

POSITION PAPER

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Suggestions for a revision of the Blue Guide on the implementation of EU product rules 2016 *

* <https://ec.europa.eu/docsroom/documents/18027/attachments/1/translations>

EXECUTIVE SUMMARY

Orgalim welcomes the update of the **Blue Guide** which supports the application of the **New Legislative Framework (NLF)**. We believe that the latter is **still fit for purpose** to support the smooth operation of the European Single Market.

We are happy to suggest several areas for clarification, including:

- **Legal concepts and definitions** in relation to the application of the Lex Specialis, 'Making available on the market', 'Placing on the market', 'fulfilment service provider', 'online interface', 'end user', 'Authorised representative', 'serious risk', and more;
- **Alternative to comply through digital means** to facilitate the provision of documentary evidence via electronic means and likewise increase the efficiency of market surveillance controls, including traceability requirements (web address as an alternative to on-product printed address or the declaration of conformity);
- **Alternative to paper instructions and safety information for products**, which the manufacturer could provide to the end user as an acceptable alternative to the printed paper format. There would be many benefits attached to this, among them costs savings for all stakeholders including customers and the authorities, a decreased environmental impact and an improved level of safety;
- **New provisions in Regulation 2019/1020 on market surveillance and compliance of products**, such as the setting up and the operation of 'joint initiatives' between trade associations and market surveillance authorities (MSAs), the principle of presumption of non-compliance, product recall, or the recovery of costs by MSAs.

Orgalim represents Europe's technology industries: companies that innovate at the crossroads of digital and physical technology. Our industries develop and manufacture the products, systems and services that enable a prosperous and sustainable future. Ranging from large globally active corporations to regionally anchored small and medium-sized enterprises, the companies we represent directly employ 11 million people across Europe and generate an annual turnover of around €2,000 billion. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

1. GENERAL CONSIDERATIONS

The free circulation of manufactured products within the European Single Market is overall a success story for over thirty years, thanks to the New Legislative Framework (NLF) for the placing of products falling under Union harmonisation legislation¹. **Europe's technology industries care very much for maintaining the NLF up and running** to remain competitive within the EU and, through innovation, to become world leaders in many smart technologies and a driver for manufacturing growth and jobs.

Orgalim believes that the NLF is still fit for purpose to support the smooth operation of the European Single Market and subsequently fully supports the European Commission's intention to implement an industrial strategy that efficiently addresses the challenges of the digital and sustainable transformation of the European economy.

Therefore, **we welcome the plans of the European Commission to revise** the Guide to the implementation of directives based on the New Approach and the Global Approach (known as **the "Blue Guide"**), to promote a common understanding of certain new aspects arising from the NLF. This becomes even more important as legislation adopted since its last edition 2016 has introduced new concepts and obligations to economic operators whose national implementation may give rise to diverging interpretations among Member States and consequently undue administrative burdens for economic operators. This is especially true for the new elements arising from the new Regulation (EC) 2019/1020 on market surveillance and compliance of products, which is now replacing and completing substantial parts of the NLF.

Further to the update of the Blue Guide 2016, **we are calling on the European Commission to promote a strict application of the Decision 768/2008 (EC)** on a common framework for the marketing of products. It is, in our view, paramount to ensure the consistent application of the NLF principles in all existing and future pieces of Union harmonisation legislation.

We look forward to an improvement of the Blue Guide to which we are prepared to contribute actively in close co-operation with the Commission, Member States and other stakeholders.

2. LEGAL CONCEPTS AND DEFINITIONS

Orgalim would like to see clarifications of certain legal concepts and new definitions brought by Regulation 2019/1020:

1. **Application of the Lex Specialis:** according to the lex specialis principle, whenever a matter is regulated by two rules, the more specific one should be applied first (Blue Guide page C 272/11, first paragraph). In practice, this principle is not always easy to understand and implement.

¹ The New Legislative Framework is a legislative framework formed by the following complementary pieces of EU legislation: Regulation (EC) 765/2008 on accreditation and the CE marking, Decision 768/2008 (EC) on a common framework, Regulation (EC) 1025/2012 and Regulation (EC) 2019/1020 on market surveillance and compliance of products

