

POSITION PAPER

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For a restored mutual trust in a market-relevant European Standardisation System

Orgalim answer to the Consultation of stakeholders on a Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 (11 July 2019) - Ref. Ares(2019)4465012

EXECUTIVE SUMMARY

In a recent letter, the European Commission consulted stakeholders on a 'Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012' (11 July 2019) - Ref. Ares(2019)4465012.

Orgalim sees value in such Guidance provided that it builds on prerequisites of mutual confidence and trust in the European standardisation system, to bring value to and perspective for the parties involved. Unfortunately, such prerequisites are not reflected in the tabled Commission Communication on "Harmonised standards" of 22 November 2018, despite three years of interactive dialogue within the Joint Initiative on Standardisation.

Further steps must be taken by the European Commission to build a better relationship with the standardisation community. Applying legal formality to the standardisation process does not fully address the changes needed to modernise the public-private partnership between the European standardisation organisations and the Commission. The resulting output – **harmonised standards to support the application of EU law – should remain both technically and commercially market relevant** to the industry stakeholders who are the primary target of Union harmonisation legislation and users of standards.

We need common ground between the Commission, the European standardisation organisations and standardisation stakeholders, and above all with industry. Without common ground, producing a 'Guidance' risks adding confusion and will not avoid conflicts between involved parties.

Therefore, **we call on the Commission to launch a thorough discussion among the key stakeholders – including the European technology industries – to restore trust and confidence in the European standardisation system**. Such a discussion would start after an **independent assessment of the legal basis, proportionality and impact on stakeholders** of the formal legal steps that the Commission has set out prior to the citation of European harmonised standards in the Official Journal of the EU. Thereafter, the drafting of application guidelines could deliver a commonly shared approach, as does the Blue Guide for the application of Union harmonisation legislation.

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.

Introduction

Orgalim believes that there is an urgent need to restore and maintain confidence in the good performance of the European standardisation process. This should facilitate the free circulation of goods without unnecessary administrative burden, to support the application of technical legislation aligned with the New Legislative Framework (NLF), the Construction Product Regulation (CPR) and the General Product Safety Directive (GPSD). Such confidence will only result from a shared trust derived from a mutual recognition of the role and competence of involved parties.

Legal certainty, predictability, efficiency and transparency are more essentially rooted in Union harmonisation legislation aligned with the NLF than in Regulation (EC) 1025/2012 on European standardisation, which merely describes the role of the Commission and other parties in using harmonised standards to apply Union legislation.

In Orgalim's view, the Commission has a duty to monitor the overall quality of the European standardisation system, to ensure the smooth functioning of the internal market, including the relevance of harmonised standards for end-users. Its role is not to control each technical specification detail of the requested harmonised standards, in line with the Council Resolution of 7 May 1985 on the New Approach¹. If this is done only for legal purposes it might not be practical for the market and the resulting harmonised standards will not be used (see our views in the Annex under the point 3.1.a on the responsibility of the Commission regarding the preparation and the adoption of standardisation requests).

Compliance of products with the essential requirements of Union harmonisation legislation is ultimately not the Commission's responsibility. This is the responsibility of manufacturers when designing products and Member States through enforcement, as laid down in the recently adopted Regulation on market surveillance and compliance of products².

Therefore, Orgalim calls on the Commission to:

- **Initiate an independent assessment of the legal prerequisites, proportionality and impact on stakeholders of the formal legal steps that the Commission has set out.** This should take place prior to the citation of European harmonised standards in the Official Journal of the EU, as described in its Communication on "Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market" of 22 November 2018 .
- **Set up a key stakeholders' group to provide input on guiding the work of this independent assessment, with consideration for both the legal prerequisites and the practical implications for stakeholders.**

¹ See section X.2 on page C 136/8 of the OJEU: <https://publications.europa.eu/en/publication-detail/-/publication/9f7c3a42-449e-4ccc-9a29-5a544003b338/language-en>

² Regulation (EU) 2019/1020:

Orgalim answers to the questions raised

1. **Do the foreseen elements of the Guidance cover the relevant aspects of the process of harmonised standards development, which require clarification in order to improve its transparency and increase its predictability and efficiency?**

We believe that the planned Guidance should clarify the nature and role of standards in relation to European Union legislation.

