretation of the extent to which the Commission has a right to scrutinise and make decisions on the content of the standards, and further explores the consequences of this perception of responsibility.

Finally, a group of 17 Member States have drafted a non-paper on standardisation which asks the Commission to find a solution to the problem.

With this in mind we also have to take note that the Commission has not provided stakeholders with an explanation as to why the new interpretation is necessary, or justified its proportionality. Furthermore, there has been no impact assessment on the new obligations outlined in this revision of the Blue Guide. Although the Blue Guide is ‘only’ a guidance document, such an impact assessment is in line with the principles of better regulation and should be taken for granted given that it is seen as the interpretation of the New Legislative Framework (NLF) and is moreover described as a document based on consensus.

We therefore ask the Commission to take due consideration of the [legal assessment](#) of the European system of harmonised standards published by the German government and the non-paper on standardisation presented by the Member States before approving the revision of the Blue Guide. Should this discussion prove too lengthy we insist that the chapter on the application of hEN’s (section 4.2) remains unchanged until a suitable solution has been found.

## 3. Further developments of the Blue Guide draft

Finally, Orgalim would propose further developments of the Blue Guide draft, in particular on the following points:

### Market Surveillance

It would be helpful if the Blue Guide clarified to a greater extent the obligations of Member States in building Market Surveillance capacity. As online sales grow, the Market Surveillance Authorities need to develop effective tools to prevent non-compliance through online sales and a clearly defined enforcement plan should be put in place. Requesting the product information through the fulfilment centre will not help if an adequate capacity is not allocated to this growing sector. Cooperation between business organisations and Market Surveillance Authorities should be developed further in accordance with article 9 of Regulation EU 2019/1020 and would help to improve capacity. We stand ready to share our experience of cooperation gained in the MSSI Electrical in Europe platform.

## Definitions

Orgalim finds the additional clarifications concerning what a product is, and when it is marketed, valuable. However, there is still some confusion due to definitions being introduced in different chapters and amendments particularly for the definitions of “making available on the market”, “placing on the market” and the position of “offering a product” during the sales stage. The situation is additionally complicated by the reality of distance/internet sales and the fact that online sales are organised on platforms based in the EU as well as platforms based outside the EU where there is always an “offer”. The interpretation advocated by the Commission in the Blue Guide would lead to losing the “importer” as one of the main economic operators responsible for certain tasks in relation to product conformity.

In general, definitions need to be introduced in a clear and concise manner in one section of the Guide rather than having the information spread through various chapters. Furthermore, once a definition is established the vocabulary should then be used in a consistent way throughout the text of the Guide. We have noticed this is not always the case, for example when referring to the “user” and the “end-user”, and in this particular case we suggest developing two separate definitions, using for reference the concepts introduced in the EMC Directive. Other definitions that could be reviewed include: “online interface”, “information society service providers”, “authorised representative” and “serious risk”.

## Abbreviations

It might be useful to introduce a list of abbreviations as an annex of the Blue Guide to assist readers who may not be familiar with all the abbreviations.

## Conclusion

The Blue Guide is a valuable tool that can support the proper functioning of the European Single Market for Goods. The document should reflect “the broadest possible common understanding on implementation of the NLF for the marketing of products” as the preface boldly declares. Europe’s technology industries stand ready to play their part.

Orgalim represents Europe’s technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU’s largest manufacturing sector, generating annual turnover of over €2,100 billion, manufacturing one-third of all European exports and providing 11.5 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

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