2. There are two main cases:
 - a. **Horizontal vs vertical:** the preamble 4 and Article 2 'Scope' of Reg. 2019/1020 indicate that if the product is intended or likely **to be used by consumers**, the horizontal Directive 2001/95/EC on general product safety – GPSD on consumer protection may bring **more obligations** that market surveillance authorities may see necessary to enforce on top of product-specific Union harmonisation legislation (cf. Whereas 5 and article 2§3). What is more specific? That a product is covered by specific essential requirements because of its intrinsic nature or embedded technology (machinery, electricity, radio...) or that it is intended to be used by a specific category of end users (consumers vs. others)? If the combination of both is relevant, in which order?
 - b. **Competing product-specific provisions:** Where several pieces of Union legislation are applicable to the same product and contain diverging provisions, for instance on the minimum height of the CE marking, could the manufacturer choose the order to apply them? See also example provided below under point 3b.
3. **'Making available on the market'** (n°1 in Reg. 2019/1020): Orgalim suggests providing more information and examples illustrating the concept of making available and placing on the market, in a revised version of the Blue Guide. In particular:
 - a. **Clarification of the concept of making available a 'finished product'** would be most useful. EU-based manufacturers are increasingly outsourcing the components of their finished products across increasingly large, decentralised and complex supply chains, which could consist of dozens or even hundreds of subcontractors. The technical details of imported unfinished products (i.e. components, spare parts or sub-assemblies) are directly incorporated in the risk assessment made by the 'end' manufacturer of the finished product who is ultimately liable for placing compliant products on the market. In the light of this, overly restrictive or diverging interpretation by enforcement authorities as to what makes up a 'finished' product could severely impact the administrative costs and the competitiveness of EU-based manufacturers vs. those that make the final assembly or even the complete refurbishing of the product outside of the EU.

More: See also below under 'authorised representative' for the application of the provisions of Article 4 under Regulation 2019/1020.
 - b. **Application examples of making available on the market** would be welcome, like the ones included in the [EU Q&A on Brexit](#) for industrial products would be most useful.
4. **'Placing on the market'** (Blue Guide Section 2.4 and definition n°2 in Reg. 2019/1020): Orgalim suggests clarifying more specifically that:
 - a. if a product is placed on the market in one EEA country, the product is considered placed on the market in all the EEA countries." Experience shows that some Member States still tend to interpret "placing on the market" as a first making available on their own market only. This causes unnecessary barriers to free trade with the Single Market;
 - b. if a product is imported from outside the EU, how the different economic operators come into play when a product is covered by multiple legislations some of which do not consider the Importer (e.g. the Machinery Directive) while others do (Low Voltage Directive, Electromagnetic Compatibility Directive, Radio Equipment Directive, and more);

- c. that manufacturers that directly sell products via a Web platform to EU consumers are subject to applicable EU legislation, as these direct sales are considered as a first making available on the EU-EEA market.
5. **'fulfilment service provider'** (n°11 in Reg. 2019/1020), where examples would be useful;
6. **'information society service provider'** (n°14 in Reg. 2019/1020), in line with the 'Directive on electronic commerce' 2000/31/EC of 8 June 2000;
7. **'online interface'** (n°15 in Reg. 2019/1020) that are defined to serve "to give end users access to the economic operator's products" while the current Blue Guide refers to "Products offered for sale by online operators" which have "been already manufactured" for "supply to EU consumers or other end-users". (C 272/19 middle paragraph).
8. "product presenting a **serious risk**" (n°20 in Reg. 2019/1020) should be clarified as applying under the General Product Safety Directive for MSAs to act against unlawful consumer products. However, the Guide should clarify that MSAs should start assessing whether the consumer product presents a (substantial) non-compliance, when it is already covered by a more specific Union harmonisation legislation (cf. section 2 paragraph 1 above on the Lex Specialis).
9. **'end user'** (n°21 in Reg. 2019/1020) is a new definition that requires clarification in the Blue guide, in relation to 'user', as in several NLF-type directives such as Directive 2006/42/EC on Machinery or Directive 2001/95/EC on general product safety – GPSD (Article 18 paragraph 1). Currently, the Blue Guide only refers to 'end user' in section 2.5 'putting into service or use' (p. C 272/21) and section 4.2.2.4. 'Identification of economic operators' (p. C 272/55 last paragraph).
10. **'Authorised representative'** as per Reg. 2019/1020 Article 5 and the related provisions in Article 4 (Tasks of economic operators regarding products subject to certain Union harmonisation legislation) and Article 7 (Obligation of cooperation): it has to be clarified whether non-EU based manufacturers of components, spare parts or sub-assemblies intended for end-use as an assembly or incorporation into a finished product, shall be regarded as subject to the above provisions. In the latter case, this would significantly impact the supply chain of B2B products and add administrative burdens beyond the purpose of the law.
11. **"all information and documentation necessary to demonstrate the conformity of the product"** as per Reg. 2019/1020 Article 4 §3b is pretty vague and should be clarified through examples.

3. ALTERNATIVE TO COMPLY THROUGH DIGITAL MEANS

Compliance information is both intrinsically linked to a given product model or category and is intended either for market surveillance authorities or professional purchasers, both of whom have the proficiency to read and understand it.