Whilst we acknowledge that a certain level of control on submitted harmonised standards is needed, we wish to draw your attention to the following elements:

- the **Commission's main mission** is to ensure the prerequisite confidence of Member States in the smooth functioning of the New Approach system to ensure the free circulation of goods under Article 114 Treaty on the Functioning of the European Union (TFEU);
- **harmonised standards** should remain a trustworthy reference tool for Member States' market surveillance authorities as well as end-users, certifiers, and Annex III organisations, so that they can remain confident in the presumption of conformity attached to the use of such harmonised standards;
- **the legal effect attached to the citation of harmonised standards in the OJEU has no impact on the placing of products on the market until these standards are used**, voluntarily for most products, by manufacturers and other economic operators, according to the various procedures laid down in EU law to demonstrate conformity with it.
- **Compliance of products with EU law is the primary responsibility of manufacturers** and other economic operators, not the Commission, as clearly stated in all basic acts of Union harmonisation legislation.
- **The verification of such compliance is the primary responsibility of Member States authorities**, even in the face of a manufacturer's claim of the benefit of the presumption of conformity with EU derived from the use of harmonised standards that were cited in the OJEU, as clarified in the CJEU Court cases.

2. **Are there any particular aspects from the recent relevant case law that you would like to see addressed in particular in this Guidance?**

Yes, we have an additional comment pertaining to the explicit timeline obligations for improving the **efficiency and predictability of the system**, which has been altered by the Commission's internal decisions further to the relevant case-law:

a. EC to commit to an explicit timeline for action

The Guidance should commit the Commission to an explicit timeline for checking harmonised standards prior to their citation in the official journal. Where the relevant services of the Commission in charge do not have sufficient time, resources, or expertise available, the Guidance should reassure involved stakeholders

and future users of the standard that the Commission's decision will not be delayed and that the standard title will be cited in the OJEU within a reasonable time.

This particular aspect of the citation "without delay" of a harmonised standard in the OJEU is a prerequisite according to both Article 10(6) of the Regulation 1025/2012 and the Court of Justice of the European Union (CJEU) ruling in the case [Global Garden \(26 January 2017\)](#). This case law criticises the Commission for having "very significantly reduced the number of harmonised standards which can be used" and "therefore adversely affects the effectiveness of the system" (whereas 66). It further insists that the Commission's decision "conflicted with the [NA] system" and that such "adverse effect" did "not contribute, at least during a certain period, to facilitating the free movement of goods in the internal market" (whereas 67).

b. The Commission to commit to increased capacity to meet its self-instated set of obligations

It appears that the Commission seeks legal certainty for itself under Article 340 of the Treaty. However, we consider that the likelihood of the Commission being challenged in the future by economic operators under Article 114 of the TFEU is much more relevant and acute if the Commission's verification process before citation in the Official Journal of the European Union (OJEU) is not drastically improved and speeded-up. To avoid increasing the backlog of non-cited harmonised standards, we advise the Commission to increase staff levels and proficiency to cope with the workload in proportion to the extent of legal scrutiny it still wishes to apply in line with the Article 10 of the Regulation 1025/2012. Otherwise, the Guidance will fall short in practical application.

3. Do you have any other comments?

In our view, it is high time to reassure manufacturers with an operating base within the EU, and especially the standardisation community which is to a large extent dependent on the expertise and funding from the industry, that the Commission trusts the European standardisation system.

a. The Commission to flag clearly that the European standardisation system could be trusted

Therefore, we invite the Commission to make use of this planned Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 to:

1. **Acknowledge that harmonised standards are a legal facilitation for end-users** to operate within the EU internal market, under Article 114 TFEU, even though their citation in the OJEU may grant a legal effect to their use.
2. **State its confidence in the accountability of the European standardisation system**, with which it has established a public-private partnership, to conceive, manage and monitor the development of standards in an open, transparent and inclusive way.
3. **Preserve enough flexibility in its standardisation requests to allow the development of standards requested by the market and a swift citation of submitted harmonised standards**, without systematic 'sunset' deadlines, requests for dated references or detailed cross-referencing to primary EU law (Annex ZA/ZB/ZZ).
4. **Respect the procedures and timelines for developing European standards**, which are often initially led by the ISO and IEC international standards organisations, by making sure that all the

stages of Commission's joint assessment with ESOs prior to a citation in the OJEU is done well ahead of the final voting of the final draft standards.

Without such clarifications, we fear that the planned guidelines risk adding confusion to industry stakeholders as the primary users of standards and addressees of Union harmonisation legislation.

b. We are pleased to provide our detailed comments in the Annex.

In view of such a fundamental preliminary step – working on a common understanding of the legal prerequisites and their impact on the ESS and its stakeholders– we are pleased to submit our recommendations on the functioning of the European standardisation system so that it can provide legal certainty, predictability, efficiency and transparency to all parties in support of the application of Union legislation (see enclosed Annex).

