

POSITION PAPER

Brussels, 17 April 2020

Orgalim comments on the Draft Guidelines for the practical implementation of Article 4 of Regulation 2019/1020 on market surveillance and compliance of products ¹

Open consultation until 17 April 2020 ([more](#))

EXECUTIVE SUMMARY

Orgalim thanks the European Commission for the opportunity to comment on the Commission's Draft Guidelines for the practical implementation of Article 4 and for the recent opportunity to discuss the preliminary text of these guidelines during a stakeholder workshop on the 21 February 2020.

In this position paper we insist on the need for such guidelines to:

- 1) **Complement without preempting the general Blue Guide** on the implementation and application of Union harmonisation legislation, whose general concepts and definitions should be clarified in this Blue Guide rather than in guidelines specific to the application of Article 4 of the Regulation 2019/1020 on market surveillance.
- 2) **Help to ensure a level-playing field between manufacturers established within the EU and those established outside** while providing more legal certainty for the responsible economic operator acting on behalf of a non EU-based manufacturer.
- 3) **Refrain from adding unnecessary administrative requirements** which would not be specified in sector-specific legislation for the sake of evidencing traceability and compliance requirements, whose digital format should wherever possible be regarded as acceptable as an alternative to the printed format, upon the free choice of the economic operators.
- 4) **Encourage an effective and proportionate enforcement of the application of this Article 4**, to contribute to the building of a safer EU single market with a chain of responsible economic operators.

We also encourage the Commission to promote integration of this product compliance culture and accompanying procedures in their bilateral or multi-lateral trade dialogues with other countries in the world.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019R1020>

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1. COMMENTS ON SECTION 1 – INTRODUCTION OF THE GUIDELINES

Page 1 (1st paragraph): EU legal requirements cannot “guarantee” safety, etc... therefore, we suggest using the more appropriate formulation “provide for a high level of safety” instead.

Page 2 (top): We disagree with referring in these guidelines to the economic operator located in the EU by the expression “**responsible person**”: this is misleading, as in national law it could refer to a specific individual while it is the legal entity concerned that is responsible, including designation of the competent member of staff that will carry out the appropriate tasks. We believe this is the reason why the EU regulator has not retained the EC proposal for a “person responsible for compliance information”. We suggest **using the expression** laid down in the legal text of the Regulation which is “**responsible economic operator**”.

2. COMMENTS ON SECTION 2 – SCOPE AND APPLICATION

Point 2 (top): Orgalim prefers a reference to the Blue Guide regarding the definition of “placing on the market”, because it is a horizontal concept which does not pertain to this Regulation only, in contrast to the one of “responsible economic operator”.

Besides, the explanations of how market surveillance authorities (MSAs) will assess whether an offer is targeted at end users in the EU are not convincing. In particular, the “available language” is an unreliable criterion as several European languages are national languages in several other countries of the world, such as English, Spanish or French. We suggest discarding this criterion.

Point 2.2.: Orgalim suggests

- **a reference to the Blue Guide regarding definition of “placing on the market”**, because it is a horizontal concept which does not pertain to this Regulation only, in contrast to the one of “responsible economic operator”.
- **using the legal wording, wherever possible**. For instance, the proposed text in the guidelines of a “product... supplied for distribution” we prefer “product... available for distribution” which removes the misunderstanding that the product may have already been released for free circulation at a point of entry to EU territory.
- With regard to who can be the responsible economic operator, **a decision tree may help**:
 - It would be clearer to start with the manufacturer’s choice to designate an authorised representative to carry out the tasks set in Article 4: yes/no. This would then determine the fallback option(s) on who takes over the responsibility in case no such choice has been made and formalised in a mandate.
 - This would be clearer, as it would not create confusion about what matters first:
 - the physical establishment of a responsible entity in the EU territory (designated or not),
 - not that the manufacturer is established outside of the EU; in modern and globalised supply chains, the manufacturers’ headquarters are often established

outside the EU, although the actual manufacturing or assembly of the final product is done within the EU.

Point 2.3. (last but one sentence): Orgalim asks for clarification that the manufacturer can choose the format for providing authorities with the contact details of the economic operators responsible for compliance information.