Orgalim considers that in the age of the digitalisation of the European economy, traceability of the responsible economic operator in the application's framework of NLF legislation could be significantly improved for the benefit of all parties: economic operators, authorities, and end-users of products. Therefore, it should be possible to **allow manufacturers to provide documentary evidence via electronic means to increase the efficiency of market surveillance controls**, so that more resources become available for physical checks on products.

Consequently, we call on the Commission to consider through a revision of the Blue Guide, for a modern interpretation of administrative obligations in NLF legislation to provide various markings and documentary evidence in a **digital format as a possible alternative** to the traditional physically “on-product printed” **markings** and other “on-paper” support of various **administrative requirements**.

In any case, this should be presented as a choice for economic operators to provide compliance information in such a digital format under entirely their own responsibility. However, in that latter case, the provision of the legally required information should be considered as fulfilled by market surveillance authorities.

This could apply to:

12. **Traceability requirements**, especially to the **address on products or packaging** (Blue Guide page C 272/52-54): we suggest that the requirement for a postal address on the product could be considered as fulfilled if the product or its packaging bears a **web address**: it would allow both market surveillance and end users to get quick access to the required information, including a unique physical address in several countries, which can be updated when needed. Interpreting traceability requirements may also allow for explicit icons to be used to identify the role of the economic operator whose name and address is provided with the product (manufacturer, importer, authorised representative).
13. **Electronic labelling**: as an alternative to the existing paper format, the manufacturer should be considered as complying with the law when mandatory **markings primarily intended for market surveillance or business-to-business purposes** would be provided in a digital format. This would be relevant to the **CE marking** and for example the specific '**ATEX**' marking for explosion protection  ("epsilon-x", or "the hexagon") followed by the symbol of the group and category of products. Such markings could be considered as 'affixed' when provided either as part of the declaration of conformity in a portable document format (PDF), in a HTML format in a Web-based document repository hosted by the manufacturer (which could be prompted by e.g. a QR code on a smart portable device connected to the Internet) or through an electronic built-in display screen on the product.
14. **Declaration of conformity** (Blue Guide page C 272/55): as an alternative to the existing paper format, the manufacturer should be able to **provide the declaration of conformity** with applicable Union harmonisation legislation **in electronic format**, such as in a portable document format (PDF, via electronic mail) or in a HTML format in a Web-based document repository solution hosted by the manufacturer.

4. DIGITALISED INSTRUCTIONS AND SAFETY INFORMATION FOR PRODUCTS

Orgalim proposes that wherever it is possible without contradicting the law, the Blue Guide suggests that the manufacturer could provide the instruction for use in electronic format, as an acceptable alternative to the printed paper format. This could be done via an electronic label/QR code which would prompt the end-user to read on a Web page or download in PDF format the full documentation in the language of the user's choice.

This would provide many benefits to all parties:

- **Cost efficiency** for the product manufacturer (no printing and packaging costs for the documentation), the carrier of the product (smaller packaging, lighter shipping and handling especially for small items such as electric fuses) and the end-user (cheaper prices);
- **Resource/Environmental efficiency**: saving on paper pulp production, inking, and printing, transport, and recycling of used paper instructions or outdated instructions;
- **Safety efficiency**: several studies give rise to concerns as to the ineffectiveness of paper instructions to draw the user attention to safe practices on using technical products, especially for products used by untrained professionals or consumers. The digital era provides for much more efficient alternatives such as:
 - **Automatic on-display-screen-warnings** in the chosen user's language after the initial setting-up of the product. This could be considered as a valid alternative for electronic equipment and machines fitted with a built-in display screen.
 - **A picture or video format of warning messages and user instructions** often prove to be more fit for purpose than a cumbersome to read, paper format (which is often lost or deteriorates after a while).
 - **Key word searches throughout the operating and safety instructions**, prompted on the user's personal smart telephone/device, could more efficiently assist the user throughout the lifetime of the product. If web-based, these safety instructions could be usefully updated and improved over time, as opposed to a printed copy.

For more details, see "Orgalim Contribution to the Guide of Interpretation to the Machinery Directive" released on 26 September 2019: <https://www.orgalim.eu/position-papers/machinery-directive-orgalim-contribution-guide-interpretation-machinery-directive>

5. NEW PROVISIONS IN REGULATION 2019/1020 ON MARKET SURVEILLANCE AND COMPLIANCE OF PRODUCTS

a. JOINT INITIATIVES WITH MSAs (Reg. 2019/1020, Article 9)

Orgalim welcomes the provision of Article 9. Which paves the way forward to a more efficient and effective market surveillance for both off-line and online products; we consider that future joint initiatives, whether at national or European level are necessary to make more intelligence and knowledge available to market surveillance authorities, because there is no other way to bridge their lack of human and financial resources.