Annex

to Orgalim draft answer to the Consultation of stakeholders on the Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 (11 July 2019)

Detailed Orgalim views on the planned sections of a possible Application Guide

1) Objective:

- legal clarity

Regulation (EU) 1025/2012 of 25 October 2012 on European standardisation is based **“in particular”** on **Article 114 of the Treaty** on the Functioning of the European Union (TFEU) about “measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market” [Article 114 §1]. Therefore, Orgalim supports the creation of guidelines which should clarify as precisely as possible the roles and responsibilities of relevant parties involved with harmonised standards used to support the application of Union legislation - **with the good functioning of the internal market in mind** - as noted by the Court of Justice of the EU (CJEU) in the Global Garden Case.

- legal certainty

Legal certainty for economic operators is the assurance that they will not suffer any barrier to trade in placing their goods and services on the internal market provided that they show compliance with the high level of safety set in Union harmonisation legislation. The New Approach to technical harmonisation³ has been successful in that the use of harmonised standards establishes trust among Member States in economic operators’ presumption of compliance with Union law requirements. Likewise, under the responsibility of Member States’ authorities to police their own markets, economic operators could remain competitive in fulfilling their market needs. Such needs are highly dependent on globalisation and rapid technological changes, often reflected in the development of international standards. To address these challenges to their competitiveness, economic operators expect European harmonised standards to match the latest state-of-the-art developments in a timely manner.

Orgalim believes it is necessary for the good functioning of the internal market to ‘enforce’ Regulation (EU) 1025/2012 with due consideration for these present and future economic and technical realities. To achieve this, the Commission should not systematically hold a candidate harmonised standard as a draft Union Act over which it would have full ex-ante control. This goes against four decades of smooth operation of New Approach legislation, and will confuse industry, as the addressee of Union harmonisation legislation, as to what is the relevance of the legislative (essential) requirement compared to a technical specification in a harmonised standard.

³ The better regulation principles of the New Approach to technical harmonisation and standards have been laid down in the Council Resolution of 7 May 1985

The recent changes to both the formal statute of standardisation requests and the citation of harmonised standards in the OJEU may trigger diverging interpretations from market surveillance authorities across the EU and give rise to more in-depth judicial review on the role of standards as implementing measures of EU law. As stressed by the CJEU in the [Global Garden Case T 474/15 \(paragraph 63\)](#), depriving economic operators of the potential benefit of using harmonised standards is against “*the application of the principle of legal certainty*”⁴.

- **Transparency**

Orgalim recognises that the Joint Initiative on Standardisation has improved transparency between stakeholders and we encourage the active use of the outcomes of the initiative in all areas. However, we also look forward to a deeper cooperation between the Commission and the standardisation community that is based on an open dialogue.

Transparency is necessary for both parties. It should apply as much to the Commission’s internal decision-making process and the HAS processes as to the development of harmonised standards. It is essential to secure the confidence of the standardisation community that they will not lose the result of their hard work because of a verification process that remains unspecified in time and unjustified in relevance, especially if it is dependent on the positive opinion of the HAS consultant.

Orgalim recommendation:

A suggestion to improve transparency could be to introduce an online system, similar to the legislative train of the European Parliament website, to track the mandate/ development/ conformity check/ citation stage of standards. This would allow stakeholders to easily consult the current status of the standards they are interested in.

- **Predictability and efficiency**

A functional New Legislative Framework (NLF)⁵ brings predictability and legal certainty for manufacturers for the placing of their products on the internal market: The publication of the reference of harmonised standards in the OJEU prompts economic operators to make use of harmonised standards. Depending on the applicable conformity assessment procedure, their claim to the benefit of the presumption of conformity by use of harmonised standards (in the Declaration of Conformity) binds Member States to accept the availability of the product in their territory - unless they rebut it by demonstrating an infringement of the essential requirements of the harmonisation legislation.

⁴ The ECJ has annulled a Commission Implementing Decision (EU) 2015/902 of 10 June 2015 on a measure taken by Latvia in accordance with Directive 2006/42/EC to prohibit the placing on the market of a lawnmower manufactured by an Italian manufacturer. Namely, the Court ruled that the Commission decision had an adverse effect as it resulted “*in a type of machinery which has been covered for several years by a published harmonised standard being ‘without a harmonised standard’ during (...) approximately 15 months before obtaining a new published harmonised standard*”. Consequently, according to the Court, “*the Commission position, (...) results in very significantly reducing the number of harmonised standards which can be used during the early part of the application of that [new EU legislation] and therefore adversely affects the effectiveness of the system*” (Paragraph 67 of ECJ Ruling of 26/01/2017 in the Case T 474/15 that upholds the claim of Global Garden Products Italy SpA (GGP Italy) against the European Commission): <http://curia.europa.eu/juris/document/document.jsf?text=&docid=187179&pageIndex=0&doclang=EN>

⁵ The NLF is formed by [Regulation \(EC\) 765/2008](#) on accreditation and market surveillance, [Decision 768/2008 \(EC\)](#) on a common framework for the marketing of products and [Regulation \(EU\) 2019/1020](#) on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011.