While sector specific legislation often mentions a postal address as an administrative obligation, there is no specification in Regulation 2019/1020 for other mandatory contact detail formats. These guidelines could usefully provide a list of examples such as an email address and/or a telephone number. More alternatives should be provided such as a web address where all the contact details could be found or even a QR/ bar code providing such information on a mobile device with or without an internet connection.

3. COMMENTS ON SECTION 3 – TASK OF THE RESPONSIBLE ECONOMIC OPERATOR

Orgalim recommends referring as often as possible to the Blue Guide for the exact extent of responsible economic operator tasks. We believe that the added-value of this section would be to explain the cooperation duties of responsible economic operators, especially if they are not supported by a clear mandate from the manufacturer. In particular, the guidelines should detail what is meant by the expression “mitigate the risk” depending on the role of the economic operator down the supply chain, bearing in mind that these operators cannot be sanctioned for the non-compliance of the product itself, but only for knowingly exposing their customers to the risks deriving from the product non-compliance.

Top of page 7: In order to clarify that the technical file as a whole does not need to be handed over to the requesting authority, Orgalim suggests clarifying that only "**relevant**" **technical documentation** should be provided to those authorities.

4. COMMENTS ON SECTION 4 – PRACTICAL IMPLICATIONS FOR THE DIFFERENT TYPES OF ECONOMIC OPERATORS

Orgalim strongly recommends referring to the content of the Blue Guide for this section.

Point 4.1. (practical obligations for a manufacturer in the EU), page 8 last paragraph: Orgalim urges the Commission to formulate this section not only in the form of possible additional sector-specific requirements, but also in the form of possible alternative formats. The affixing of electronic traceability could be regarded as a valid alternative to fulfil the legal obligation of contact details on the product or packaging (see above our view on point 2.3).

Furthermore, these guidelines should also recall the **principle of equal treatment** for manufacturers and other economic operators established in **non-EU countries with which the EU has concluded specific agreements**, such as Mutual Recognition Agreements (e.g. with Switzerland), Free Trade Agreements (e.g. with EFTA and soon the UK) and Customs Union Agreements (e.g. with Turkey).

It should be explicitly clarified that, where such agreements state that manufacturers established in these non-EU countries are to be treated in the same way as if they were established in the EU with regard to their obligations under EU product legislation (cf. for example the MRA EU-Switzerland of 2017), this should also apply to their tasks and obligations under Article 4 of this Regulation (EU) 2019/1020.

5. COMMENTS ON SECTION 5 – MARKET SURVEILLANCE AND CONTROLS AT CUSTOMS

Orgalim welcomes EU-wide campaigns to raise awareness of the responsibilities of various types of economic operators regarding their cooperation duties with market surveillance authorities, especially those that make products available for the first time on the EU single market without a clear mandate from the manufacturer of those products.

To strengthen the practical effectiveness of Article 4, we suggest the Commission encourages market surveillance authorities to take dissuasive but proportional sanctions against economic operators that disregard their duties to cooperate fully with them, in the upcoming revision of the Blue Guide.

In relation to Point 2.2 of section 2, the guidelines should clarify that the manufacturer cannot always be held liable for a product that does not bear the contact details of a responsible entity established within the EU on it or its packaging; often products are imported into the EU by third parties when they were not initially intended for EU customers by the manufacturer. Whether an email address, a telephone number or any other contact information, these could easily be faked and should not stop authorities acting. Authorities could for instance request the economic operators in the European distribution chain to trace the economic operator responsible for placing the product on the single market.

6. LAST COMMENT ON THE PLANNED EVALUATION OF ARTICLE 4

Besides drawing up guidelines for the practical implementation of Article 4, the Regulation requires the Commission to prepare an evaluation report by the 16 July 2023 on the implementation of Article 4, and in particular its scope, effects, costs and benefits (cf. Article 42 paragraph 3).

Therefore, Orgalim calls on the Commission to explain in these guidelines how it intends to fulfil this requirement with particular attention to the collection of high-quality data and key performance indicators that it would apply.

This would be especially relevant to assess the level playing field and legal certainty that economic operators based in Europe deserve when they take responsibility under Article 4 for a non-EU based manufacturer (for instance, one of their sub-component suppliers).

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