Therefore, we believe it is essential to incentivise Member States Authorities (MSAs) to enter as soon as possible into such partnerships with trade associations representing the interest of manufacturers. To that end the Blue Guide should provide clarifications on the application of Article 9 of Regulation 2019/1020.

In support of clarifications in the Blue Guide, Orgalim is ready to proactively work with all interested parties, possibly within an ad hoc sub-working group of the Union Product Compliance Network, to develop more specifically:

- **A charter of standard conditions** for authorities to conclude agreements with "organisations representing economic operators or end-users carrying out joint activities",

- clear **criteria** for assessing the **objectivity, independence and impartiality** of the parties or creating unfair competition between economic operators in implementing the referred **joint activities** under Article 9 of Regulation 2019/1020.

We can draw on the experience we have gained over the past few years in supporting the secretariat of the Market Surveillance Support Initiative of electrical manufacturers, MSSI Electrical: <http://mssi-electrical.org>.

b. PRESUMPTION OF NON COMPLIANCE (Reg. 2019/1020, Article 11 paragraph 9)

Regulation 2019/1020 establishes the principle of presumption of non-compliance: "(...) Products that have been deemed to be non-compliant based on a decision of a market surveillance authority in one Member State shall be presumed to be non-compliant by market surveillance authorities in other Member States".

Orgalim wishes the Blue Guide to provide concrete guidance on the conditions of application of this article to safeguard the rights of manufacturers, who have timely responded to an MSA request for evidence of compliance according to Article 7 of the Regulation on 'Obligation of cooperation', but do not agree with the interpretation and decision of the national enforcement authority of one of the Member States.

In the latter case, guidance and criteria would be welcome as to when or under which circumstances an MSA in another Member State could have a second opinion, based on existing material provided by the manufacturer, or conditions under which material might be needed. Such guidance would be helpful to businesses that experience unfair treatment in the first Member State.

c. PRODUCT RECALL (Reg. 2019/1020, Article 3 (22) and Article 20 'RAPEX')

Orgalim wishes to see clarifications as to the definition 22 in Article 3 of the new Regulation 2019/1020 which describes a recall as 'any measure' aimed at achieving the return of a product that has already been made available to the end user. For instance, it might be desirable to set a limit as to how long market surveillance authorities could reasonably and effectively request a product to be recalled by the manufacturer of this product. If a product was placed on the market more than 10 years ago can it still be requested to be recalled?

d. RECOVERY OF COSTS BY MARKET SURVEILLANCE AUTHORITIES

(Reg. 2019/1020, Article 15)

Without prejudice to the discretionary powers of MSAs, we strongly suggest that the Blue Guide provides general guidance to MSAs as to what they may ask business operators to pay for and to provide as a justification for the costs they claim recovery. For example

- Number of samples for testing;
- Assistance from external consultancies taking into account the minimum level of knowledge which MSA is expected to have;
- Analysis of the test reports made by accredited conformity assessment bodies, when these exist.

Furthermore, it should be clear that MSAs can only claim costs related to assessing the non-compliance of a product when it has been proved; MSAs may not claim the recovery of their running expenses that are already covered by their general operating budget, such as a site-visit or standard market surveillance check.

6. SECTIONS OF THE BLUE GUIDE THAT SHOULD REMAIN ESSENTIALLY UNCHANGED

Orgalim believes that some sections of the Blue Guide do not need to be challenged in their essence:

- **The overall concept of 'placing on the market' should not be changed.** While its application could be clarified through practical examples (see section 2, paragraph 2), Orgalim industries happily rely on the current interpretation provided by the Blue Guide. In particular, it is key to preserve the 'timestamp' element linked with the first making available of a product on the market to analyse the split of responsibilities among economic operators (and possibly of liabilities for defective products). This is especially important to preserve legal certainty in the following cases:
 - a software update by a third-party to the manufacturer and which would affect the safety features of the product after its placing on the market;
 - a cyber-attack that would alter the safe operation of the product beyond the built-in cyber-security features at the time the product was placed on the market.
- **The section on the use of harmonised standards** in support to the application of Union harmonisation legislation. Orgalim strongly disagrees with the Commission's interpretation of the legal effect and corresponding administrative steps which it sees necessary for the citation of harmonised standards in the Official Journal of the EU. Therefore, before a mutually agreeable interpretation of the Regulation 1025/2012 is found among all stakeholders, we recommend keeping the Section 4.1.2. "conformity with the essential requirements: harmonised standards" unchanged.

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