Such facilitation remains helpful only if it is timely for economic operators and does not depend on the discretionary decision of the Commission whether or not to cite a harmonised standard in the OJEU. The recent one-sided decisions of the Commission to apply legal formality to this process do not make it more efficient or predictable for economic operators.

Orgalim recommendation:

We suggest setting up an ad-hoc task force which would not only involve the Commission, EFTA, Member States and stakeholders mentioned in Regulation (EU) 1025/2012, but also industry stakeholders. This task force would assess the legal prerequisite and the proportionality of legal formal steps on the Commission side, to preserve the market relevance and the timeliness of the process.

2) Scope of the Guidance

a) whole process of the development of harmonised standards

We welcome the Commission's plan to address in the planned Guidance the whole process of initiating, developing, adopting and citing in the OJEU harmonised standards. We hereby provide detailed suggestions as to the content under the section "3) Structure of the Guidance".

b) Articles 17 and 18 of Regulation (EU) No 305/2011 on construction products

The predictability, transparency, and efficiency of the standardisation process is equally relevant in the construction sector⁶.

The backlog of completed harmonised standards that are not cited in the OJEU creates a significant obstacle for manufacturers to quickly place their products on the European single market and undermines their drive for innovation. The situation has affected construction product manufacturers more than those of any other sector because of the compulsory use of harmonised standards under the CPR, which differs from that of standards under legislation following the New Legislative Framework (NLF). This, in turn, leads to further application issues as manufacturers struggle to find solutions that often vary across Member States.

To remain relevant to both international and European market needs, European harmonised standards under the Construction Product Regulation should not deviate from international standards for purely legal reasons.

To avoid future errors, the guidelines concerning denial or rejection of a draft EN ISO/IEC standard submitted as a harmonised standard if not all the essential requirements of the Construction Product Regulation are met in the technical specifications of that standard should be clarified.

In addition, there are issues linked with legal certainty, because of the varying interpretations on how to use standards to draw up a Declaration of Performances (DoP), the format and content of the DoP document, or the obligations of the economic operators under the CPR. This results in hindering the free circulation of construction products in the EU.

⁶ See [Orgalim position paper on the revision of the CPR, 14/05/2019](#)

Orgalim recommendation:

Orgalim urgently calls for an improvement in the basic objectives of the standardisation process to support the application of the CPR: for example to clarify product-specific classes, thresholds revision and voluntary characteristics versus essential characteristics. We have provided further suggestions for improvement in our position paper on the Construction Product Regulation of 14 May 2019.

c) Article 4 of Directive (EC) No 2001/95 on general product safety

The procedure laid down in the GPSD Article 4 provides a presumption of conformity for users of harmonised standards cited in the OJEU under the GPSD, in a very similar way to NLF legislation. As the fundamental requirement in the GPSD that consumer products shall be safe is unspecific, it is therefore essential for the Commission to set the content requirement more precisely in the standardisation request.

3. Structure of the Guidance**3.1 Standardisation request**

Orgalim views on the elements that the Commission intends to address in this Guidance:

a) Responsibility of the Commission with regards to the preparation and adoption of standardisation requests

Orgalim believes that the planning of standardisation requests should acknowledge the reality that, as stated in Article 10.1 of Regulation 1025/2012 (the enabling act), “European standards and European standardisation deliverables shall be market-driven”.

In our view, it would be inadvisable to handle the planning of standardisation requests only by considering the ability of the expected standards and other deliverables to support the application of EU law; legally inspired scrutiny should not come at the expense of manufacturers’ innovation capacities, the timely marketing of their market-relevant solutions and, finally, their ability to compete at a world level with the faster-to-market users of international standards.

In addition, the market relevance of all standardisation requests should be examined. Only market-relevant standards fulfil their purpose. Normally, standardisation projects are initiated when there is a market demand (bottom-up approach). Standardisation projects that are driven by political decisions only (top-down approach) entail the risk of not being relevant to the market.

As per the last four decades of successful New Approach application, future standardisation requests should trust European Standards Organisations to initiate new standard projects and adapt existing standards. We therefore see no need, even in the light of the reading of European Court cases, for the Commission to change standardisation requests in their current form or set them a limited life span.

Orgalim recommendation:

We advise the Commission to focus on the “policy objectives” of future standardisation requests as clearly as possible with due consideration for the needs of end-users (often the industry stakeholders including SMEs) to ensure that the requested European harmonised standards will remain attractive to them. To facilitate this, we call on the Commission to consult not only the European Standardisation Organisations, but also the industry sectors concerned at an early stage of the preparation of a standardisation request. The Standards Market Relevance Roundtable “SMARRT”, created as a result of the Joint Initiative on Standardisation (JIS), is a suitable platform for such a consultation.

b) Need for a clear definition of the scope of standardisation requests

Taking into account state-of-the-art developments is one of the core principles for standardisation to respond to rapidly evolving market needs. This requires maximum flexibility.

