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## Criteria for common specifications

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### Introduction

Orgalim, Europe's Technology Industries, represents manufacturers in a dynamic and competitive sector that relies heavily on the success of European Union harmonisation legislation. Our industries' experts drive the work on state-of-the-art standards within the European Standardisation Organisations (ESOs) to develop the technologies which enable the EU's digital and sustainability objectives. The efficient functioning of the European standardisation system is a key priority to deliver these objectives.

The European Commission stated in the [Standardisation Strategy](#) of 2 February 2022 that common specifications – also designated as 'technical specifications' in some pieces of EU harmonisation legislation<sup>1</sup> – should be treated as a fallback solution to ensure that the public interest is served, based on the development of a horizontal approach for the establishment of common specifications. We remain convinced that harmonised standards are the best and most effective tool to support harmonised legislation. We are doubtful that common specifications developed outside the well-established and recognised processes for standardisation would successfully achieve the desired result and could be implemented in a workable and competitive way.

Our experts feel strongly that the empowerment of the Commission to draft common specifications should be used with the utmost caution to avoid undermining the Standardisation System, which is, and should remain, market driven, i.e. relevant for use by economic operators. Therefore, we support the initiative of developing a horizontal approach for the establishment of common specifications.

Orgalim has developed a list of horizontal criteria to govern the development process and ensure the applicability of common specifications which we hope will constructively contribute to the dialogue between the EU regulator and the end users of such specifications and ensure that the procedure for the new framework remains inclusive and consensus-based.

We suggest that the Commission considers amending Regulations where these specifications are already provided for to align with the horizontal criteria once they are developed.

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<sup>1</sup> Orgalim recommends using the term common specifications for documents drafted by the Commission to grant presumption of conformity with legislation. The term 'technical specification' according to the definition of Articles 2(1) and 2(4) of Regulation (EU) 1025/2012 covers all types of standards (ISO, IEC, CEN, CENELEC) and other papers developed by consortia or even companies for their internal standards (which imply de facto that they are not necessarily common to one sector). Therefore, the use of the term 'technical specification' for this new type of document developed by the Commission may lead to confusion.

# Criteria and guidelines for common specifications

## Recourse to Common Specifications can occur in the following circumstances:

- Where a standardisation request has been issued by the Commission and
  - the European Standardisation Organisations (ESOs) have not issued an acceptance statement of the request set within the required deadline, which was provided with a reasonable timeframe, or
  - the deadline to adopt the standard as agreed between the Commission and the ESOs has elapsed (cf. Article 10(1) Regulation (EU) No 1025/2012) and the ESOs have not requested a justified extension of the deadline.

The withdrawal of a standardisation request by the Commission, before the deadline, does not justify recourse to common specifications.

Once a standardisation request has been accepted by the ESOs and work is in progress on the specified item, the Commission should have good and justified reasons to take recourse to common specifications. In particular, recourse to common specifications should not be undertaken if:

- The Commission has issued a standardisation request, but once work commences it transpires that the agreed timeline does not allow sufficient time for a consensus-driven development of harmonised standards.<sup>2</sup> or
- A reasonable delay has occurred and has been justified in a statement from the ESOs to the Commission. Reasonable delays include for example:
  - Setbacks resulting from intensive technical examinations or
  - The issuing of additional requirements by the Commission which resulted in delays in reaching consensus.
- The ESOs have prepared the requested standard in answer to the Commission mandate but the Commission is not satisfied with the result (“quality”) and does not publish the reference of the standard in the Official Journal of the European Union (OJEU). In such cases the Commission should
  - organise a dedicated discussion with the related ESO to provide clear (and detailed) information on the reason for refusal
  - give the ESO a defined period of time to react regarding the identified deficits and to improve the standard.

## Governance and development process

- Common specifications should be subject to transparency and inclusion requirements in the development process:
  - stakeholders should be involved in the development of the technical content of a common specification to ensure that the result corresponds to market needs, and similarly to the provisions of Chapter II of Regulation (EU) 1025/2012
  - common specifications should undergo the scrutiny process by the Committee on Standards as described in Article 22 of Regulation (EU) 1025/2012

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<sup>2</sup> While we should always aim for a fast development of standards, reaching a consensus is more important than getting to a result quickly. It is important to remember that it is not the publication of the harmonised standard but the use of it which gives presumption of conformity. If companies don't use it because it was developed without reaching the right level of consensus, that standard will not serve the purpose.

- To maintain the competitiveness of European industry, any specification should be based on the internationally recognised 'state-of-the-art'.

### Applicability and withdrawal of common specifications

- In any case as for harmonised standards, applying common specifications established by the Commission should be voluntary<sup>3</sup>.
- Common specifications should be subject to periodic systematic reviews (for confirmation, revision or withdrawal) in alignment with the ESOs' standardisation procedures. Time specific framework conditions should be defined for the entry into force as well as the withdrawal of common specifications.
- Entry into force: publication by the Commission of the implementing act linked to the common specifications, provided that no listing of the assigned harmonised standards has taken place in the Official Journal of the European Union in the meantime.
- Withdrawal: when equivalent harmonised standards are cited in the Official Journal of the European Union common specifications should continue to confer a presumption of conformity with the essential requirements for a transitional period of 18 months and will then become invalid.

<sup>3</sup> As provided for in Whereas 41 of COM(2021) 202 final on a Proposal for a Regulation on machinery products.

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 €2,480 billion, manufacturing one-third of all European exports and providing 10.97 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.



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