Therefore, we call on the Commission to refrain from short-listing standards that need to be developed or revised in future standardisation requests. There is no legal basis in Article 10 of the Regulation for such a discretionary Commission **requirement**: Article 10 §1 requires ESOs to deliver according to “the public interest as well as the policy objectives clearly stated in the Commission’s request” and “after consultation” of “stakeholders” and “sectoral experts”.

Draft standardisation requests should continue to trust European Standards Organisations to review periodically and amend (harmonised) standards with due care to meet the essential requirements in EU law, as has been the case for over three decades of successful operation of the New Approach to technical harmonisation.

Orgalim recommendation:

The scope of standardisation requests should be limited to “policy objectives” that are in line with:

- technically open “content requirements” with room for adaptation to the state-of-the-art
- flexible deadlines for the development of standards agreed case by case
- minimal formalistic constraints (e.g. *ad-hoc* Annex Z and dated references) that may facilitate the Commission’s administration, but are to be balanced with the costs and loss of time-to-release that such constraints have on the main funders and users of standards.

c) Need for a clear definition of the temporary validity of standardisation requests

Naturally, the Commission remains in control of the decision to start a revision of a standardisation request whenever necessary, further to the opinion of Member States and standardisation stakeholders in the Committee on Standards. This could be done on a case-by-case basis: for instance, in the annex to the rejected standardisation request (as shown in the Annex I table 1 and 2 of the draft standardisation request on Personal Protective Equipment (PPE)).

However, a new standardisation request should not include a date of termination. Otherwise, every time a standardisation request ends it would require the Commission to undertake the lengthy and detailed adoption procedure of a new or revised standardisation request.

Given the lack of resources and technical expertise of the Commission – even with the support of a handful of HAS consultants – this would represent a bureaucratic obstruction with a disastrous impact on the standardisation process and position of existing standards:

1. We see more confusion arising from a conflicting situation: on the one hand cited harmonised standards that will continue to give a presumption of conformity based on an ended standardisation request, while on the other hand updates of such standards that will suddenly lack a legal basis for standards users to claim presumption of conformity until the Commission adopts a new standardisation request. This will trigger more legal uncertainty and unpredictability for manufacturers placing their harmonised products on the internal market.
2. Eventually, such a situation would increasingly create an imbalance between international standards adopted as soon as they are technically ready and non-cited European standards based on the latter. This would be unfavourable to the technology industries operating in Europe, and create an unnecessary impediment to their competitiveness. They would be obliged to either choose more costly conformity assessment procedures or to delay the marketing of their products until the standards could be adopted as harmonised standards with a valid legal basis.
3. It will impact the workload of European standardisation experts who will be obliged to change all linked harmonised standards and adapt them for purely legal reasons.
4. It will deter the many technical experts, sponsored voluntarily by private companies, to continue to invest in the European formal standardisation process. They currently contribute through financing and in kind to 95% of the European standardisation system costs.

Orgalim recommendation:

we advise the Commission to refrain from including a prescribed date of termination in all new standardisation requests.

d) Indication in the requested documents of the correspondence between the technical specifications and the legislative requirements they aim to cover

○ **Annex Z: Cross-references to the essential requirements in EU law**

In its new model of standardisation requests, the Commission requires standardisers to always present a so-called 'Annex ZA' (for CEN standards) or 'ZZ' (for CENELEC standards) that establishes a correspondence between each technical specification in harmonised standards with the corresponding essential requirements in the Union law. This is requested even for cases where the piece of Union law does not specify the essential requirements in a suitable format (e. g. Machinery Directive 2006/42/EC). There are no requirements in Regulation 1025/2012 that impose such a systematic requirement. When acknowledged by all parties as both necessary and useful, it is a complex task to achieve.

Indeed, harmonised standards, like any other standards, are drafted by experts from interested parties to assist the designers of products, processes and systems in their technical work. Their technical content differs greatly in both form and content from legal provisions in regulations. For instance, standards may not always cover all the essential requirements of EU law, especially if these standards are developed under the Vienna or Frankfurt agreements in the respective international ISO or IEC committee.

Therefore, seeking to assert through a legalistic approach that technical standards should always coincide with the essential requirements of EU law can create a misconception which deters technical experts from constructively participate in formal standardisation. When not acknowledged by technical experts, the requirement of an annex Z increases the administrative burden of the standardisation process and eventually generates more European deviations to international standards for no reason .

Orgalim recommendation:

The Commission should consider requiring an annex Z in requested standards for new or revised standards, only after consideration of the opinion of the ESOs / technical committee(s) concerned (including its level of detail), in view of the joint assessment foreseen in Article 10(5) of Regulation (EU) No. 1025/2012). For existing standards without annex Z, introducing such an annex Z should not be the only reason to call for the revision of the standards, especially if these are considered as state-of-the-art by the end-users and are satisfactory in use.

○ **Dated normative references to standards**

A normative reference is a document to which reference is made in the standard in such a way as to make it indispensable for the application of the standard (C.f. CEN "BOSS" Guidance document [here](#)).

There are no requirements in Regulation 1025/2012 that impose dated normative references in standards. In many technology areas, technological changes cause the market to update standards at a rapid pace, especially in the ICT fields. This may require many other standards referred to by those updated standards to have the dated reference changed. We believe that this would be time-consuming and complicated, and would disproportionately impact the workload in some standardisation technical committees for purely legal purposes. For those cases it could be much easier to recommend the ESOs to publish a list of the actual

versions of updated or new standards that are normatively referenced in a harmonised standard, to bring clarity to standards users as to which version reflects the latest state-of-the-art.

More importantly, the continuous updating process of the dated normative references in standards is very costly to companies: First, companies need to repeatedly purchase the latest version of all updated standards. As a practical consequence, certificates of conformity ought to be updated accordingly to refer correctly to the latest standards. Where Union law requires the mandatory involvement of a third party, companies are required to request them to update their certificates with reference to the latest standards, often with no added value from testing or evaluation of the product.

Therefore, it should be up to the experts in the standardisation technical committees to determine when dated normative reference are needed; these should not be the result of a systematic bureaucratic request.

Orgalim recommendation:

Future standardisation requests should consider, on a case-by-case basis, the need for such dated normative references in standards. While these could bring more clarity as to what are the relevant technical specifications that a manufacturer should comply with to claim the presumption of conformity, we strongly suggest that the Commission refrains from imposing them systematically in future standardisation requests. This is especially true where the legal text of the enabling act does not refer to a specific standard - for instance for a measurement purpose.

In addition, we call on the Commission to undertake a thorough cost-benefit analysis of its plan to require systematically dated normative references in standards, as we believe that its cost for companies would disproportionately discourage economic operators from using harmonised standards.

e) Elaboration and the nature of the work programme prepared by an ESO in response to a standardisation request

European standards organisations should continue to be regarded as competent, trustworthy and accountable; the ex-ante verification of the technical results provided in response to a standardisation request should be limited to some random checks of essential elements. The work programme prepared by an ESO in response to a standardisation request should allow a certain flexibility and should be of an indicative and not binding nature. In any case, the standardisation request should allow for the revision/amendment of already existing harmonised standards. Such flexibility would not be possible if the standardisation requests are formulated as a predetermined list of standards to be covered.

Orgalim recommendation:

We suggest allowing the possibility for ESOs' work programme to identify the need to develop additional standards so that new standardisation projects could be added beyond what was initially foreseen and acknowledged in the Commission request.

f) Procedure to amend standardisation requests.

The procedure should be as streamlined as possible so as not to risk delaying the preparation of required harmonised standards.

Orgalim recommendation:

For the sake of legal stability and continuity, the procedure to amend standardisation requests should foresee the application of the original identification number (less the year) on the new standardisation request; the version/date only should be adapted.

3.2 Assessment of the standard, publication of its reference in the OJ and formal objections

Orgalim views on the points that the Commission intends to address in these guidelines:

a) Submission of the standard and necessary documents to the Commission; the responsibility of the Commission and ESOs in the assessment of the standard;

The assessment of whether the requirements were fulfilled before publishing the references of the standards in the Official Journal should be made jointly with the ESOs, in accordance with Article 10(5) of Regulation (EU) No. 1025/2012), and not as a one-sided legalistic procedure.

Orgalim recommendations:

1. **harmonised standards that are indirectly referred to in EU legislation** as a voluntary tool for manufacturers to facilitate their demonstration of conformity with EU law. This latter category of standards is widely used in New Approach/NLF-type of legislation and cannot be considered as “complementary legislation”. The legal effect of such standards, once cited in the OJEU, is a legal benefit – to claim presumption of conformity in view of market access across the territory of all Member States.
For these standards, the CJEU noted that the claim of presumption of conformity does not preclude in any way whether or not the manufacturer has effectively and correctly applied the cited standards in the product's design. It is the primary duty of the Member States' authorities to conduct market surveillance inspections to deter such a situation - it is not the responsibility of the Commission.
Therefore, standardisation requests for voluntary standards (i.e. most product standards) should be subject to a lighter ex-ante control prior to their citation in the OJEU. The Commission should reverse its discretionary decision to publish the title of harmonised standards in the 'L' series of the OJEU, instead of the 'C' series as used to be the case over the past four decades as this is misleading.

2. **Harmonised standards that are directly referred to in EU legislation**, such as [Directive 2014/94/EU](#) on the deployment of alternative fuels infrastructure, which, for instance, directly refers to the use of EN 62196-2 and EN 62196-3 in its Annex II (technical specifications). Where standards become a de-facto mandatory 'complement' (but not a substitute for EU law), they may deserve a more in-depth scrutiny by the Commission prior to a citation in the OJEU.

b) Role of the "Harmonised Standards Consultants" in the assessment

Since the Commission took over CEN and CENELEC's administration of Harmonised Standards Consultants (HAS - formerly "New Approach Consultants") industry stakeholders have been confronted by two major issues disruptive to the legal certainty and predictability in using harmonised standards for placing products on the market:

- 1) **First**, we look forward to more transparency from the Commission administration and its contractor managing HAS consultants to disclose information on the capacity and expertise of the HAS consultants in the respective fields of standardisation. Standardisation stakeholders should be allowed to provide the Commission with feedback on the capacity and proficiency of the system of HAS consultants in an open, transparent and regular manner. Therefore we ask for:
 - A timely delivery of HAS consultant assessments to the standardisation committees
 - An improvement of the consistency of the HAS consultant assessments (across the different assessment stages for the same consultant and between different HAS consultants in a dedicated sector)
 - The establishment of a clear and transparent process for the recognition of the responses made by the standardisation committees in the case of non or partially compliant HAS assessment results in the crucial Formal Vote stage. This is an essential measure to increase the currently insufficient number of positively assessed standards before their publication.
- 2) **Second**, the HAS consultant's assessment often arrives too late to be effective in aligning the technical specifications with the set requirements in case of mismatch. This is commonly the case for CPR, LVD, EMCD, and RED standards. As the rules and guidelines are constantly changing, it is very difficult for the technical experts to follow these changes. We should make sure that both the essential legislative requirements and the complementary requirements of the standardisation request are taken into consideration from the early stages of the standard's development.
- 3) **Third**, the final HAS consultant's assessment should not take place prior to the Formal Vote on a draft harmonised standard which is developed in parallel with technical bodies of ISO or IEC (as is now the case contrary to homegrown European standards) but during the Formal Vote (FDIS). Recent experience has shown that this approach causes disruption to the process – over the past

two years in the machinery sector approximately 60 standards were approved before being rebuffed in the HAS consultant's assessment, and their citation in the OJEU was therefore adversely delayed. Such a situation is detrimental to the confidence of technical experts, especially to convince non-European member organisations who contributed to ISO and IEC to support further the development of parallel projects in ISO and IEC.

Orgalim recommendations:

- 1) The Commission, EY and ESOs should improve processes, consistency and transparency of the HAS consultant system and jointly create a "structural feedback mechanism". Such a mechanism would provide many benefits and would:
 - provide stakeholders that are active in the development of harmonised standards as well as end-users of standards with periodic evaluations of the capacity, expertise and quality of the HAS advisory system;
 - allow for constructive feedback from these standards developers and end-users;
 - stimulate the participation of stakeholders in the development of harmonised standards.
- 2) The Commission, together with ESOs, should urgently align the HAS consultant process of candidate harmonised standards developed in parallel by international technical committees with the process of homegrown European harmonised standards:
 - a. the **final HAS consultant's assessment should occur before approval of the final draft international standard (FDIS)**.
 - b. HAS consultants should be allowed to attend multiple meetings with the respective standardisation committees to ensure that the procedures set by the ESOs and by the Commission can be followed at all times.

c) **Responsibility of the Commission regarding the publication of the reference of the standard in the OJEU.**

Orgalim acknowledges the CJEU ruling that infers from the Elliott Case that a harmonised standard may be "considered being part of the EU legal order when that standard was conceived, managed and monitored by the Commission and when it produces binding legal effects following publication of its references in the OJEU".⁷

Even though the CJEU declared itself competent to rule on the content and legal effect of harmonised standards cited in the OJEU, it did not change the role and competence of the Commission in that respect. In particular, this interpretation does not imply that the Commission has been empowered by the Judicial Order to produce "harmonised standards" as new examples of implementing acts of EU law. **Harmonised standards** are to be considered as "supporting EU law" or "forming part of EU law" insofar as they serve as a **conformity assessment tool to facilitate their placing of goods on the internal market of the EU**.

Therefore, the Commission should not overestimate the need to protect its responsibility regarding the publication of the reference of harmonised standards. The Commission's non-contractual liability under

⁷ Case C-185/17 – Saska: <http://curia.europa.eu/juris/celex.jsf?celex=62017CJ0185&lang1=en>

Article 340 TFEU is very unlikely to be engaged in a case of non-conformity of a standard with EU law, as the CJEU equally **acknowledged that the legal effects attached to harmonised standards are limited in scope, impact and time** as follows:

- The Court stresses that “conformity of a harmonised standard (...) with the essential health and safety requirements set out therein, provides **merely a presumption of conformity** with those requirements” ([Case T-474/15 – Global Garden, Paragraph 69](#)).
- Therefore, it is an “**error of law**” to consider the **non-compliance of a product with a harmonised standard as implying an infringement of the essential requirements of the Union law** (Ibid. [Paragraph 71](#)).
- The legal effect attached to cited harmonised standards is limited to the free circulation of goods, and not to the actual compliance of the product with the essential requirements of EU law, which is to be presumed **from the use of the harmonised standards** ([Case C-92/17 – Cobra, Paragraph 41](#)), and consequently not from the publication of their reference in the OJEU.
- Such legal effect **applies to Member States** who are bound to accept the free circulation within their territory of products claiming the presumption of conformity with EU law.
- Finally, the legal effect attached to harmonised standards is **limited in time**: from the date of the manufacturer’s first declaration of conformity until the last manufacturing date of the corresponding product.

- d) **Case in which the Commission considers that the standard does not satisfy the requirements it aims to cover;**

Given the limited responsibility of the Commission with the citation of harmonised standards in the OJEU, **we invite the Commission to acknowledge**, in the framework of the planned guidelines, that **its primary role is to facilitate the smooth operation of the internal market under Article 114 of the TFEU** as stressed by the Court in the Global Garden Case.

Orgalim recommendation:

Therefore, with due consideration for keeping the system as efficient as possible and attractive for economic operators, we call on the Commission to refrain from too detailed and unnecessary control, because the ultimate responsibility in the case of non-conformity lies with the manufacturer under Member States’ ex-post control: the **burden is on them to prove a failure to conform with the essential requirements of EU law**. (cf. Paragraph 69 in the Global Garden Case).

- e) **Relationship between the procedure leading to the publication of the reference of the standard and a formal objection.**

There are several issues, which have led to legal uncertainty that needs to be prevented in the future:

- In the past, Member States have challenged harmonised standards before their citation in the OJEU, informally, without following the formal objection procedure. This resulted sometimes in a delayed citation by the Commission of concerned harmonised standards for several years. For those cases, it is necessary that the Commission sets a clear time limit for the Member State to withdraw their informal claim against the standard or to turn it into a formal objection.
- The formal objection procedure that is implemented in NLF directives and article 11 of the Regulation (EU) No 1025/2012 deserves clarification. We believe that the strict application of this procedure is essential to keep it transparent to all stakeholders. Some standards that were not withdrawn by the ESOs simply disappeared from the OJEU listing. For instance, hEN 55020 cited under the EMCD was unlisted without notice in 2016; neither Cenelec or the EC desk officer ever provided any rationale for such a decision, which was leading to uncertainty and confusion for manufacturers.
- The withdrawal of a standard further to a formal or informal objection without prior notice from the OJEU may lead to the unfortunate situation where a product model becomes non-compliant overnight. Conversely, the huge backlog on the citation of harmonised standards in the OJEU led the ESO and NSOs to withdraw from their catalogues some submitted harmonised standards as they became obsolete to meet market needs. For instance, hEN 55032:2012 under the EMCD was eventually cited in the OJEU without any date of cessation of presumption of conformity, but it is no longer available in the CENELEC catalogue. It is also unclear whether, and for how long, the former version of the harmonised standard will remain cited in the OJEU.

Orgalim recommendation:

We suggest applying a minimum 18-month delay between the first publication in the OJEU and the withdrawal of the former edition. Such a minimum transition period would allow manufacturers to modify the design of their products, test it against the new standard, prepare the technical documentation, and update the EU Declaration of conformity.

- According to some directives (e.g. the RED), the use of a Notified Body is compulsory when the harmonised standard is not listed in the OJEU (conformity assessment modules B+C or H). The situation has occurred that the former version of the harmonised standard was listed in the OJEU while the updated version published by the ESOs was rejected by the Commission. Such a situation is counter-productive and should be avoided because it discourages manufacturers from applying the latest acknowledged state-of-the-art in the design of their products. In this case investing in a notified body assessment does not bring any added value, only an additional cost.

4. Relation to the existing guidance documents

Orgalim welcomes the need for such guidance on the application of Regulation 1025/2012 to complement the Blue Guide and the Vademecum rather than to replace them.

5. Implementation of the Guidance

Should the guidance reflect our expectations, we commit to its successful implementation in cooperation with the Commission and the European standardisation organisations.